DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-25-10-CLIA REVISED

DATE: June 23, 2025

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: REVISED: Revisions to State Operations Manual (SOM), Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services (Clinical Laboratory Improvement Amendments (CLIA)) – Advance Copy

Memo Revision Information:
Revisions to: *QSO-25-10-CLIA* ***Original release date:*** *December 06, 2024*

Memorandum Summary

- **Updates to the SOM:** The Centers for Medicare & Medicaid Services (CMS) is releasing updates to Appendix C of the SOM for laboratories and laboratory services. Appendix C provides interpretative guidance on the laboratory requirements at 42 CFR Part 493.
- **Updates to Appendix C:** The updates to Appendix C:
  - Remove survey protocols found in SOM Chapter 6;
  - Provide guidance and new and revised D-tags for the regulations finalized in the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing – Analytes and Acceptable Performance Final Rule (CMS-3355-F) and Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees, Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories Final Rule (CMS-3326-F);
  - Incorporate guidance and information from several previously released QSO (previously S&C) and Admin Info memos;
  - Added an approved HHS training program for neuromuscular pathology; and
  - Incorporate feedback previously received from stakeholders.
- **Updates to the advance copy of Appendix C:** The updates include:
  - Removing and adding guidance as outlined below in the discussion section; and
  - Correcting clerical errors.
- **Several previously released QSO (previously S&C) memos are now expired.** Memos: S&C: 17-11-CLIA (incorporated into the SOM), S&C: 16-02-CLIA (incorporated into the SOM), and S&C: 15-17-CLIA (incorporated into the SOM) are now expired. CMS will note the expiration date on these memos, which are currently on the CMS website. This memo and the associated SOM updates supersede the expired memos upon the Effective Date.

Background:
On July 11, 2022, CMS-3355-F appeared in the *Federal Register*, and updated proficiency testing regulations, added 29 new analytes, and deleted five analytes from subpart I of 42 CFR Part 493. On December 28, 2023, CMS-3326-F appeared in the *Federal Register*, updating fee, histocompatibility, personnel, and alternative sanctions for Certificate of Waiver labs regulations. The updates and revisions to Appendix C seek to provide guidance on the regulations adopted in both final rules.

CMS also updated and revised Appendix C to incorporate stakeholder feedback and previously released QSO (previously S&C) and Admin Info memos, and to provide further clarity based on frequently asked questions from stakeholders and surveyors.

Discussion:
CMS has revised Appendix C of the SOM to provide guidance to CMS staff, State Agencies (SA), and the laboratory community. A general summary of the changes to Appendix C of the SOM is as follows:

- **Removed survey protocols**. The information in this section is included in SOM Chapter 6 – Special Procedures for Laboratories.
- **Added guidance for new and revised regulations** finalized in CMS-3355-F and CMS-3326-F.
- **Created new and revised D-tags** for regulatory changes finalized in CMS-3355-F and CMS-3326-F and for clarity.
- **Incorporated guidance and information from several previously released QSO (previously S&C) and Admin Info memos**, including S&C-16-18-CLIA, QSO-18-19-CLIA, QSO-18-20-CLIA, and Admin Info-23-11-CLIA.
- **Added an approved HHS training program for neuromuscular pathology,** United Council for Neurologic Subspecialties (UCNS).
- **Incorporated feedback and addressed frequently asked questions from stakeholders and surveyors.**
    - **Revised guidance for clarity** with respect to quality assessment, temperature and humidity monitoring, calibration verification, alternative control materials for provider-performed microscopy procedures, cytology annual statistical laboratory evaluation, test reports, and other areas.
    - **Added guidance and probes to applicable regulations for cybersecurity and advancements in laboratory medicine,** including a probe on the use of the race-free equation for the estimated glomerular filtration rate (eGFR).
    - **Corrected general font, spelling, and organizational contacts** throughout the document.

Updates to the Advanced SOM Appendix C
On December 6, 2024, CMS published an advance copy of SOM Appendix C- Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services. Stakeholders had concerns regarding the guidance contained in the advance copy of SOM Appendix C, especially in evaluating courses on transcripts for personnel qualifications. Specifically, these stakeholders noted that the narrow interpretation of what constitutes a biological or chemical course creates a burden on individuals to provide documentation for courses labeled differently by a university or college. Stakeholders had concerns regarding the guidance for performing

competency in person for direct observation in light of technology that allows virtual observation. CMS will be removing the following guidance from the final publication:

- Guidance on the use of BIO/CHEM identifiers on transcripts for personnel qualifications under §§493.1405(b), 493.1443(b)(3), 493.1489(b)(2)(ii), and 493.1489(b)(3); and
- Guidance that direct observation needs to be performed in person under §§493.1413(b)(8)(i), 493.1413(b)(8)(iv), 493.1451(b)(8)(i), 493.1451(b)(8)(iv), and 493.1359(c)(1).

In addition, stakeholders had concerns that nursing degrees would no longer meet the educational requirements under the high complexity testing personnel regulations under §493.1489(b). As a result, nurses would no longer be able to perform the patient bedside glucometer tests that fall under the CLIA high complexity test categorization. CMS will be adding the following guidance on nursing degrees in the final publication:

- Limited exception to allow qualified individuals with a Bachelors of Nursing degree to perform high complexity glucometer testing.

CMS will also fix technical errors in the final publication. The technical errors include the following:

- Guidance previously published regarding the equivalency of the American Osteopathic Board of Dermatology for technical supervisors in dermatopathology will be included under §493.1449(f)(2)(i)(B)(3);
- Guidance previously published on The American Academy of Neurology Committee for Neuromuscular Pathology training program for technical supervisors in neuromuscular pathology will be included under §493.1449(f)(1)(i)(B); and
- An inaccurately transcribed regulation at §493.1443(b)(3)(i)(B)(2).

Following the release of these updates, additional training will be provided to help surveyors navigate the regulations finalized in CMS-3355-F and CMS-3326-F.

Contact:
For questions or concerns relating to this memorandum, please contact LabExcellence@cms.hhs.gov.

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Attachment – Transmittal – Advance Copy State Operations Manual (SOM), Appendix C

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid. Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

Get guidance memos issued by the Quality, Safety, and Oversight Group by going to the CMS.gov page and entering your email to sign up. Check the box next to "CCSQ Policy, Administrative, and Safety Special Alert Memorandums" to be notified when we release a memo.

State Operations Manual
Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services

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Requesting or Issued a Certificate of Accreditation

The items listed below replace the current Publication 7, Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services. This material was rewritten due to:

1. *Deletion of Sections I-X – The Outcome Oriented Survey Process.*
2. ***Changes made to the following Subparts:***
   a. ***Subparts A-H*** *- General Provisions, Certificates and Proficiency Testing of the CLIA regulations - Sections 493.1 through 493.865*
   b. ***Subpart J*** *- Facility Administration - Sections 493.1100 through 493.1105*
   c. ***Subpart K,*** *Quality System for Nonwaived Testing; General Laboratory Systems, Preanalytic Systems & Analytic Systems (general requirements), Postanalytic Systems - Sections 493.1200 through 493.1299*
   d. ***Subpart M*** *- Personnel - Sections 493.1351 through 493.1495*
   e. ***Subpart Q*** *- Inspection - Sections 493.1771 through 493.1780*

A. SURVEY *PROCESS*

The Survey process is found in State Operations Manual Chapter 6 - Special Procedures for Laboratories.

B. INDEX
REGULATIONS AND INTERPRETIVE GUIDELINES FOR LABORATORIES AND LABORATORY SERVICES

This appendix provides survey protocols and additional guidance on the following sections of the Clinical Laboratory Improvement Amendment (CLIA) Regulations.

(Rev. 140, Issued 05-29-15)

Subpart A--General Provisions

§493.1 Basis and scope

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861(e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act, as amended by section 2 of the Taking Essential Steps for Testing Act of 2012. This part applies to all laboratories as defined under "laboratory" in §493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification.

§493.2 Definitions

(Rev.)

As used in this part, unless the context indicates otherwise--

***"Acceptance limit"* means the symmetrical tolerance (plus and minus) around the target value.**

"Accredited institution" means a school or program which--

> **(a) Admits as regular student only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate;**
>
> **(b) Is legally authorized within the State to provide a program of education beyond secondary education;**

(c) Provides an educational program for which it awards a bachelor's degree or provides not less than a 2-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master's or doctoral degree;

(d) Is accredited by a nationally recognized accrediting agency or association.

This definition includes any foreign institution of higher education that HHS or its designee determines meets substantially equivalent requirements.

Interpretive Guidelines §493.2

An individual is considered to have an "earned" degree from an "accredited institution" if the institution is accredited throughout the timeframe(s) in which the individual completes the applicable academic requirements as determined by the accredited institution. An authentic academic transcript must be provided. If there is any question about the accreditation status of the institution, contact the appropriate accrediting institution(s) to confirm the institution's status.

NOTE: If the institution itself asserts in writing that it meets one of the criteria described in paragraphs (a)-(c) of the definition of "accredited institution", then, absent contravening evidence, HHS will presume that assertion to be valid for the purposes of the CLIA program. As with all records, the laboratory must maintain documentation along with their personnel records.

Individuals who have degrees from foreign institutions must have an evaluation of their credentials to determine the equivalency of their education to an education obtained in the United States (U.S.). The equivalency evaluations should be on a course-by-course basis and may be performed by a nationally recognized organization. These may include such organizations as the National Association Credential Evaluation Services, Inc. (NACES) (http://www.naces.org) and the Association of International Credential Evaluators, Inc. (AICE) (http://www.aice-eval.org).

"Accredited laboratory" means a laboratory that has voluntarily applied for and been accredited by a private, nonprofit accreditation organization approved by CMS in accordance with this part;

"Adverse action" means the imposition of a principal or alternative sanction by CMS.

"ALJ" stands for Administrative Law Judge.

"Alternative sanctions" means sanctions that may be imposed in lieu of or in addition to principal sanctions. The term is synonymous with "intermediate sanctions" as used in section 1846 of the Act.

"Analyte" means a substance or constituent for which the laboratory conducts testing.

"Approved accreditation organization for laboratories" means a private, nonprofit accreditation organization that has formally applied for and received CMS's approval based on the organization's compliance with this part.

"Approved State laboratory program" means a licensure or other regulatory program for laboratories in a State, the requirements of which are imposed under State law, and the State laboratory program has received CMS approval based on the State's compliance with this part.

"Authorized person" means an individual authorized under State law to order tests or receive test results, or both.

"Calibration" means a process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of the substance that is being measured by the test procedure.

"Calibration verification" means the assaying of materials of known concentration in the same manner as patient samples to substantiate the instrument or test system's calibration throughout the reportable range for patient test results.

"Challenge" means, for quantitative tests, an assessment of the amount of substance or analyte present or measured in a sample. For qualitative tests, a challenge means the determination of the presence or the absence of an analyte, organism, or substance in a sample.

"CLIA" means the Clinical Laboratory Improvement Amendments of 1988.

"CLIA certificate" means any of the following types of certificates issued by CMS or its agent:

> **(1) "Certificate of compliance" means a certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition level requirements, or reissued before the expiration date, pending an appeal, in accordance with §493.49, when an inspection has found the laboratory to be out of compliance with one or more condition level requirements.**
>
> **(2) "Certificate for provider-performed microscopy (PPM) procedures" means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with §493.47, to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than PPM procedures and, if desired, waived tests listed in §493.15(c).**

(3) "Certificate of accreditation" means a certificate issued on the basis of the laboratory's accreditation by an accreditation organization approved by CMS (indicating that the laboratory is deemed to meet applicable CLIA requirements) or reissued before the expiration date, pending an appeal, in accordance with §493.61, when a validation or complaint survey has found the laboratory to be noncompliant with one or more CLIA conditions.

(4) "Certificate of registration or registration certificate" means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with §493.45, that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined to be in compliance through a survey by CMS or its agent; or in accordance with §493.57 to an entity that is accredited by an approved accreditation organization.

(5) "Certificate of waiver" means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with §493.37, to a laboratory to perform only the waived tests listed at §493.15(c).

"CLIA-exempt laboratory" means a laboratory that has been licensed or approved by a State where CMS has determined that the State has enacted laws relating to laboratory requirements that are equal to or more stringent than CLIA requirements and the State licensure program has been approved by CMS in accordance with subpart E of this part.

"CMS agent" means an entity with which CMS arranges to inspect laboratories and assess laboratory activities against CLIA requirements and may be a State survey agency, a private, nonprofit organization other than an approved accreditation organization, a component of HHS, or any other governmental component CMS approves for this purpose. In those instances where all of the laboratories in a State are exempt from CLIA requirements, based on the approval of a State's exemption request, the State survey agency is not the CMS agent.

"Condition level deficiency" means noncompliance with one or more condition level requirements.

"Condition level requirements" means any of the requirements identified as "conditions" in subparts G through Q of this part.

"Confirmatory testing" means testing performed by a second analytical procedure that could be used to substantiate or bring into question the result of an initial laboratory test.

"Continuing education (CE) credit hours" means either continuing medical education (CME) or continuing education units (CEUs). The CE credit hours must cover the

applicable laboratory director responsibilities and be obtained prior to qualifying as a laboratory director.

"Credible allegation of compliance" means a statement or documentation that--

(1) Is made by a representative of a laboratory that has a history of having maintained a commitment to compliance and of taking corrective action when required;

(2) Is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and

(3) Indicates that the problem has been resolved.

"Dentist" means a doctor of dental medicine or doctor of dental surgery licensed by the State to practice dentistry within the State in which the laboratory is located.

"Distributive testing" means laboratory testing performed on the same specimen, or an aliquot of it, that requires sharing it between two or more laboratories to obtain all data required to complete an interpretation or calculation necessary to provide a final reportable result for the originally ordered test. When such testing occurs at multiple locations with different CLIA certificates, it is considered distributive testing.

"Doctoral degree" means an earned post-baccalaureate degree with at least 3 years of graduate level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science, medical laboratory science, or medical technology. For purposes of this part, doctoral degrees do not include doctors of medicine (MD), doctors of osteopathy (DO), doctors of podiatric medicine (DPM), doctors of veterinary medicine (DVM) degrees, or honorary degrees.

Interpretive Guidelines §493.2 Doctoral degree

An example of an acceptable professional doctoral degree is the Doctorate in Clinical Laboratory Science (DCLS). The DCLS is an advanced professional doctorate designed for practicing clinical laboratory scientists (CLSs), medical laboratory scientists (MLSs), or medical technologists (MTs) who have at least a bachelor's degree and wish to further their level of clinical expertise and develop leadership and management skills. Individuals with a DCLS are experts in clinical laboratory testing.

"Equivalency" means that an accreditation organization's or a State laboratory program's requirements, taken as a whole, are equal to or more stringent than the CLIA requirements established by CMS, taken as whole. It is acceptable for an accreditation organization's or State laboratory program's requirements to be organized differently or otherwise vary from the CLIA requirements, as long as (1) all of the requirements taken as a whole would provide at least the same protection

as the CLIA requirements taken as a whole; and (2) a finding of noncompliance with respect to CLIA requirements taken as a whole would be matched by a finding of noncompliance with the accreditation or State requirements taken as a whole.

"Experience directing or supervising" means that the director or supervisory experience must be obtained in a facility that meets the definition of a laboratory under this section and is not excepted under § 493.3(b).

Interpretive Guidelines §493.2 Experience directing or supervising

The laboratory director should have documentation, e.g., signed procedure manuals, test reports, and worksheets, that indicates the director assumes the responsibilities in § 493.1407 and § 493.1445. Teaching experience directly related to a medical technology, medical laboratory science, clinical laboratory sciences program, or a clinical laboratory section of a residency program, would be considered acceptable experience because we understand that such experience from teaching related to a medical technology, medical laboratory sciences, or clinical laboratory sciences program would include all aspects of the entire testing process (pre-analytic, analytic, and post-analytic), as well as quality control and quality assessment. These are critical responsibilities of a laboratory director as defined by CLIA.

"FDA-cleared or approved test system" means a test system cleared or approved by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use. Unless otherwise stated, this includes test systems exempt from FDA premarket clearance or approval.

"HHS" means the Department of Health and Human Services, or its designee.

"Immediate jeopardy" means a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

"Intentional violation" means knowing and willful noncompliance with any CLIA condition.

"Kit" means all components of a test that are packaged together.

"Laboratory" means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Interpretive Guidelines §493.2

Currently, in-vivo and externally attached patient dedicated monitoring devices, e.g., pulse oximetry, SvO2 pulmonary artery catheters, capnographs, are not subject to CLIA. Should it be determined at a later date that they are subject to CLIA, proper notice and opportunity for public comment will be provided.

Gender testing for informational purposes is not covered under CLIA.

Tissue cassette embedding, paraffin block sectioning, and slide staining (e.g., for ultimate use in Pathology testing) are considered part of specimen preparation and are not part of the "examination" etc. referenced in the definition of laboratory. As such, entities that only conduct these preparatory steps to testing are not laboratories, and would not be subject to CLIA. The laboratory that ultimately interprets these histopathology preparations should ensure that the preparer also creates a control slide for specimen(s) blocks that are tested with differential stains to aid the identification of specific agents (this refers to immunohistochemistry and/or special stains as required under §493.1273, not Hematoxylin & Eosin which only requires documentation of QC management).

Furthermore, laboratories that screen or interpret cytopathology slides that are prepared by another person/entity are responsible for confirming with that entity that the cytology slides were stained in compliance with the applicable requirements at §493.1274(b). In addition, such laboratories should confirm that cytology specimens that were prepared using automated and/or semi-automated liquid-based preparatory techniques were done in a manner that complies with the manufacturer's instructions.

"Laboratory training or experience" means that the training or experience must be obtained in a facility that meets the definition of a laboratory under this section and is not excepted under § 493.3(b).

Each individual must have documentation of training or experience applicable to the types and complexity of testing performed. This training should be such that the individual can demonstrate that he or she has the skills required for the proper performance of pre-analytic, analytic, and post-analytic phases of testing.

For example, if the individual performs blood gas testing on a nonwaived point of care device, demonstration of skills should include, but is not limited to, the following:

- *Proper specimen collection, handling and labeling;*
- *Proper test performance according to the laboratory's policies and manufacturer's instructions;*

• Verification of performance specifications;
• Calibration and preventive maintenance;
• Proficiency testing; and
• Proper reporting of patient test results.

Training may include, but is not limited to, attendance at:
• Seminars given by experts in the field;
• On-site or off-site instrument training given by a manufacturer;
• Technical training sessions, workshops, or conferences given by a professional laboratory organization; or
• A formal laboratory training program.

Documentation may consist of, but is not limited to, the following:
• Letters from training programs or employers;
• Attestation statements of an individual's training and experience by the LD;
• Log sheet(s) initialed by the individual indicating attendance at a training session or in-service; and
• Certificates from organizations providing training sessions, workshops, conferences, and specialty courses.

All documentation supporting an individual's education, training, and experience must be generated by an individual other than the person attempting to meet CLIA personnel qualification requirements. For example, a curriculum vitae (CV) is not acceptable verification, in and of itself, to document an individual's education, training or experience. Letters on letterhead from previous employment, competency assessment, and a comprehensive list of job responsibilities may be examples of acceptable documentation.

Laboratory testing of non-human specimens is not acceptable experience, for example, environmental or animal testing, as it is not used for the purpose of providing information used in the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

"Midlevel practitioner" means a nurse midwife, nurse practitioner, *nurse anesthetist, clinical nurse specialist,* or physician assistant licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.

"Nonwaived test" means any test system, assay, or examination that has not been found to meet the statutory criteria specified at section 353(d)(3) of the Public Health Service Act.

"Operator" means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes--

(1) A director of the laboratory if he or she meets the stated criteria; and

(2) The members of the board of directors and the officers of a laboratory that is a small corporation under subchapter S of the Internal Revenue Code.

"Owner" means any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded. (That is e.g., the purchase of shares of stock or securities on the New York Stock Exchange in a corporation owning a laboratory would not make a person an owner for the purpose of this regulation.)

"Party" means a laboratory affected by any of the enforcement procedures set forth in this subpart, by CMS or the OIG, as appropriate.

"Peer group" ***means a group of laboratories whose testing process utilizes similar instruments, methodologies, and/or reagent systems and is not to be assigned using the reagent lot number level.***

"Performance characteristic" means a property of a test that is used to describe its quality, e.g., accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, etc.

"Performance specification" means a value or range of values for a performance characteristic, established or verified by the laboratory, that is used to describe the quality of patient test results.

"Physician" means an individual with a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine degree who is licensed by the State to practice medicine, osteopathy, or podiatry within the State in which the laboratory is located.

"Principal sanction" means the suspension, limitation, or revocation of any type of CLIA certificate or the cancellation of the laboratory's approval to receive Medicare payment for its services.

"Prospective laboratory" means a laboratory that is operating under a registration certificate or is seeking any of the three other types of CLIA certificates.

"Rate of disparity" means the percentage of sample validation inspections for a specific accreditation organization or State where CMS, the State survey agency or other CMS agent finds noncompliance with one or more condition level requirements but no comparable deficiencies were cited by the accreditation organization or the State, and it is reasonable to conclude that the deficiencies were present at the time of the most recent accreditation organization or State licensure inspection.

Example: Assume the State survey agency, CMS or other CMS agent performs 200 sample validation inspections for laboratories accredited by a single accreditation organization or licensed in an exempt State during a validation review period and finds that 60 of the 200 laboratories had one or more condition level requirements out of compliance. CMS reviews the validation and accreditation organization's or State's inspections of the validated laboratories and determines that the State or accreditation organization found comparable deficiencies in 22 of the 60 laboratories and it is reasonable to conclude that deficiencies were present in the remaining 38 laboratories at the time of the accreditation organization's or State's inspection. Thirty-eight divided by 200 equals a 19 percent rate of disparity.

"Referee laboratory" means a laboratory currently in compliance with applicable CLIA requirements, that has had a record of satisfactory proficiency testing performance for all testing events for at least one year for a specific test, analyte, subspecialty, or specialty and has been designated by an HHS approved proficiency testing program as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specific test, analyte, subspecialty, or specialty.

"Reference range" means the range of test values expected for a designated population of individuals, e.g., 95 percent of individuals that are presumed to be healthy (or normal).

"Reflex testing" means confirmatory or additional laboratory testing that is automatically requested by a laboratory under its standard operating procedures for patient specimens when the laboratory's findings indicate test results that are abnormal, are outside a predetermined range, or meet other pre-established criteria for additional testing.

"Repeat proficiency" testing referral means a second instance in which a proficiency testing sample, or a portion of a sample, is referred, for any reason, to another laboratory for analysis prior to the laboratory's proficiency testing program event cut-off date within the period of time encompassing the two prior survey cycles (including initial certification, recertification, or the equivalent for laboratories surveyed by an approved accreditation organizations).

"Replacement certificate" means an active CLIA certificate that is reissued with no changes made.

"Reportable range" means the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response.

"Revised certificate" means an active CLIA certificate that is reissued with changes to one or more fields displayed on the certificate, such as the laboratory's name, address, laboratory director, or approved specialties/subspecialties. For purposes of this part,

revised certificates do not include the issuance, renewal, change in certificate type, or reinstatement of a terminated certificate with a gap in service.

"Sample" in proficiency testing means the material contained in a vial, on a slide, or other unit that contains material to be tested by proficiency testing program participants. When possible, samples are of human origin.

"State" includes, for purposes of this part, each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and a political subdivision of a State where the State, acting pursuant to State law, has expressly delegated powers to the political subdivision sufficient to authorize the political subdivision to act for the State in enforcing requirements equal to or more stringent than CLIA requirements.

"State licensure" means the issuance of a license to, or the approval of, a laboratory by a State laboratory program as meeting standards for licensing or approval established under State law.

"State licensure program" means a State laboratory licensure or approval program.

"State survey agency" means the State health agency or other appropriate State or local agency that has an agreement under section 1864 of the Social Security Act and is used by CMS to perform surveys and inspections.

"Substantial allegation of noncompliance" means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would have an impact on the health and safety of the general public or of individuals served by a laboratory and raises doubts as to a laboratory's compliance with any condition level requirement.

"Target value" for quantitative tests means*:*

(1) If the peer group consists of 10 participants or greater:

> ***(i) The mean of all participant responses after removal of outliers (that is, those responses greater than three standard deviations from the original mean, as applicable);***
>
> ***(ii) The mean established by a definitive method or reference methods; or***
>
> ***(iii) If a definitive method or reference methods are not available, the mean of a peer group; or***

(2) If the peer group consists of fewer than 10 participants, the mean of all participant responses after removal of outliers (as defined in paragraph (1) of this definition) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

"Test system" means the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

"Unsatisfactory proficiency testing performance" means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

"Unsuccessful participation in proficiency testing" means any of the following:

(1) Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.

(2) Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.

(3) An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events.

(4) Failure of a laboratory performing gynecologic cytology to meet the standard at §493.855.

"Unsuccessful proficiency testing performance" means a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

"Validation review period" means the one year time period during which CMS conducts validation inspections and evaluates the results of the most recent surveys performed by an accreditation organization or State laboratory program.

"Waived test" means a test system, assay, or examination that HHS has determined meets the CLIA statutory criteria as specified for waiver under section 353(d)(3) of the Public Health Service Act.

§493.3 Applicability

(Rev.)

(a) Basic rule. Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act

unless it--

> **(1) Has a current, unrevoked or unsuspended certificate of waiver, a registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or**

Interpretive Guidelines §493.3(a)(1)

NOTE: See *section 6036* of the *State Operations Manual (*SOM*)* for instructions on handling a laboratory operating without a CLIA certificate.

> **(2) Is CLIA-exempt.**
>
> **(b) Exception. These rules do not apply to components or functions of--**
>
> **(1) Any facility or component of a facility that only performs testing for forensic purposes;**
>
> **(2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or**
>
> **(3) Laboratories certified by the Substance Abuse and Mental Health Service Administration (SAMHSA), in which drug testing is performed which meets SAMHSA guidelines and regulations. However, all other testing conducted by a SAMHSA-certified laboratory is subject to this rule.**

Interpretive Guidelines §493.3(b)

The purpose for which the test is conducted, not the test itself, determines whether a facility conducting testing is subject to the CLIA requirements. Testing that is used to gather evidence for legal purposes, and is not performed for purposes of clinical treatment, medical diagnosis, health assessment or disease prevention is not subject to CLIA.

Industrial laboratories that monitor employee health, insurance company laboratories that assess an individual's health for insurance purposes, health maintenance organizations, and other facilities such as pharmacies and health fairs that perform screening test procedures are subject to the CLIA requirements.

Individuals who self-administer a test in their own home with a device that has been cleared specifically for home use by the FDA are not regulated under CLIA. An employee of a home health agency (HHA) or hospice that provides assistance to an

individual as that individual uses such a device is not, by virtue of that assistance, subject to CLIA. However, an HHA or hospice that performs laboratory testing on individuals such that they meet the definition of "laboratory" in §493.2 is subject to CLIA requirements.

CDC's National Center for Environmental Health (NCEH) Division of Laboratory Sciences (DLS) has developed a number of tests for hazardous chemicals for use in laboratories that are members of the Laboratory Response Network (LRN). The laboratories that are performing the tests are expected to be environmental laboratories, as opposed to laboratories engaged in specimen testing for medical use. While these tests will include test systems that utilize human samples to assess hazardous chemical exposure in instances of chemical terrorism and other catastrophic situations, the results are not expected to be used to diagnose or treat the specimen source. Where individual results are not used for treatment, medical diagnosis, health assessment or disease prevention or reported out to the individual or other individuals such as the individual's medical providers in order to assess and/or treat the individual for exposure, CLIA will not apply to this testing.

If such laboratories wish to be prepared to release their results to individuals and assessing/treating individuals such as medical providers in instances in which the situation warrants doing so, they should enroll for CLIA certification in order to be able to begin immediate testing of human specimens for medical purposes when the need arises. For ease of registration, the laboratories may use the minimum test volume of less than 2,000 per year for the purpose of certificate and survey fees. These test volumes can be adjusted later, if necessary. Surveyors would review policies and procedures and test method verification.

(c) Federal laboratories. Laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate.

Interpretive Guidelines §493.3(c)

Refer to *sections 6028* and *6240* of the State Operations Manual (SOM) to assist in distinguishing which laboratories are under the jurisdiction of the Federal government for purposes of inspecting for CLIA.

§493.5 Categories of Tests by Complexity

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

(a) Laboratory tests are categorized as one of the following:

(1) Waived tests.

(2) Tests of moderate complexity, including the subcategory of PPM procedures.

(3) Tests of high complexity.

(b) A laboratory may perform only waived tests, only tests of moderate complexity, only PPM procedures, only tests of high complexity or any combination of these tests.

(c) Each laboratory must be either CLIA-exempt or possess one of the following CLIA certificates, as defined in §493.2:

(1) Certificate of registration or registration certificate.

(2) Certificate of waiver.

(3) Certificate for PPM procedures.

(4) Certificate of compliance.

(5) Certificate of accreditation.

§493.15 Laboratories Performing Waived Tests

§493.15(a) Requirement

Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.

§493.15(b) Criteria

Test systems are simple laboratory examinations and procedures which--

(1) Are cleared by FDA for home use;

(2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or

(3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

D1000
(Rev.)

§493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others:

Interpretive Guidelines §493.15(c)

Cite D1000 on the Form CMS-2567 and solicit a Plan of Correction when a laboratory has failed to obtain a registration, accreditation or compliance certificate before performing and reporting patient results for tests not categorized as waived. To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity tests), refer to the following web link for the FDA categorization database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm?sAN=0). Test systems, assays, and examinations not yet classified are considered high complexity. Test systems, assays and examinations that are waived, but are used in a manner that is inconsistent with manufacturer's instructions are also considered high complexity. Significant deficiencies cited under this condition may also indicate deficiencies under personnel responsibilities.

Notify *CMS* of a possible action by the OIG if the laboratory does not obtain the appropriate certificate or cease nonwaived testing.

(1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following:

(i) Bilirubin;

(ii) Glucose;

(iii) Hemoglobin;

(iv) Ketone;

(v) Leukocytes;

(vi) Nitrite;

(vii) pH;

(viii) Protein;

(ix) Specific gravity; and

(x) Urobilinogen.

(2) Fecal occult blood - non-automated

(3) Ovulation tests -visual color comparison tests for human luteinizing hormone;

(4) Urine pregnancy tests - visual color comparison tests;

(5) Erythrocyte sedimentation rate-non-automated;

(6) Hemoglobin-copper sulfate-non-automated;

(7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use;

(8) Spun microhematocrit; and

(9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

(d) Revisions to criteria for test categorization and the list of waived tests. HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the FEDERAL REGISTER in a notice with opportunity for comment.

D1001
(Rev.)

§493.15(e) Laboratories eligible for a certificate of waiver must--

(1) Follow manufacturers' instructions for performing the test; and

(2) Meet the requirements in subpart B, Certificate of Waiver, of this part.

Interpretive Guidelines §493.15(e)

Tests listed on the waiver list in §493.15(c) **are not** subject to routine survey. A survey of waived tests may be conducted **only** when authorized by *CMS* in the following instances:

- Determine if a laboratory is testing outside its certificate;
- Collect information regarding the appropriateness of tests specified as waived tests;
- Investigate a complaint from the public; and/or
- Determine if the laboratory is operated and if testing is performed in a manner that does not constitute an imminent and serious risk to public health.

Refer to §§493.1773 and 493.1775 for additional guidelines for inspecting laboratories issued a certificate of waiver.

Laboratories holding a *c*ertificate of *w*aiver must follow the current manufacturer's

instructions for the waived test systems they are using for patient testing. To meet the waived testing regulatory requirements, these laboratories must comply with the manufacturer's requirements. We encourage laboratories to also comply with the manufacturer's recommendations for testing. These laboratories may only use the specimen types that were approved by the Food and Drug Administration (FDA) with the waived test system they are using, and they must follow the manufacturer's quality control (QC) and test performance requirements. We encourage laboratories to also comply with manufacturer's recommendations for the waived test system. Some manufacturers produce tests that can be run as a waived test or a moderate complexity test. Any laboratory with a *c*ertificate of *w*aiver that uses the nonwaived test system instructions from a manufacturer should be advised that they must use the manufacturer's instructions for waived testing. If the situation remains uncorrected, the laboratory may be cited for performing tests beyond the scope of the certificate held by the laboratory, as well as failing to follow manufacturer's instructions.

NOTE: It is never acceptable for a laboratory operating under a *c*ertificate of *w*aiver to modify the manufacturer's instructions for the waived test system. Any such changes will result in a test that is **no longer waived** (i.e., the waived test is uncategorized for CLIA and therefore becomes a high complexity test). For example, if a test specifies urine as the waived specimen type and the laboratory tests a different body fluid, then the laboratory is no longer performing a waived test and the lab is then subject to routine inspections and the CLIA requirements for high complexity testing. Waived laboratory testing personnel must follow the manufacturer's instructions in their entirety and without variation. Great care should be taken to add the proper reagents in the order and amount specified by the manufacturer's instructions to ensure compliance with the CLIA regulations and reliable test results.

§493.17 Test categorization

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

(a) Categorization by criteria. Notices will be published in the FEDERAL REGISTER which list each specific test system, assay, and examination categorized by complexity. Using the seven criteria specified in this paragraph for categorizing tests of moderate or high complexity, each specific laboratory test system, assay, and examination will be graded for level of complexity by assigning scores of 1, 2, or 3 within each criteria. The score of "1" indicates the lowest level of complexity, and the score of "3" indicates the highest level. These scores will be totaled. Test systems, assays or examinations receiving scores of 12 or less will be categorized as moderate complexity, while those receiving scores above 12 will be categorized as high complexity.

NOTE: A score of "2" will be assigned to a criteria heading when the characteristics for a particular test are intermediate between the description listed for scores of "1" and "3."

(1) Knowledge.

(i) Score 1.

(A) Minimal scientific and technical knowledge is required to perform the test; and

(B) Knowledge required to perform the test may be obtained through on-the-job instruction.

(ii) Score 3. Specialized scientific and technical knowledge is essential to perform preanalytic, analytic or postanalytic phases of the testing.

(2) Training and experience.

(i) Score 1.

(A) Minimal training is required for preanalytic, analytic and postanalytic phases of the testing process; and

(B) Limited experience is required to perform the test.

(ii) Score 3.

(A) Specialized training is essential to perform the preanalytic, analytic or postanalytic testing process; or

(B) Substantial experience may be necessary for analytic test performance.

(3) Reagents and materials preparation.

(i) Score 1.

(A) Reagents and materials are generally stable and reliable; and

(B) Reagents and materials are prepackaged, or premeasured, or require no special handling, precautions or storage conditions.

(ii) Score 3.

(A) Reagents and materials may be labile and may require special handling to assure reliability; or

(B) Reagents and materials preparation may include manual steps such as gravimetric or volumetric measurements.

(4) Characteristics of operational steps.

(i) Score l. Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled.

(ii) Score 3. Operational steps in the testing process require close monitoring or control, and may require special specimen preparation, precise temperature control or timing of procedural steps, accurate pipetting, or extensive calculations.

(5) Calibration, quality control, and proficiency testing materials.

(i) Score 1.

(A) Calibration materials are stable and readily available;

(B) Quality control materials are stable and readily available; and

(C) External proficiency testing materials, when available, are stable.

(ii) Score 3.

(A) Calibration materials, if available, may be labile;

(B) Quality control materials may be labile, or not available; or

(C) External proficiency testing materials, if available, may be labile.

(6) Test system troubleshooting and equipment maintenance.

(i) Score l.

(A) Test system troubleshooting is automatic or self-correcting, or clearly described or requires minimal judgment; and

(B) Equipment maintenance is provided by the manufacturer, is seldom needed, or can easily be performed.

(ii) Score 3.

(A) Troubleshooting is not automatic and requires decision-making and direct intervention to resolve most problems; or

(B) Maintenance requires special knowledge, skills, and abilities.

(7) Interpretation and judgment.

(i) Score 1.

(A) Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and

(B) Resolution of problems requires limited independent interpretation and judgment; and

(ii) Score 3.

(A) Extensive independent interpretation and judgment are required to perform the preanalytic, analytic or postanalytic processes; and

(B) Resolution of problems requires extensive interpretation and judgment.

(b) Revisions to the criteria for categorization

The Clinical Laboratory Improvement Advisory Committee, as defined in subpart T of this part, will conduct reviews upon request of HHS and recommend to HHS revisions to the criteria for categorization of tests.

(c) Process for device/test categorization utilizing the scoring system under §493.17(a).

(1)(i) For new commercial test systems, assays, or examinations, the manufacturer, as part of its 510(k) and PMA application to FDA, will submit supporting data for device/test categorization. FDA will determine the complexity category, notify the manufacturers directly, and will simultaneously inform both CMS and CDC of the device/test category. FDA will consult with CDC concerning test categorization in the following three situations:

(A) When categorizing previously uncategorized new technology;

(B) When FDA determines it to be necessary in cases involving a request for a change in categorization; and

(C) If a manufacturer requests review of a categorization decision by FDA in accordance with 21 CFR 10.75.

(ii) Test categorization will be effective as of the notification to the applicant.

(2) For test systems, assays, or examinations not commercially available, a laboratory or professional group may submit a written request for categorization to PHS. These requests will be forwarded to CDC for evaluation; CDC will determine complexity category and notify the applicant, CMS, and FDA of the categorization decision. In the case of request for a change of category or for previously uncategorized new technology, PHS will receive the request application and forward it to CDC for categorization.

(3) A request for recategorization will be accepted for review if it is based on new information not previously submitted in a request for categorization or recategorization by the same applicant and will not be considered more frequently than once per year.

(4) If a laboratory test system, assay or examination does not appear on the lists of tests in the FEDERAL REGISTER notices, it is considered to be a test of high complexity until PHS, upon request, reviews the matter and notifies the applicant of its decision. Test categorization is effective as of the notification to the applicant.

(5) PHS will publish revisions periodically to the list of moderate and high

complexity tests in the FEDERAL REGISTER in a notice with opportunity for comment.

Interpretive Guidelines §493.17(c)(5)

To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity tests), refer to the following web link for the FDA categorization database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm?sAN=0). Test systems, assays, and examinations not yet classified are considered high complexity.

Significant deficiencies cited under this condition may also indicate deficiencies under personnel responsibilities.

NOTE: A modified waived or moderate complexity test (including modifications in its intended use) is considered uncategorized for CLIA purposes, and therefore becomes a high complexity test.

§493.19 Provider-performed microscopy (PPM) procedures.

(Rev.)

(a) Requirement. To be categorized as a PPM procedure, the procedure must meet the criteria specified in paragraph (b) of this section.

(b) Criteria. Procedures must meet the following specifications:

(1) The examination must be personally performed by one of the following practitioners:

(i) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or an employee.

(ii) A midlevel practitioner, under the supervision of a physician or in independent practice only if authorized by the State, during the patient's visit on a specimen obtained from his or her own patient or from a patient of a clinic, group medical practice, or other health care provider of which the midlevel practitioner is a member or an employee.

(iii) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

(2) The procedure must be categorized as moderately complex.

(3) The primary instrument for performing the test is the microscope, limited to bright-field or phase-contrast microscopy.

(4) The specimen is labile or delay in performing the test could compromise the accuracy of the test result.

(5) Control materials are not available to monitor the entire testing process.

Interpretive Guidelines for 493.19(b)(5)

Refer to the interpretive guidelines at 493.1256(h) for more guidance on PPM quality control.

(6) Limited specimen handling or processing is required.

(c) Provider-performed microscopy (PPM) examinations. A laboratory may qualify to perform tests under this section if it restricts PPM examinations to one or more of the following procedures (or additional procedures added to this list as provided under paragraph (d) of this section), waived tests and no others:

(1) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements.

Interpretive Guideline for 493.19(c)(1)

All direct wet mounts for scabies (which includes mineral oil preparations) are PPM examinations. All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements include the direct wet mount examinations for Clue cells. Clue cells are vaginal epithelial cells covered with bacteria.

(2) All potassium hydroxide (KOH) preparations.

Interpretive Guideline for 493.19(c)(2)

All KOH preparations include KOH that is mixed directly with a stain or the stain is a drop added directly to the KOH preparation and the slide is examined with bright-field microscopy.

(3) Pinworm examinations.

(4) Fern tests.

(5) Post-coital direct, qualitative examinations of vaginal or cervical mucous.

(6) Urine sediment examinations.

Interpretive Guideline for 493.19(c)(6)

It is acceptable in a PPM laboratory to add stain to resuspend the urine sediment to assist in identifying the formed elements in the urine.

(7) Nasal smears for granulocytes.

(8) Fecal leukocyte examinations.

(9) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

(d) Revision to criteria and the list of PPM procedures

(1) The CLIAC conducts reviews upon HHS' request and recommends to HHS revisions to the criteria for categorization of procedures.

(2) HHS determines whether a laboratory procedure meets the criteria listed under paragraph (b) of this section for a PPM procedure. Revisions to the list of PPM procedures proposed by HHS are published in the FEDERAL REGISTER as a notice with an opportunity for public comment.

(e) Laboratory requirements

Laboratories eligible to perform PPM examinations must--

(1) Meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, and M of this part.

(2) Be subject to inspection as specified under subpart Q of this part.

§493.20 Laboratories performing tests of moderate complexity.

(Rev.)

(a) A laboratory may qualify for a certificate to perform tests of moderate complexity provided that it restricts its test performance to waived tests or examinations and one or more tests or examinations meeting criteria for tests of moderate complexity including the subcategory of PPM procedures.

(b) A laboratory that performs tests or examinations of moderate complexity must meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, and Q of this part. Under a registration certificate or certificate of compliance, laboratories also performing PPM procedures must meet the inspection requirements at §§493.1773 and 493.1777.

(c) If the laboratory also performs waived tests, compliance with *§ 493.801(a) and (b)(7) and* subparts J, K, and M of this part is not applicable to the waived tests. However, the laboratory must comply with the requirements in

§§ 493.15(e), *493.801(b)(1) through (6), 493.1771,* 493.1773, and 493.1775*.*

§493.25 Laboratories performing tests of high complexity*.*

(Rev.)

(a) A laboratory must obtain a certificate for tests of high complexity if it performs one or more tests that meet the criteria for tests of high complexity as specified in §493.17(a).

(b) A laboratory performing one or more tests of high complexity must meet the applicable requirements of subpart C or subpart D, and subparts F, H, J, K, M, and Q of this part.

(c) If the laboratory also performs tests of moderate complexity, the applicable requirements of subparts H, J, K, M, and Q of this part must be met. Under a registration certificate or certificate of compliance, PPM procedures must meet the inspection requirements in §§493.1773 and 493.1777.

(d) ***If the laboratory also performs waived tests, compliance with §§ 493.801(a) and 493.801(b)(7) and subparts J, K, and M of this part are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§493.15(e), 493.801(b)(1) through (6), 493.1771, 493.1773 and 493.1775.***

Subpart B--Certificate of Waiver

§493.35 Application for a certificate of waiver

(Rev.)

(a) Filing of application.

Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in §493.15 must file a separate application for each laboratory location.

Interpretive Guidelines §493.35(a)

NOTE: See *section 6036* of the SOM for instructions on handling a laboratory operating without a CLIA certificate. *Per policy letter QSO18-20-CLIA, multiple laboratories with separate CLIA numbers may operate at one location as long as it can be demonstrated that each laboratory is operating as a separate and distinct entity.*

(b) Exceptions

(1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

Interpretive Guidelines §493.35(b)(1)

A mobile unit is a laboratory located within a self-contained vehicle, such as a van. The vehicle moves from location to location to perform laboratory testing activities. Mobile vans will be distinguished by the vehicle identification number (VIN#).

If a mobile laboratory operates in more than one State and does not obtain a separate certificate from each State, contact *CMS* to determine which State conducts the inspection. See *section 6010.1.1* of the SOM for additional information on mobile laboratories.

Each laboratory that moves from testing site to testing site, or has a temporary testing location, should provide the survey agency with the home base or central dispatch phone number and the locations where additional testing is performed.

A temporary testing site is considered a location not used to permanently house instruments, equipment, personnel and records, e.g., a health fair. See *section 6010.1.2* of the SOM for further guidance.

See *section 6010.1.2.1* of the SOM for guidance for Home Health Agencies with multiple sites.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

Interpretive Guidelines §493.35(b)(2)

See *section 6010.2* of the SOM for the definition for limited public health testing. Note that laboratories operating under a certificate of waiver may not perform moderate or high complexity testing.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

Interpretive Guidelines §493.35(b)(3)

Common direction means that all testing sites are under one designated director.

Street address is the address assigned by the Post Office and is the physical location of the laboratory. The street address may be different from the mailing address, which can be a Post Office box or a billing address. For large hospitals, such as a university campus facility, that may contain laboratories in separate buildings, consult with *CMS* to determine if the hospital is eligible for a single certificate.

(c) Application format and contents

The application must--

(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including--

(i) The name and the total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance or proficiency testing purposes;

(ii) The methodologies for each laboratory test procedure or examination

performed, or both; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) Access requirements

Laboratories that perform one or more waived tests listed in §493.15(c) and no other tests must meet the following conditions:

Interpretive Guidelines §493.35(d)

Cite deficiencies for not following manufacturer's instructions at §493.15(e). (Use D1001)

(1) Make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section and §493.15(e);

(2) Agree to permit announced and unannounced inspections by HHS in accordance with subpart Q of this part under the following circumstances:

(i) When HHS has substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health.

Interpretive Guidelines §493.35(d)(2)(i)

Consult with *CMS* for assistance in determining when there is substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health.

An example of a substantive reason to inspect waived testing is if testing personnel are observed cutting urine dipsticks in half. (This violates both the manufacturer's instructions and causes questionable results to be reported.)

(ii) To evaluate complaints from the public.

(iii) On a random basis to determine whether the laboratory is performing tests not listed in §493.15.

Interpretive Guidelines §493.35(d)(2)(ii)-(iii)

NOTE: See Chapter 5 of the SOM for specific procedures regarding complaint investigations.

(iv) To collect information regarding the appropriateness of waiver of tests listed in §493.15.

(e) Denial of application

If HHS determines that the application for a certificate of waiver is to be denied, HHS will--

(1) Provide the laboratory with a written statement of the grounds on which the denial is based and an opportunity for appeal, in accordance with the procedures set forth in subpart R of this part;

(2) Notify a laboratory that has its application for a certificate of waiver denied that it cannot operate as a laboratory under the PHS Act unless the denial is overturned at the conclusion of the administrative appeals process provided by subpart R; and

(3) Notify the laboratory that it is not eligible for payment under the Medicare and Medicaid programs.

§493.37 Requirements for a certificate of waiver

(Rev.)

(a) HHS will issue a certificate of waiver to a laboratory only if the laboratory meets the requirements of §493.35.

(b) Laboratories issued a certificate of waiver--

(1) Are subject to the requirements of this subpart and §493.15(e) of subpart A of this part; and

Interpretive Guidelines §493.37(b)(1)

Cite the laboratory's failure to follow manufacturer's instructions at §493.15(e). (Use D1001.)

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part.

(c) Laboratories must remit the certificate of waiver fee specified in subpart F of this part.

(d) In accordance with subpart R of this part, HHS will suspend or revoke or limit a laboratory's certificate of waiver for failure to comply with the requirements of this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid in accordance with

subpart R of this part.

Interpretive Guidelines §493.37(d)

NOTE: See the Adverse Action section of the SOM beginning at *section* 6250 for enforcement procedures.

(e)(1) A certificate of waiver issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination resulting in HHS action to revoke, suspend, or limit the laboratory's certificate of waiver, HHS will provide the laboratory with a statement of grounds on which the determination of non-compliance is based and offer an opportunity for appeal as provided in subpart R of this part.

(2) If the laboratory requests a hearing within the time specified by HHS, it retains its certificate of waiver or reissued certificate of waiver until a decision is made by an administrative law judge, as specified in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(3) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a non-compliance determination even if there has been no appeals decision issued.

(f) A laboratory seeking to renew its certificate of waiver must--

(1) Complete the renewal application prescribed by HHS and return it to HHS not less than 9 months nor more than 1 year before the expiration of the certificate; and

(2) Meet the requirements of §§493.35 and 493.37.

§493.37(g) A laboratory with a certificate of waiver that wishes to perform examinations or tests not listed in the waiver test category must meet the requirements set forth in subpart C or subpart D of this part, as applicable.

§493.39 Notification requirements for laboratories issued a certificate of waiver

(Rev.)

Laboratories performing one or more tests listed in §493.15 and no others must notify HHS or its designee--

(a) Before performing and reporting results for any test or examination that is not specified under §493.15 for which the laboratory does not have the appropriate certificate as required in subpart C or subpart D of this part, as applicable; and

Interpretive Guidelines §493.39(a)

NOTE: *See section 6036 of the SOM for instructions on handling a laboratory operating without an appropriate CLIA certificate.*

(b) Within 30 days of any change(s) in--

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

Interpretive Guidelines §493.39(b)

NOTE: *See section 6016 of the SOM for applicable instructions on handling changes in ownership, name, location, or director.*

Because there is no D-tag assigned to this regulation, you may use D0000 to cite non-compliance with this requirement.

Subpart C--Registration Certificate, Certificate for Provider-Performed Microscopy Procedures, and Certificate of Compliance

§493.43 Application for registration certificate, certificate for provider-performed microscopy (PPM) procedures, and certificate of compliance *(Rev.)*

(a) Filing of application

Except as specified in paragraph (b) of this section, all laboratories performing nonwaived testing must file a separate application for each laboratory location.

Interpretive Guidelines §493.43(a)

NOTE: See *section 6036* of the SOM for instructions on handling a laboratory operating without a CLIA certificate. *Per policy letter QSO 18-20 CLIA, multiple laboratories with separate CLIA numbers may operate at one location as long as it can be demonstrated that each laboratory is operating as a separate and distinct entity.*

(b) Exceptions

(1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

Interpretive Guidelines §493.43(b)(1)

A mobile unit is a laboratory located within a self-contained vehicle, such as a van. The vehicle moves from location to location to perform laboratory testing activities. Mobile vans will be distinguished by the vehicle identification number (VIN#).

If a mobile laboratory operates in more than one State and does not obtain a separate certificate for each State, contact *CMS* to determine which State conducts the inspection. See *section 6010.1.1* of the SOM for additional information on mobile laboratories.

Each laboratory that moves from testing site to testing site, or has a temporary testing location, should provide the survey agency with the home base or central dispatch phone number and the locations where additional testing is performed.

A temporary testing site is considered a location not used to permanently house instruments, equipment, personnel and records, e.g., a health fair. See §6036.3 of the SOM for further guidance.

NOTE: See *section 6010.1.2.1* of the SOM for guidance for home health agencies with

multiple sites.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

Interpretive Guidelines §493.43(b)(2)

NOTE: See *section 6010.2* of the SOM for information on limited public health testing.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

Interpretive Guidelines §493.43(b)(3)

In instances where the main laboratory is certified to perform waived, moderate and/or high complexity tests, the alternate sites may perform testing in all complexities covered by the certificate provided that all other applicable requirements are met (e.g., quality control, personnel).

Common direction means that all sites are under one designated director.

Street address is the address assigned by the Post Office and is the physical location of the laboratory. The street address may be different from the mailing address, which can be a Post Office box or a billing address. For large hospitals, such as a university campus facility, that may contain laboratories in separate buildings, consult with *CMS* to determine if the hospital is eligible for a single certificate.

(c) Application format and contents

The application must--(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including--

> **(i) The name and total number of test procedures and examinations performed annually (excluding waived tests or tests for quality control, quality assurance or proficiency testing purposes);**

(ii) The methodologies for each laboratory test procedure or examination performed, or both;

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the examinations and test procedures.

(d) Access and reporting requirements

All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

§493.45 Requirements for a registration certificate.

(Rev.)

Laboratories performing only waived tests, PPM procedures, or any combination of these tests, are not required to obtain a registration certificate.

(a) A registration certificate is required—

(1) Initially for all laboratories performing test procedures of moderate complexity (other than the subcategory of PPM procedures) or high complexity, or both; and

(2) For all laboratories that have been issued a certificate of waiver or certificate for PPM procedures that intend to perform tests of moderate or high complexity, or both, in addition to those tests listed in §493.15 (c) or specified as PPM procedures.

Interpretive Guidelines §493.45(a)

All facilities performing laboratory testing must have a registration, compliance or accreditation certificate, *a certificate for provider-performed microscopy procedures* or a certificate of waiver prior to performing patient testing.

NOTE: See *section 6036* of the SOM for instructions on handling a laboratory operating without an appropriate CLIA certificate.

(b) HHS will issue a registration certificate if the laboratory--

(1) Complies with the requirements of §493.43;

(2) Agrees to notify HHS or its designee within 30 days of any changes in ownership, name, location, director or technical supervisor (laboratories performing high complexity testing only);

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Remits the fee for the registration certificate, as specified in subpart F of this part.

(c) Prior to the expiration of the registration certificate, a laboratory must--

(1) Remit the certificate fee specified in subpart F of this part;

(2) Be inspected by HHS as specified in subpart Q of this part; and

(3) Demonstrate compliance with the applicable requirements of this subpart and subparts H, J, K, M, and Q of this part.

(d) In accordance with subpart R of this part, HHS will initiate suspension or revocation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of compliance for failure to comply with the requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart will result in suspension of payments under Medicare and Medicaid as specified in subpart R of this part.

(e) A registration certificate is--

(1) Valid for a period of no more than two years or until such time as an inspection to determine program compliance can be conducted, whichever is shorter; and

(2) Not renewable; however, the registration certificate may be reissued if compliance has not been determined by HHS prior to the expiration date of the registration certificate.

(f) In the event of a noncompliance determination resulting in an HHS denial of a laboratory's certificate of compliance application, HHS will provide the laboratory with a statement of grounds on which the noncompliance determination is based and offer an opportunity for appeal as provided in subpart R.

Interpretive Guidelines §493.45(f)

NOTE: See the Appeals section of the SOM beginning at *sections 6258 and* 6300 for instructions on denial of a certificate application.

(g) If the laboratory requests a hearing within the time specified by HHS, it retains its registration certificate or reissued registration certificate until a decision is made by an administrative law judge as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(h) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the certificate application even if there has been no appeals decision issued.

§493.47 Requirements for a certificate for provider-performed microscopy (PPM) procedures.

(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

(a) A certificate for PPM procedures is required--

(1) Initially for all laboratories performing test procedures specified as PPM procedures; and

(2) For all certificate of waiver laboratories that intend to perform only test procedures specified as PPM procedures in addition to those tests listed in §493.15(c).

(b) HHS will issue a certificate for PPM procedures if the laboratory--

(1) Complies with the requirements of §493.43; and

(2) Remits the fee for the certificate, as specified in subpart F of this part.

(c) Laboratories issued a certificate for PPM procedures are subject to--

(1) The notification requirements of §493.53;

(2) The applicable requirements of this subpart and subparts H, J, K, and M of this part; and

(3) Inspection only under the circumstances specified under §§493.1773 and 493.1775, but are not routinely inspected to determine compliance with the requirements specified in paragraphs (c)(1) and (2) of this section.

(d) In accordance with subpart R of this part, HHS will initiate suspension, limitation, or revocation of a laboratory's certificate for PPM procedures for failure to comply with the applicable requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart may result in suspension of all or part of payments under Medicare and Medicaid, as specified in subpart R of this part.

(e) A certificate for PPM procedures is valid for a period of no more than 2 years.

§493.49 Requirements for a certificate of compliance.

(Rev.)

A certificate of compliance may include any combination of tests categorized as high complexity or moderate complexity or listed in §493.15(c) as waived tests. Moderate complexity tests may include those specified as PPM procedures.

(a) HHS will issue a certificate of compliance to a laboratory only if the laboratory--

(1) Meets the requirements of §§493.43 and 493.45;

(2) Remits the certificate fee specified in subpart F of this part; and

(3) Meets the applicable requirements of this subpart and subparts H, J, K, M, and Q of this part.

(b) Laboratories issued a certificate of compliance--

(1) Are subject to the notification requirements of §493.51; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part--

(i) To determine compliance with the applicable requirements of this part;

(ii) To evaluate complaints;

(iii) When HHS has substantive reason to believe that tests are being performed, or the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health; and

(iv) To collect information regarding the appropriateness of tests listed in §493.15 or tests categorized as moderate complexity (including the subcategory) or high complexity.

(c) Failure to comply with the requirements of this subpart will result in--

(1) Suspension, revocation or limitation of a laboratory's certificate of compliance in accordance with subpart R of this part; and

(2) Suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(d) A certificate of compliance issued under this subpart is valid for no more than 2 years.

(e) In the event of a noncompliance determination resulting in an HHS action to

revoke, suspend or limit the laboratory's certificate of compliance, HHS will--

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based; and

(2) Offer an opportunity for appeal as provided in subpart R of this part. If the laboratory requests a hearing within 60 days of the notice of sanction, it retains its certificate of compliance or reissued certificate of compliance until a decision is made by an administrative law judge (ALJ) as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health or when the criteria at §493.1840(a)(4) and (5) are met.

(f) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a noncompliance determination even if there has been no appeals decision issued.

(g) A laboratory seeking to renew its certificate of compliance must--

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of compliance; and

(2) Meet the requirements of §493.43 and paragraphs (a)(2) and (b)(2) of this section.

(h) If HHS determines that the application for the renewal of a certificate of compliance must be denied or limited, HHS will notify the laboratory in writing of the--

(1) Basis for denial of the application; and

(2) Opportunity for appeal as provided in subpart R of this part.

Interpretive Guidelines §493.49(h)(2)

NOTE: See the Appeals section of the SOM beginning at *sections 6258 and* 6300 for instructions on denial of a certificate application.

(i) If the laboratory requests a hearing within the time period specified by HHS, the laboratory retains its certificate of compliance or reissued certificate of compliance until a decision is made by an ALJ as provided in subpart R, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(j) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the

laboratory of nonrenewal of the certificate of compliance even if there has been no appeals decision issued.

§493.51 Notification requirements for laboratories issued a certificate of compliance

(Rev.)

Laboratories issued a certificate of compliance must meet the following conditions:

(a) Notify HHS or its designee within 30 days of any change in--

(1) Ownership;

(2) Name;

(3) Location;

(4) Director; or

(5) Technical supervisor (laboratories performing high complexity only).

(b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined.

(c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance.

Interpretive Guidelines §493.51(a)-(c)

See the section of the SOM beginning at *section* 6016 for handling changes in ownership, name, location, personnel and test methodology, or additions or deletions of specialties or subspecialties that may result in changes in complexity levels for the laboratory.

See the SOM beginning at *section 6260* for instructions on handling laboratories that are going out of business or voluntarily withdrawing from all testing*, including laboratories that are taking these actions while an enforcement action is pending*.

Because there is no D-tag assigned to this regulation, you may use D0000 to cite non-compliance with this requirement.

§493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures.

(Rev.)

Laboratories issued a certificate for PPM procedures must notify HHS or its designee--

(a) Before performing and reporting results for any test of moderate or high complexity, or both, in addition to tests specified as PPM procedures or any test or examination that is not specified under §493.15(c), for which it does not have a registration certificate as required in subpart C or subpart D, as applicable, of this part; and

(b) Within 30 days of any change in--

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director

Interpretive Guidelines §493.53(b)

See the section of the SOM beginning at *section* 6016 for handling changes in ownership, name, location, personnel and test methodology, or additions or deletions of specialties or subspecialties that may result in changes in complexity levels for the laboratory.

See the SOM beginning at *section 6260* for instructions on handling laboratories that are going out of business or voluntarily withdrawing from all testing*, including laboratories that are taking these actions while an enforcement action is pending*.

Because there is no D-tag assigned to this regulation, you may use D0000 to cite non-compliance with this requirement.

Subpart D--Certificate of Accreditation

§493.55 Application for registration certificate and certificate of accreditation.

(Rev.)

(a) Filing of application

A laboratory may be issued a certificate of accreditation in lieu of the applicable certificate specified in subpart B or subpart C of this part provided the laboratory--

(1) Meets the standards of a private non-profit accreditation program approved by HHS in accordance with subpart E; and

Interpretive Guidelines §493.55(a)(1)

When HHS approves accreditation organizations and State licensure programs, *CMS* is notified and the approved organizations and programs are published as a notice in the FEDERAL REGISTER.

NOTE: See *sections* 6150-6151 of the SOM.

(2) Files a separate application for each location, except as specified in paragraph (b) of this section.

Interpretive Guidelines §493.55(a)(2)

See *section 6036* of the SOM for instructions on handling a laboratory operating without a CLIA certificate. *Per policy letter QSO 18-20 CLIA, multiple laboratories with separate CLIA numbers may operate at one location as long as it can be demonstrated that each laboratory is operating as a separate and distinct entity.*

(b) Exceptions

(1) Laboratories that are not at fixed locations, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

Interpretive Guidelines §493.55(b)(1)

A mobile unit is a laboratory located within a self-contained vehicle, such as a van. The vehicle moves from location to location to perform laboratory testing activities. Mobile vans will be distinguished by the vehicle identification number (VIN#).

If a mobile laboratory operates in more than one State and does not obtain a separate

certificate from each State, contact *CMS* to determine which State conducts the inspection. See *section 6010.1.1* of the SOM for additional information on mobile laboratories.

Each laboratory that moves from testing site to testing site, or has a temporary testing location, should provide the survey agency with the home base or central dispatch phone number and the locations where additional testing is performed.

A temporary testing site is considered a location not used to permanently house instruments, equipment, personnel and records, e.g., a health fair. See *section* 6036.3 of the SOM for further guidance.

See *section 6010.1.2.1* of the SOM for guidance for home health agencies with multiple sites.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

Interpretive Guidelines §493.55(b)(2)

See *section 6010.2* of the SOM for the definition of limited public health testing.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

Interpretive Guidelines §493.55(b)(3)

Common direction means that all sites are under one designated director.

Street address is the address assigned by the Post Office and is the physical location of the laboratory. The street address may be different from the mailing address, which can be a Post Office box or a billing address. For large hospitals, such as a university campus facility, that may contain laboratories in separate buildings, consult with *CMS* to determine if the hospital is eligible for a single certificate.

(c) Application format and contents

The application must--

(1) Be made to HHS on a form or forms prescribed by HHS;

(2) Be signed by an owner or authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the

requirements established by the Secretary under section 353 of the Public Health Service Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including--

(i) The name and total number of tests and examinations performed annually (excluding waived tests and tests for quality control, quality assurance or proficiency testing purposes);

(ii)The methodologies for each laboratory test procedure or examination performed, or both; and

(iii)The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) Access and reporting requirements.

All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

§493.57 Requirements for a registration certificate.

(Rev.)

A registration certificate is required for all laboratories seeking a certificate of accreditation, unless the laboratory holds a valid certificate of compliance issued by HHS.

Interpretive Guidelines §493.57

See *section 6036* of the SOM for instructions on handling a laboratory operating without a CLIA certificate.

§493.57(a) HHS will issue a registration certificate if the laboratory--

(1) Complies with the requirements of §493.55;

(2) Agrees to notify HHS within 30 days of any changes in ownership, name, location, director, or supervisor (laboratories performing high complexity testing only);

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Remits the fee for the registration certificate specified in subpart F of this part.

(b)(1) The laboratory must provide HHS with proof of accreditation by an approved accreditation program--

(i) Within 11 months of issuance of the registration certificate; or

(ii) Prior to the expiration of the certificate of compliance.

(2) If such proof of accreditation is not supplied within this timeframe, the laboratory must meet, or continue to meet, the requirements of §493.49.

(c) In accordance with subpart R of this part, HHS will initiate suspension, revocation, or limitation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of accreditation for failure to comply with the requirements set forth in this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid as specified in subpart R of this part.

(d) A registration certificate is valid for a period of no more than 2 years. However, it may be reissued if the laboratory is subject to subpart C of this part, as specified in §493.57(b)(2) and compliance has not been determined by HHS before the expiration date of the registration certificate.

(e) In the event that the laboratory does not meet the requirements of this subpart, HHS will--

Interpretive Guidelines §493.57*(c)-(e)*

See the Appeals section of the SOM beginning at *sections 6258 and* 6300 for instructions on denial of a certificate of accreditation application.

(1) Deny a laboratory's request for certificate of accreditation;

(2) Notify the laboratory if it must meet the requirements for a certificate as defined in subpart C of this part;

(3) Provide the laboratory with a statement of grounds on which the application denial is based;

(4) Offer an opportunity for appeal on the application denial as provided in subpart R of this part. If the laboratory requests a hearing within the time specified by HHS, the laboratory will retain its registration certificate or reissued registration certificate until a decision is made by an administrative law judge as provided in subpart R, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(5) For those laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the request even if there has been no appeals decision issued.

§493.61 Requirements for a certificate of accreditation.

(Rev.)

(a) HHS will issue a certificate of accreditation to a laboratory if the laboratory--

(1) Meets the requirements of §493.57 or, if applicable, §493.49 of subpart C of this part; and

(2) Remits the certificate of accreditation fee specified in subpart F of this part.

(b) Laboratories issued a certificate of accreditation must--

(1) Treat proficiency testing samples in the same manner as patient samples;

(2) Meet the requirements of §493.63;

(3) Comply with the requirements of the approved accreditation program;

(4) Permit random sample validation and complaint inspections as required in subpart Q of this part;

(5) Permit HHS to monitor the correction of any deficiencies found through the inspections specified in paragraph (b)(4) of this section;

Interpretive Guidelines §493.61(b)(5)

See sections 6166 and 6184 of the SOM for procedures on follow-up of correction of deficiencies cited during validation inspections.

(6) Authorize the accreditation program to release to HHS the laboratory's inspection findings whenever HHS conducts random sample or complaint inspections; and

(7) Authorize its accreditation program to submit to HHS the results of the laboratory's proficiency testing.

(c) A laboratory failing to meet the requirements of this section--

(1) Will no longer meet the requirements of this part by virtue of its

accreditation in an approved accreditation program;

(2) Will be subject to full determination of compliance by HHS;

(3) May be subject to suspension, revocation or limitation of the laboratory's certificate of accreditation or certain alternative sanctions; and

(4) May be subject to suspension of payments under Medicare and Medicaid as specified in subpart R.

(d) A certificate of accreditation issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination as a result of a random sample validation or complaint inspection, a laboratory will be subject to a full review by HHS in accordance with §488.11 of this chapter.

Interpretive Guidelines §493.61(d)

42 CFR §488.11 lists State survey agency functions.

(e) Failure to meet the applicable requirements of part 493, will result in an action by HHS to suspend, revoke or limit the certificate of accreditation. HHS will--

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based;

(2) Notify the laboratory if it is eligible to apply for a certificate as defined in subpart C of this part; and

(3) Offer an opportunity for appeal as provided in subpart R of this part.

(f) If the laboratory requests a hearing within the time frame specified by HHS--

(1) It retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(2) For those laboratories receiving payments from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory even if there has been no appeals decision issued.

(g) In the event the accreditation organization's approval is removed by HHS, the laboratory will be subject to the applicable requirements of subpart C of this part or §493.57.

Interpretive Guidelines §493.61(g)

Accrediting organizations which lose deemed status are required to notify their participating laboratories. These laboratories must re-apply for accreditation with another CMS-approved accrediting organization or apply for the appropriate CLIA certificate with CMS.

(h) A laboratory seeking to renew its certificate of accreditation must--

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of accreditation;

(2) Meet the requirements of this subpart; and

(3) Submit the certificate of accreditation fee specified in subpart F of this part.

(i) If HHS determines that the renewal application for a certificate of accreditation is to be denied or limited, HHS will notify the laboratory in writing of--

(1) The basis for denial of the application;

(2) Whether the laboratory is eligible for a certificate as defined in subpart C of this part;

(3) The opportunity for appeal on HHS's action to deny the renewal application for certificate of accreditation as provided in subpart R of this part. If the laboratory requests a hearing within the time frame specified by HHS, it retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(4) Suspension of payments under Medicare or Medicaid for those laboratories receiving payments under the Medicare or Medicaid programs.

§493.63 Notification requirements for laboratories issued a certificate of accreditation.

(Rev.)

Laboratories issued a certificate of accreditation must:

(a) Notify HHS and the approved accreditation program within 30 days of any changes in--

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

(b) Notify the approved accreditation program no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included in the laboratory's accreditation, so that the accreditation organization can determine compliance and a new certificate of accreditation can be issued.

(c) Notify the accreditation program no later than 6 months after of any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of accreditation.

Interpretive Guidelines §493.63(a)-(c)

See the section of the SOM beginning at *section* 6016 for handling changes in ownership, name, location, personnel and test methodology, or additions or deletions of specialties or subspecialties that may result in changes in complexity levels for the laboratory.

See the SOM beginning at *section 6260* for instructions on handling laboratories that are going out of business or voluntarily withdrawing from all testing*, including laboratories that are taking these actions while an enforcement action is pending*.

Because there is no D-tag assigned to this regulation, you may use D0000 to cite non-compliance with this requirement.

Subpart H--Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

Subpart H – General Guidelines

(Rev.)

By law, proficiency testing (PT) programs are evaluated initially for CMS approval and annually thereafter for re-approval. After review, *CMS* will issue PT program approvals and/or re-approvals provided they meet the requirements of Subpart I, Proficiency Testing Programs for Nonwaived Testing. A listing of these programs with the specialties, subspecialties, and specific analytes for which they are approved is available on the CMS CLIA web site at *https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/proficiency-testing.*

A CMS-approved PT program has been evaluated and found to be in compliance with the requirements of Subpart I and the applicable sections of Subpart H. When a laboratory experiences problems with PT samples, it resolves them with the PT program. When the SA experiences problems with an approved program, report all available information to *CMS*. *CMS* renders a decision on the termination or continued approval of the PT program, as appropriate. The Centers for Disease Control and Prevention may be requested by *CMS* to provide technical advice.

D2000

(Rev.)

§493.801 Condition: Enrollment and testing of samples.

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

Interpretive Guidelines §493.801

Each laboratory must determine the extent of patient testing it performs. The laboratory must review the specialty, subspecialties and analytes listed in Subpart I and determine which specialty, subspecialties and analytes they must enroll in to meet this requirement. Enrollment must be in a CMS-approved PT program that offers modules containing at least three (3) testing events annually (excluding mycobacteriology, which only needs to contain two (2) testing events annually) with a minimum of five (5) samples per event (§§493.909 – 493.459). The surveyor should verify that the laboratory is properly

enrolled in an approved PT program.

Every laboratory that examines or screens gynecologic specimens (Pap Test) must annually enroll in a CMS-Approved Gynecologic Cytology Proficiency Testing (PT) Program. CMS recognizes that Gynecologic Cytology PT may not occur at every laboratory that examines Pap Tests because a laboratory's cytotechnologist may complete proficiency testing at another laboratory. Regardless of whether a cytotechnologist will perform proficiency testing at a laboratory, each laboratory that examines Pap Tests must still enroll in an approved PT program.

NOTE: If a laboratory *is* not enrolled *at the time of the survey* for one or more tests that it performs and the tests are listed in Subpart I, cite ONLY D2000, Enrollment and testing of samples. *D*o **not** cite D2016, Successful Participation. *However, if the laboratory is enrolled for all applicable testing at the time of the survey, but was not enrolled when reporting patient test results, do not cite D2000. Instead, use D6015 or D6088 as applicable.*

PT requirements apply to the nonwaived tests listed in Subpart I, except for PT referral which applies to PT for all testing (waived, nonwaived, tests listed in Subpart I and tests not listed in Subpart I).

PT enrollment and participation is required, as applicable, for each certificate other than a *c*ertificate of *w*aiver. A facility offering testing at more than one site, with testing included under one certificate, must enroll in an approved PT program(s) for the collective tests covered under that certificate, not for each site.

A general rule is "PT enrollment per certificate."

Facilities that perform laboratory testing at multiple sites and are certified under one CLIA certificate include the following examples:

- A hospital with satellite laboratories throughout the hospital;
- Different departments of the laboratory;
- A hospital that performs point-of-care testing;
- Limited public health testing performed by non-profit or Federal, State or local government laboratories; or
- Mobile laboratories or temporary testing sites.

The following examples give instruction and guidance for determining compliance with the PT requirement for enrollment where a specialty, subspecialty or analyte is performed by different methods, specimen types and locations:

- A laboratory with a single certificate must enroll in an approved PT program for each analyte listed in Subpart I that it performs. **When an analyte is performed** using different methodologies within the laboratory, only one PT enrollment is required. After the laboratory has determined which analyte to enroll for, it must participate in PT using its primary method for patient testing during the event. Other methods for the same analyte must be evaluated as required in §493.1236. If the laboratory performs unsuccessfully for an analyte and sanctions are imposed, the sanctions are applicable to the analyte, not to the test methodology. For example, if a laboratory uses three different methods to perform cholesterol measurements, it must participate in PT using the primary method at the time of the PT event. If the laboratory is unsuccessful in PT performance for cholesterol and the CLIA certificate is limited for cholesterol, the laboratory would be precluded from performing cholesterol by **any test method**.

- A multisite laboratory that performs testing at the various sites under a single certificate must participate in PT for each analyte listed in Subpart I that is under that certificate. The performance of PT testing events may be rotated between different sites, provided the primary method at the time of the PT event is used to perform the PT. All samples from the testing event must be evaluated at **a single** site. Should the facility not perform successfully for an analyte, that analyte may not be tested at **any location** under that certificate.

- A laboratory with multiple sites **covered by a single certificate that participates in one PT program per analyte, must be aware that a failure in PT could lead to the limitation or revocation of its certificate for all sites for the failed analyte, subspecialty, or specialty, not just the one participating in PT**.

  When problems occur that cannot be resolved with the instructions in these guidelines, gather all information available and consult with *CMS* for guidance and resolution.

D2001
(Rev.)

§493.801(a) Standard: Enrollment.

The laboratory must -

(1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart.

(2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and

Interpretive Guidelines §493.801(a)(1)-(a)(2)(i)

During the on-site survey, verify that the laboratory is enrolled in an approved program or programs for all specialties, subspecialties, analytes, or tests listed in Subpart I for which it performs patient testing.

To meet the requirements of this section, it may be necessary for a laboratory to enroll in more than one program to cover all tests listed in Subpart I for which the laboratory performs testing. The approved program in which a laboratory has enrolled may not offer every analyte that the laboratory performs. The laboratory must then enroll in an additional program(s) to cover the testing not included in the first program.

The laboratory must indicate to the PT program which specialty, subspecialty, analyte, or test it intends the program to grade and score for regulatory purposes. This is particularly necessary when the laboratory subscribes to multiple PT modules that contain the same analyte(s).

D2003
(Rev.)

§493.801(a) Standard: Enrollment.

(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with §493.1236(c)(1).

Interpretive Guidelines §493.801(a)*(2)(ii)*

Methods laboratories may use which may meet the accuracy requirement for tests that are not listed in subpart I include, but are not limited to, the following:

- *Enrolling in a PT program*
- *Split sampling*
- *Blind sampling*

The laboratory should have a written procedure that outlines how the accuracy of tests not listed in subpart I will be verified twice annually.

D2004
(Rev.)

§493.801(a) Standard: Enrollment.

(a)(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation; and

Interpretive Guidelines §493.801(a)(3)

When a laboratory initially applies for CLIA certification or adds a specialty or subspecialty in the middle of the calendar year, it may change PT programs at the next enrollment period instead of having to wait until a full year has passed. Otherwise, laboratories may not change programs after they have enrolled and participated in a PT program for a given calendar year.

D2005
(Rev.)

§493.801(a) Standard: Enrollment.

(a)(4) Authorize the proficiency testing program to release to HHS all data required to--

Interpretive Guidelines §493.801(a)(4)

The laboratory director authorizes PT data to be released to regulatory agencies when he/she signs the CLIA application for certification. The laboratory should also provide the PT program with the appropriate accreditation organization or Federal or State Agency address to which PT results must be sent. Laboratories that are accredited by a CMS-approved accreditation organization must meet the PT requirements in subpart H of the CLIA regulations, including, but not limited to, releasing all required PT data to its accreditation organization (§493.551(b)(3)).

All CLIA-exempt laboratories must enroll and participate in a CMS-approved program(s) for all analytes performed that are listed in Subpart I.

(i) Determine the laboratory's compliance with this subpart; and

(ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.

D2006
(Rev.)

§493.801(b) Standard: Testing of proficiency testing samples.

(b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it

would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

Interpretive Guidelines §493.801(b)

Review testing records to determine if special handling was given to PT samples. Consider the unique requirements of many PT samples when evaluating "same manner" of testing. The laboratory should document any necessary reconstitution, longer mixing times, unit conversion of results, etc., as required in §493.801(b)(5).

A laboratory that routinely performs only presumptive testing or screening methods and refers patient samples to another laboratory for definitive or confirmatory testing or comparison of test results **must not refer PT samples to another laboratory for confirmatory testing**. A laboratory should limit the testing of PT specimens to the *patient testing* which is done in-house. With the exception of specimen preparation such as Immunohistochemistry (IHC) staining, laboratories need to take great care to avoid sending PT specimens or results to any entity other than their PT provider prior to the PT testing event cutoff date.

A central laboratory with more than one instrument or methodology for the same test may alternate methods or instruments from one testing event to the next as long as both are routinely used to test patient specimens. All samples for one analyte within a shipment must be tested with the same instrument.

Probes §493.801(b)

- What procedure or test method was used?
- Is this a routine test method used in the laboratory?
- Did routine personnel perform the PT?
- How often were PT samples tested? Does this conform with the laboratory's written policies for patient specimens?
- How are deviations from general laboratory practices (if any) justified?
- Do the PT results documented in the laboratory work records (worksheet) correlate with the results reported to the PT program?
- Do reports submitted to the PT program provider accurately reflect the procedure (i.e., instrument, method) used in the laboratory?

Check to see if patient samples were reported on the same day that PT samples were tested. (In a small facility, infrequent testing may necessitate the testing of PT samples without patient specimens to ensure that the PT test results are returned on time.) Did the

laboratory use the same procedure for both patient specimens and PT samples?

D2007
(Rev.)

§493.801(b) Standard: Testing of proficiency testing samples.

(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.

D2009
(Rev.)

§493.801(b) Standard: Testing of proficiency testing samples.

(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

Interpretive Guidelines §493.801(b)(1)

This requirement is NOT to be interpreted as prohibiting more than one testing individual from performing PT if the laboratory routinely performs patient testing using more than one "individual". PT samples are to be tested in the same manner as patient specimens. If patient specimens are tested using procedures that require more than one individual to perform, PT must be performed in the same manner.

Review records to ensure that the analyst or analysts performing the testing and the director, or his/her designee have signed a statement attesting that PT samples were tested in the same manner as patient specimens. *Secure or digital electronic signatures are acceptable (e.g., Form CMS-116, PT attestation). The electronic signature should have an electronic date/time stamp. If electronic signatures are being used, the laboratory should be able to show evidence that only the authorized person can utilize the electronic signature.* For moderate complexity testing, in accordance with §493.1407(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical consultant meeting the qualifications of §493.1409. For high complexity testing, in accordance with §493.1445(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical supervisor meeting the qualifications of §493.1449.

D2010
(Rev.)

§493.801(b) Standard: Testing of proficiency testing samples.

(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.

D2011
(New)

§493.801(b) Standard: Testing of proficiency testing samples.

(b)(3) The laboratory must report PT results for microbiology organism identification to the highest level that it reports results on patient specimens.

D201*2*
(Rev.)

§493.801(b) Standard: Testing of proficiency testing samples.

(b)(4) **Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent.**

Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

Interpretive Guidelines §493.801(b)*(4)*

Handle allegations of inter-laboratory communications or referral of proficiency testing specimens as a complaint and investigate using the complaint investigation procedures outlined in *section 6061* of the SOM. Immediately contact *CMS* if you find evidence to support these kinds of allegations.

D2013
(Rev.)

§493.801(b) Standard: Testing of proficiency testing samples.

(b)*(5)* The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a

proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with § 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

Interpretive Guidelines §493.801(b)*(5)*

The regulation refers to referral of PT specimens to another laboratory for analysis. *Refer to section 6061 of the SOM.*

For those tests not listed under Subpart I (not regulated), the laboratory is free to enroll in a PT program to verify the accuracy of their test or procedure. Due to the breadth of the statutory bar on PT sample referrals, however, laboratories should take great measures to avoid sending any such PT samples (or test results) to another laboratory for any reason prior to the PT testing event cutoff date. The PT referral consequences (loss of certificate and *prohibition* on owner/operator*/laboratory director*) apply equally to all PT testing samples and results.

Do not solicit a*n Allegation of Compliance* from a laboratory when it has been determined that the laboratory referred its PT samples to another laboratory for analysis. Immediately notify *CMS* and forward to *CMS* all documentation necessary to support the findings.

D201*4*
(Rev.)

§493.801(b) Standard: Testing of proficiency testing samples.

(b)*(6)* The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

Interpretive Guidelines §493.801(b)*(6)*

Review records to ensure that the analyst or analysts performing the testing and the director or his/her designee have signed the statement attesting that PT samples were tested in the same manner as patient specimens. *Secure or digital electronic signatures are acceptable (e.g., Form CMS-116, PT attestation). The electronic signature should have an electronic date/time stamp. If electronic signatures are being used, the laboratory should be able to show evidence that only the authorized person can utilize the electronic signature.*

For moderate complexity testing, in accordance with §493.1407(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical consultant meeting the qualifications of §493.1409. For high complexity testing, in accordance with §493.1445(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical supervisor meeting the qualifications of §493.1447. The signature of the director or technical consultant/supervisor need not be obtained prior to reporting PT results to the PT provider.

D2015
(Rev.)

§493.801(b) Standard: Testing of proficiency testing samples.

(b)*(7)* PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

Interpretive Guidelines §493.801(b)*(7)*

Primary means the test system(s), assay(s) or examination(s) routinely used for patient testing at the time of the PT testing event.

D2016
(Rev.)

§493.803 Condition: Successful participation.

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

(b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part.

(c) If a laboratory fails to perform successfully in a CMS-approved proficiency

testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:

(1) There is immediate jeopardy to patient health and safety.

(2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.

(3) The laboratory has a poor compliance history.

Interpretive Guidelines §493.803

Only the PT program has the capability to correct scores in the CMS PT monitoring system. *See SOM section 6056.*

No single PT enforcement protocol is universally applicable for all situations. Unique circumstances may require special considerations or actions that may not conform to the general approach outlined below. The laboratory's compliance history, its willingness to take remedial actions, and the professional judgment of surveyors and enforcement personnel may be factors in determining an appropriate PT enforcement plan.

Careful review of PT performance reports and other available information should always be performed to determine whether the PT results truly represent failed PT. The potential of a PT program data input error or other factors beyond the laboratory's control should be considered. If the laboratory has made a transcription error(s), it is considered erroneous PT result(s).

If review and verification of PT performance reports confirm unsuccessful PT, cite as a Condition-level deficiency (use D2016 on the Form CMS-2567).

NOTE: The CMS PT monitoring system may NOT be used alone to determine unsuccessful participation. Surveyors must verify any unsuccessful participation indicated in the PT monitoring system. This may be done by reviewing PT results supplied by the approved PT program (they will send copies to the surveyor if requested) or from results sent to the laboratory by the PT program.

If the unsuccessful PT participation is the first occurrence for the laboratory, and none of the exceptions listed at §493.803(c)(1)-(3) exist, *cite the laboratory at the condition-level (D2016). N*otify the laboratory to seek training of its personnel, obtain the necessary technical assistance to correct the problem causing the unsuccessful participation, or both. SAs may initiate training and/or technical assistance after first obtaining *CMS'* concurrence. No on-site review is required to initiate this action.

The laboratory must submit an *allegation of compliance*, listing completion dates and other pertinent information for its training and/or technical assistance efforts. Follow-up is necessary to verify that the laboratory has carried out its *allegation of compliance*. If a laboratory refuses to take acceptable training and/or technical assistance actions (including failure to submit an *allegation of compliance*, or failure to complete its *allegation of compliance*), *a* sanction action may be initiated *by CMS*.

When the unsuccessful PT participation is not the first such occurrence for the laboratory, cite as a condition-level deficiency and take appropriate enforcement action. *In some cases, it may also be necessary to cite the laboratory director in order for the laboratory to achieve compliance. Citing of the laboratory director in addition to PT citations, is at the discretion of the surveyor.* For immediate jeopardy cases, the procedures in Subpart R apply. For non-immediate jeopardy situations, enforcement procedures should be completed within 90 days from the date that the unsuccessful PT was first identified. In immediate jeopardy situations, enforcement procedures should be completed within 23 days from the date unsuccessful participation of PT is first identified.

Example *1*: *Initial Unsuccessful*

A laboratory scores 60% on a testing event in *Sodium*. On the next testing event, the laboratory fails to participate in *Sodium (Na)*. The citations are *D2096 (§493.841(f))* and D2016 (§493.803). *D6000 (§493.1403) or D6076 (§493.1441) are laboratory director citations.* (Note: It is not necessary to cite the standard for unsatisfactory analyte performance. However, it is necessary to cite the standard when the laboratory fails to participate in a testing event so that the laboratory is made aware that such deficient practice results in a score of 0 for the testing event.)

Analyte	*2019*			*2020*			*2021*			*2022*		
	Event 1 Score	*Event 2 Score*	*Event 3 Score*	*Event 1 Score*	*Event 2 Score*	*Event 3 Score*	*Event 1 Score*	*Event 2 Score*	*Event 3 Score*	*Event 1 Score*	*Event 2 Score*	*Event 3 Score*
Sodium (Na)	*100%*	*80%*	*100%*	*100%*	*80%*	*80%*	*100%*	*80%*	*80%*	*60%*	*0%*	*100%*

Example *2*: *Initial Unsuccessful*

A laboratory scores 60% on uric acid PT samples. On the next testing event, the laboratory scores 40% on the same analyte. *The citations are D2096 (§493.841(f)) and D2016 (§493.803). D6000 (§493.1403) or D6076 (§493.1441) are laboratory director citations.* (Note: Cite the standard for unsuccessful performance and the condition for unsuccessful participation. It is not necessary to cite the standard for unsatisfactory analyte performance.)

Analyte	*2019*	*2020*	*2021*	*2022*

	Event 1 Score	*Event 2 Score*	*Event 3 Score*	*Event 1 Score*	*Event 2 Score*	*Event 3 Score*	*Event 1 Score*	*Event 2 Score*	*Event 3 Score*	*Event 1 Score*	*Event 2 Score*	*Event 3 Score*
Uric Acid (UA)	*100%*	*100%*	*80%*	*100%*	*100%*	*100%*	*80%*	*80%*	*100%*	*60%*	*40%*	*100%*

Example 3: Non-initial (Subsequent) Unsuccessful - Rolling Timeframe

A laboratory scores 60% in Sodium for two consecutive PT events resulting in initial unsuccessful PT performance. The citations are D2096 (§493.841(f)) and D2016 (§493.803). The laboratory scores 80% for the next three PT events. After the three successful PT events, the laboratory scores 60% in two consecutive PT events resulting in non-initial unsuccessful PT performance. The citations are D2096 (§493.841(f)) and D2016 (§493.803). D6000 (§493.1403) or D6076 (§493.1441) are laboratory director citations. Non-initial unsuccessful PT performance is referred to CMS for enforcement actions. See SOM sections 6050 and 6054.

Analyte	*2019*			*2020*			*2021*			*2022*		
	Event 1 Score	*Event 2 Score*	*Event 3 Score*	*Event 1 Score*	*Event 2 Score*	*Event 3 Score*	*Event 1 Score*	*Event 2 Score*	*Event 3 Score*	*Event 1 Score*	*Event 2 Score*	*Event 3 Score*
Sodium (Na)	*100%*	*80%*	*100%*	*80%*	*100%*	*60%*	*60%*	*80%*	*80%*	*80%*	*60%*	*60%*

When recommending to *CMS* that a laboratory be subject to sanctions, submit copies of the laboratory's testing event or analyte score(s) that were unsatisfactory and the correct responses provided by the PT program. Also, enclose copies of any correspondence sent to or received by the laboratory concerning its PT performance.

Probes:

Do the laboratory's PT results show satisfactory performance in the next PT event?

Did the laboratory verify its corrective action or training and technical assistance was successful?

D2017
(Rev.)

§493.*807* Condition: Reinstatement of laboratories performing nonwaived testing.

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test.

(b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

Interpretive Guidelines §493.807

The surveyor may review *the CLIA Data System Report* of the PT monitoring system to determine whether the laboratory has performed two consecutive PT events successfully. These data are identified as "non-routine" scores in the system. The PT program supplying the re-instatement samples will grade the events and enter the scores in the system.

PROFICIENCY TESTING BY SPECIALTY AND SUBSPECIALTY FOR LABORATORIES PERFORMING TESTS OF MODERATE COMPLEXITY (INCLUDING THE SUBCATEGORY), HIGH COMPLEXITY, OR ANY COMBINATION OF THESE TESTS

§493.821 Condition: Microbiology.

(Rev.)

The specialty of microbiology includes, for purposes of proficiency testing, the subspecialties of bacteriology, mycobacteriology, mycology, parasitology and virology.

Interpretive Guidelines §493.821

Given the connection between § 493.821 and §§ 493.911 – 493.919 for the proficiency testing requirement for the specialty of microbiology, we have included the below interpretive guidelines pertaining to §§ 493.911 – 493.919 for your awareness.

PT is not required by method or specific technology for microbiology subspecialties. Regardless of the method a laboratory uses for microorganism identification and susceptibility testing, PT is required for these subspecialties of microbiology. Each laboratory needs to identify the method or test system used when submitting PT results for programs to properly grade the PT.

A laboratory must identify the organisms to highest level that the laboratory reports results on patient specimens. If a laboratory reports patient results to the genus level, that is the expectation for PT. Similarly, if a laboratory reports patient results to the species level, that would be the expectation for reporting PT results.

D2020

(Rev.)

§493.823 Standard: Bacteriology.

§493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

D2021

(Rev.)

§493.823 Standard: Bacteriology.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2025

(Rev.)

§493.823 Standard: Bacteriology.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2026

(Rev.)

§493.823 Standard: Bacteriology.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2028

(Rev.)

§493.823 Standard: Bacteriology.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2029
(Rev.)

§493.825 Standard: Mycobacteriology.

§493.825(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

D2030
(Rev.)

§493.825 Standard: Mycobacteriology.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2034
(Rev.)

§493.825 Standard: Mycobacteriology.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2035
(Rev.)

§493.825 Standard: Mycobacteriology.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to

participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2037

(Rev.)

§493.825 Standard: Mycobacteriology.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2038

(Rev.)

§493.827 Standard: Mycology.

§493.827(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

D2039

(Rev.)

§493.827 Standard: Mycology.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2043
(Rev.)

§493.827 Standard: Mycology.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2044
(Rev.)

§493.827 Standard: Mycology.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2046
(Rev.)

§493.827 Standard: Mycology.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2047
(Rev.)

§493.829 Standard: Parasitology.

§493.829(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

D2048
(Rev.)

§493.829 Standard: Parasitology.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2052
(Rev.)

§493.829 Standard: Parasitology.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2053
(Rev.)

§493.829 Standard: Parasitology.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2055
(Rev.)

§493.829 Standard: Parasitology.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2056
(Rev.)

§493.831 Standard: Virology.

§493.831(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

D2057
(Rev.)

§493.831 Standard: Virology.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2061
(Rev.)

§493.831 Standard: Virology.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2062
(Rev.)

§493.831 Standard: Virology.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing events, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2064
(Rev.)

§493.831 Standard: Virology.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

Interpretive Guidelines §493.831(e)

Any laboratory testing patient specimens for the Human Papillomavirus (HPV) must enroll and successfully participate in a CMS-approved proficiency testing program for HPV. Laboratories should refer to Subpart H for further information. For example: A Cytology laboratory that performs HPV testing must have a CLIA certificate that includes the subspecialty of Virology.

§493.833 Condition: Diagnostic immunology.
(Rev.)

The specialty of diagnostic immunology includes for purposes of proficiency testing the subspecialties of syphilis serology and general immunology.

D2066
(Rev.)

§493.835 Standard: Syphilis serology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

D2067
(Rev.)

§493.835 Standard: Syphilis serology.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2071
(Rev.)

§493.835 Standard: Syphilis serology.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2072
(Rev.)

§493.835 Standard: Syphilis serology.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2074
(Rev.)

§493.835 Standard: Syphilis serology.

§493.835(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2075
(Rev.)

§493.837 Standard: General immunology.

Refer to Subpart I for analytes or tests for which laboratory PT performance is to be evaluated.

NOTE: If a laboratory performs both a quantitative and a qualitative procedure of a test or analyte, it may choose which to enroll in to fulfill the enrollment requirement. It need not enroll in both quantitative and qualitative PT for the same analyte. *The laboratory is required to perform twice a year verification of accuracy for the test not enrolled for PT. (See §493.1236/D5217)*

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

D2076
(Rev.)

§493.837 Standard: General immunology.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

D2077
(Rev.)

§493.837 Standard: General immunology.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2081
(Rev.)

§493.837 Standard: General immunology.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2082
(Rev.)

§493.837 Standard: General immunology.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2084
(Rev.)

§493.837 Standard: General immunology.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2085
(Rev.)

§493.837 Standard: General immunology.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.839 Condition: Chemistry.

(Rev.)

The specialty of chemistry includes for the purposes of proficiency testing the subspecialties of routine chemistry, endocrinology, and toxicology.

Refer to Subpart I for analytes or tests for which laboratory PT performance is to be evaluated, which include serum, plasma or blood samples.

D2087

(Rev.)

§493.841 Standard: Routine chemistry.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

D2088

(Rev.)

§493.841 Standard: Routine chemistry.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

D2089

(Rev.)

§493.841 Standard: Routine chemistry.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing

program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2093
(Rev.)

§493.841 Standard: Routine chemistry.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2094
(Rev.)

§493.841 Standard: Routine chemistry.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2096
(Rev.)

§493.841 Standard: Routine chemistry.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2097
(Rev.)

§493.841 Standard: Routine chemistry.

(g) Failure to achieve an overall testing event score of satisfactory performance for

two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2098
(Rev.)

§493.843 Standard: Endocrinology.

Refer to Subpart I for analytes or tests for which laboratory PT performance is to be evaluated, which include serum, plasma, blood, or urine.

NOTE: If the laboratory performs the same analyte on different specimen types, it may choose which specimen type to enroll in PT. The laboratory need not enroll for each specimen type of the same analyte. *The laboratory is required to perform twice a year verification of accuracy for the test not enrolled for PT. (See §493.1236/D5217)*

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

D2099
(Rev.)

§493.843 Standard: Endocrinology.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

D2100
(Rev.)

§493.843 Standard: Endocrinology.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to

perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2104
(Rev.)

§493.843 Standard: Endocrinology.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2105
(Rev.)

§493.843 Standard: Endocrinology.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2107
(Rev.)

§493.843 Standard: Endocrinology.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2108
(Rev.)

§493.843 Standard: Endocrinology.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2109
(Rev.)

§493.845 Standard: Toxicology.

Refer to Subpart I for analytes or tests for which laboratory PT performance is to be evaluated, which include serum, plasma, or blood.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

D2110
(Rev.)

§493.845 Standard: Toxicology.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

D2111
(Rev.)

§493.845 Standard: Toxicology.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2115
(Rev.)

§493.845 Standard: Toxicology.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2116
(Rev.)

§493.845 Standard: Toxicology.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2118
(Rev.)

§493.845 Standard: Toxicology.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2119
(Rev.)

§493.845 Standard: Toxicology.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§493.849 Condition: Hematology.
(Rev.)

The specialty of hematology, for the purpose of proficiency testing, is not subdivided into subspecialties of testing.

Refer to Subpart I for analytes or tests for which laboratory PT performance is to be evaluated.

Interpretive Guidelines §493.849

Given the connection between § 493.849 and § 493.941 for the proficiency testing requirement for the specialty of hematology, we have included the below interpretive guideline pertaining to § 493.941 for your awareness.

Laboratories performing both cell counts and differentials must enroll and participate in PT for both.

D2121
(Rev.)

§493.851 Standard: Hematology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

D2122
(Rev.)

§493.851 Standard: Hematology.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

D2123
(Rev.)

§493.851 Standard: Hematology.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the

suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2127

(Rev.)

§493.851 Standard: Hematology.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2128

(Rev.)

§493.851 Standard: Hematology.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2130

(Rev.)

§493.851 Standard: Hematology.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

D2131

(Rev.)

§493.851 Standard: Hematology.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is

unsuccessful performance.

§493.853 Condition: Pathology.

The specialty of pathology includes, for purposes of proficiency testing, the subspecialty of cytology limited to gynecologic examinations.

D2132
(Rev.)

§493.855 Standard: Cytology: *g*ynecologic *e*xaminations.

To participate successfully in a cytology proficiency testing program for gynecologic examinations (Pap smears), the laboratory must meet the requirements of paragraphs (a) through (c) of this section.

D2133
(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by CMS by January 1, 1995, if available in the State in which he or she is employed.

Interpretive Guidelines §493.855(a)

Confirm by review of the attestation of enrollment documentation that all the individuals examining gynecologic cytology slides are enrolled in a CMS-approved cytology PT program.

If an individual works at more than one laboratory, the individual will be required to indicate, prior to the first testing event, one laboratory as the primary laboratory where the individual will be tested. Each laboratory is responsible for ensuring that all individuals examining gynecologic preparations in their laboratory indicate a location of testing.

Pathologists who routinely examine gynecologic cytology slide preparations, only after they have been examined and marked by a cytotechnologist, may be tested by one of two methods:

a. Using a test that has been previously examined or marked by a cytotechnologist in their laboratory accompanied by the cytotechnologist's PT answers, or

b. Using a test set that has not been previously examined.

A pathologist, who examine and interprets slide preparations without pre-screening by a cytotechnologist, must be tested using a test set that has not been previously examined.

Each individual participating in a CMS-approved Cytology PT Program will be assigned a unique national PT registration number (PRT#) that will remain, regardless of the CMS-approved PT program utilized or future places of employment. Identifying information for individuals will be placed in a Privacy Act protected System of Records at CMS, and its confidentiality will be maintained in accordance with applicable law.

Personnel Requirement for Cytology Proficiency Testing (PT)

Cytotechnologist—Newly Certified by ASCP
New graduates of schools of cytotechnology who have taken the Certification Examination in Cytotechnology administered by the American Society for Clinical Pathology (ASCP) Board of Registry (BOR) and obtained a passing score have demonstrated an initial competency level in the examination of cervical cytology. These newly certified individuals will **not** be monitored for PT by CMS throughout the calendar year in which they passed their ASCP BOR Examination.

- New graduates of schools of cytotechnology who are employed, have taken the Certification Examination in Cytotechnology administered by the ASCP BOR, but have **not** obtained a passing score are required to participate in a CMS-approved Cytology Proficiency Testing Program.

Pathologists—Newly Board Certified

- Anatomic pathologists who are newly certified by the American Board of Pathology or the American Osteopathic Board of Pathology have demonstrated an initial level of competency interpreting cervical cytology specimens by passing the examination. These newly board certified individuals will **not** be monitored for PT by CMS throughout the calendar year in which they became board certified in Anatomic Pathology.
- Cytopathologists who receive added qualifications in Cytopathology from the American Board of Pathology or the American Osteopathic Board of Pathology have demonstrated competency interpreting cervical cytology specimens by passing this examination. These newly board certified individuals will **not** be monitored for PT by CMS throughout the calendar year in which they became board certified in Cytopathology.

Residents and Fellows

- Anatomic pathology residents are not required to participate in a CMS-approved Cytology PT Program. Pathology residents are under the constant supervision of fully licensed physicians and are not responsible for the final diagnosis of cervical cytology specimens.
- Anatomic pathology fellows whose responsibilities in the cytology laboratory include the examination and interpretation of gynecologic specimens must enroll

and achieve a passing score in a CMS-approved Cytology PT Program each calendar year.

All Other Cytotechnologists and Pathologists

- All other individuals subject to Cytology PT must enroll and be tested during each calendar year.

D2134

(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(a) The laboratory must ensure that each individual is tested at least once per year and obtains a passing score.

To ensure this annual testing of individuals, an announced or unannounced testing event will be conducted on-site in each laboratory at least once each year. Laboratories will be notified of the time of each announced on-site testing event at least 30 days prior to each event. Additional testing events will be conducted as necessary in each State or region for the purpose of testing individuals who miss the on-site testing event and for retesting individuals as described in paragraph (b) of this section.

Interpretive Guidelines §493.855(a)

The regulations require that all laboratory personnel who examine gynecologic cytology slide preparations must be present in the laboratory to take the proficiency test on the date the laboratory is scheduled for the testing. The precise dates of testing and logistical arrangements are the responsibility of the laboratory and the PT provider. Those individuals not present for the test on the scheduled date will need to have an excused absence, verified by the Laboratory Director. Participants who miss the scheduled on-site test without an excused absence will receive a failing score of "0." Laboratories must contact the PT program to determine when and where the make-up examination will take place. Examples of "excused" absences include prior scheduled leave, natural disasters, hospitalization, death in the family, etc. Those individuals working at more than one location must identify the laboratory where they will be tested prior to the first testing event. A passing score is 90%.

D2136

(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(b) The laboratory must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set as described in §493.945.

D2137
(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(b) Individuals who fail this testing event are retested with another 10-slide test set as described in paragraphs (b)(1) and (b)(2) of this section.

D2138
(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(b) Individuals who fail this second test are subsequently retested with a 20-slide test set as described in paragraphs (b)(2) and (b)(3) of this section.

Individuals are given not more than 2 hours to complete a 10-slide test and not more than 4 hours to complete a 20-slide test.

D2141
(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(b) Unexcused failure to appear by an individual for a retest will result in test failure with resulting remediation and limitations on slide examinations as specified in (b)(1), (b)(2), and (b)(3) of this section.

Interpretive Guidelines §493.855(b)

If a test is missed due to an unexcused absence, the individual receives a test score of "0".

If the test is missed for an excused absence, laboratories must contact the proficiency testing program to determine when and where the make-up examination will take place. Examples of "excused" absences include prior scheduled leave, natural disasters, hospitalization, death in the family, etc.

D2142
(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(b)(1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set.

D2143
(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(b)(1) For an individual who fails an annual proficiency testing event, the laboratory must schedule a retesting event which must take place not more than 45 days after receipt of the notification of failure.

D2144
(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(b)(2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set.

D2145
(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(b)(2) For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and

D2146

§493.855(b)(2) must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide test set and scores at least 90 percent.

D2147
(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(b)(2) Reexamination of slides must be documented.

D2148
(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(b)(3) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set.

D2149
(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(b)(3) An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and

D2150
(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(b)(3) may not resume examining gynecologic slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until he or she is retested with a 20-slide test set and scores at least 90 percent.

D2151
(Rev.)

§493.855 Standard: Cytology: gynecologic examinations.

(c) If a laboratory fails to ensure that individuals are tested or those who fail a testing event are retested, or fails to take required remedial actions as described in paragraphs (b)(1), (b)(2) or (b)(3) of this section, CMS will initiate intermediate sanctions or limit the laboratory's certificate to exclude gynecologic cytology testing under CLIA, and, if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of this part.

Interpretive Guidelines §493.855(c)

Any laboratory testing patient specimens for the Human Papillomavirus (HPV) must enroll and successfully participate in a CMS-approved proficiency testing program for HPV beginning in 2008. Laboratories should refer to Subpart H for further information. The laboratory's CLIA certificate must include the subspecialty of Virology regardless of where the testing is performed.

§493.857 Condition: Immunohematology.
(Rev.)

The specialty of immunohematology includes four subspecialties for the purposes of proficiency testing: ABO group and D (Rho) typing; unexpected antibody detection; compatibility testing; and antibody identification.

Refer to Subpart I for analytes or tests for which laboratory PT performance is to be evaluated.

D2153
(Rev.)

§493.859 Standard: ABO *g*roup and D (Rho) *t*yping.

(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.

D2154
(Rev.)

§493.859 Standard: ABO *g*roup and D (Rho) *t*yping.

(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

D2155
(Rev.)

§493.859 Standard: ABO group and D (Rho) typing.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2159
(Rev.)

§493.859 Standard: ABO group and D (Rho) typing.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2160
(Rev.)

§493.859 Standard: ABO group and D (Rho) typing.

(e)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2162
(Rev.)

§493.859 Standard: ABO group and D (Rho) typing.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2163
(Rev.)

§493.859 Standard: ABO group and D (Rho) typing.

(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2164
(Rev.)

§493.861 Standard: Unexpected antibody detection.

(a) Failure to attain an overall testing event score of at least *100* percent is unsatisfactory performance.

D2165
(Rev.)

§493.861 Standard: Unexpected antibody detection.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2169
(Rev.)

§493.861 Standard: Unexpected antibody detection.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2170
(Rev.)

§493.861 Standard: Unexpected antibody detection.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2172
(Rev.)

§493.861 Standard: Unexpected antibody detection.

(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2173
(Rev.)

§493.863 Standard: Compatibility testing.

(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

D2174
(Rev.)

§493.863 Standard: Compatibility testing.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2178
(Rev.)

§493.863 Standard: Compatibility testing.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2179
(Rev.)

§493.863 Standard: Compatibility testing.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2181
(Rev.)

§493.863 Standard: Compatibility testing.

(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2182
(Rev.)

§493.865 Standard: Antibody identification.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

D2183
(Rev.)

§493.865 Standard: Antibody identification.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.

Consideration may be given to those laboratories failing to participate in a testing event only if--

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

D2187
(Rev.)

§493.865 Standard: Antibody identification.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

D2188
(Rev.)

§493.865 Standard: Antibody identification.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2190
(Rev.)

§493.865 Standard: Antibody identification.

(e) Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.

D2191

(Rev.)

§493.865 Standard: Antibody identification.

(f) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

Subpart J--Facility Administration for Nonwaived Testing

D3000
(Rev.)

§493.1100 Condition: Facility administration.

Each laboratory that performs nonwaived testing must meet the applicable requirements under §§493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).

Interpretive Guidelines §493.1100

To determine which tests are categorized as waived or nonwaived (i.e. moderate or high complexity tests), refer to the following web link for the FDA categorization database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm?sAN=0). Test systems, assays, and examinations not yet classified are considered high complexity.

Significant deficiencies cited under this condition may also indicate deficiencies under personnel responsibilities.

D3001
(Rev.)

§493.1101 Standard: Facilities.

(a) The laboratory must be constructed, arranged, and maintained to ensure the following:

(a)(1) The space, ventilation, and utilities necessary for conducting all phases of the testing process.

Interpretive Guidelines §493.1101(a)(1)

Work areas should be arranged to minimize problems in specimen handling, examination and testing, and the reporting of test results.

Workbench space should be sufficient for test performance, well lit, and have water, gas, suction, and electrical outlets as necessary. Instruments, equipment, and computer systems should be placed in locations where their operation is not affected adversely by physical or chemical factors, such as heat, direct sunlight, vibrations, power fluctuations or fumes from acid or alkaline solutions. Equipment tops should not be used as workbench space.

Determination of proper lighting is subjective since the regulations do not specify the foot-candles or other measures of light intensity required. Ensure that lighting or background is appropriate for visual interpretation of test results (e.g., macroscopic evaluation of hemagglutination reactions or strep screen; dark background with reflected light for reading K-B disk diffusion AST). When citing deficiencies, document the circumstances in which lighting adversely or may adversely affect test performance or personnel safety.

Determine that the laboratory has a system to ensure its ventilation system properly removes vapors, fumes, and excessive heat, when appropriate, for the type of testing done in the laboratory.

Ensure that an adequate, stable electrical source is maintained at each location (e.g. outlets, not extension cords) and meets the power requirements for each piece of equipment.

D3003
(Rev.)

§493.1101 Standard: Facilities.

(a)(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.

D3005
(Rev.)

§493.1101 Standard: Facilities.

(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

Interpretive Guidelines §§493.1101(a)(2)-(a)(3)

The laboratory should establish contamination prevention procedures to minimize contamination of patient specimens, equipment, instruments, reagents, materials, and supplies.

Determine if the laboratory performs wipe tests of areas where radioactive material or amplification procedures are used in order to monitor and prevent contamination.

Laboratories performing molecular amplification procedures should have a mechanism to detect cross-contamination of patient specimens. This may be accomplished by including a "blank" control with each run of patient specimen testing (use D5425).

The “blank” control refers to a no-template control (N.T.C) or a control sample containing all reagents except the target template.

An example of a “closed system” would be an FDA-cleared or FDA-approved test system that contains amplification and detection steps in sealed tubes that are never opened or re-opened during or after the testing process and that is used as directed or suggested by the manufacturer (i.e., without any modifications).

Unidirectional workflow refers to the manner in which testing personnel and patient specimens move through the molecular testing process to prevent cross-contamination, and consists of separate areas for the following:

- Reagent preparation (as applicable);
- Pre-amplification area for specimen preparation and amplification reaction set up; and
- Post-amplification area for specimen amplification, product detection, and storage or disposal of amplified products.

Reagents must be prepared in an area that is separate (as applicable) from where specimens are processed, prepared, “amplified” and detected to prevent contamination. Once a specimen enters the amplification and product detection area it should not be brought back to the reagent or specimen preparation areas. The laboratory should store amplified specimens separately from test reagents and patient specimens. All equipment (e.g., reagents, supplies, pens, pipettes and tips, laboratory coats) should remain in designated areas.

Sources of potential cross-contamination in molecular testing include:

- Patient specimen (i.e., genomic contamination);
- Amplified patient specimen (i.e., amplicon contamination); and
- Testing personnel.

D3007
(Rev.)

§493.1101 Standard: Facilities.

(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.

Interpretive Guidelines §493.1101(b)

Base deficiencies related to inappropriate or insufficient equipment on a determination that patient results are or may be adversely affected. Ensure that the laboratory has the appropriate equipment to prepare reagents, stains, solutions, controls, and calibration materials (e.g., pipettes, hydrometers, graduated cylinders, autoclaves, balances, centrifuges, distilled/deionized water). If the equipment or instrumentation is found to be inappropriate or insufficient, document the reasons for this finding.

Ensure that the laboratory has test systems, equipment and/or instruments capable of producing results within the laboratory's stated test performance specifications.

Ensure that the laboratory has test systems, equipment and/or instruments necessary to perform the laboratory's volume of testing (preanalytic, analytic, postanalytic) within established turnaround times.

Data capacity in the laboratory's information system should be sufficient for current data entry. If capacity is maintained by deletion of data, it should be scheduled and documented.

For Cytology, laboratories should use coverslips that cover the entire surface of the specimen.

D3009
(Rev.)

§493.1101 Standard: Facilities.

(c)The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

Interpretive Guidelines §493.1101(c)

The laboratory must possess a current license issued by the State (or local government, if such licensing exists. If a State *(https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/cliasa.pdf)* or local government removes a laboratory's license and the right to operate within the State or locality, Centers for Medicare & Medicaid Services (CMS) may take an action to revoke the Clinical Laboratory Improvement Amendments (CLIA) certificate.

D3011
(Rev.)

§493.1101 Standard: Facilities.

(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

Interpretive Guidelines §493.1101(d)

If you observe or obtain information regarding potential safety violations not applicable under CLIA, notify the appropriate State or local authority. Consult with *CMS* or notification to other Federal agencies such as the Occupational Safety and Health Administration (OSHA) (*https://www.osha.gov/*), Environmental Protection Agency (EPA) (www.epa.gov), or Nuclear Regulatory Commission (NRC). The appropriate Federal, State or local authority, if warranted, will investigate and, if necessary, conduct an on-site visit.

Probes §493.1101(d)

What safety protocols are observed and practiced in the laboratory?

How does the laboratory, including temporary testing sites or mobile units:

- Dispose of radiological, chemical, and biological wastes (including blood drawing equipment);
- Clean up spills (chemical, biological, and radiological); and
- Determine the amount of waste that can safely be contained and the precautions necessary to ensure that liquid waste does not spill or splash while in travel status?

What chemical, radiological, or biological precautions are taken, if any, during the preparation or handling of reagents?

D3013
(Rev.)

§493.1101 Standard: Facilities.

(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.

Interpretive Guidelines §493.1101(e)

The laboratory must arrange a secure area for storage of records and, as applicable, slides blocks, and tissues that will provide conditions that ensure proper preservation of specimens and records.

Paraffin blocks must be stored in a cool dry environment. Exposure to excessive heat may cause blocks to melt.

Probes §493.1101(e)

For Cytology and Histology, how does the laboratory ensure that the slides have completely dried prior to being stored?

D3015
(Rev.)

§493.1103 Standard: Requirements for transfusion services.

A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities.

Interpretive Guidelines §493.1103

A "facility that provides transfusion services" is any entity that may store and/or administer blood and blood products to patients.

D3017
(Rev.)

§493.1103 Standard: Requirements for transfusion services.

(a) Arrangement for services. The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products.

Interpretive Guidelines §493.1103(a)

Determine which services are provided directly by the facility and which are provided through agreement and ensure that the agreement is being met.

D3019
(Rev.)

§493.1103 Standard: Requirements for transfusion services.

(b) Provision of testing. The facility must provide prompt ABO grouping, D (Rho) typing, unexpected antibody detection, compatibility testing, and laboratory investigation of transfusion reactions on a continuous basis through a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

Interpretive Guidelines §493.1103(b)

Review the agreement and determine if the outside laboratory is CLIA-certified or equivalent, as determined by CMS. An equivalent laboratory is a Veterans Health Administration (VHA) laboratory, a CLIA-exempt laboratory or a laboratory under the auspices of the Department of Defense (DoD).

Probes §493.1103

For laboratories performing ABO grouping, D typing, unexpected antibody detection or compatibility testing using automated methods, is there a back-up system in place to ensure availability of service on a continuous basis when the automated system is malfunctioning?

Is staff trained and competent in the back-up system?

D3021
(Rev.)

§493.1103 Standard: Requirements for transfusion services.

(c) Blood and blood products storage and distribution. (1) If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

Interpretive Guidelines §493.1103(c)(1)

Determine where blood and blood products are stored. There may be various unconventional blood storage areas such as operating rooms, nursing stations, long-term care facilities, and dialysis units. Determine that the facility ensures the appropriate temperature is maintained and documented for each storage area during the time blood and blood products are stored.

Acceptable temperature ranges must be established, and actual readings of temperature-controlled storage areas must be recorded during the time that blood or blood products for transfusion are stored. Whole Blood, Red Blood cells, and Thawed Plasma should be stored between 1 and 6ºC; Platelets and Thawed Cryoprecipitated AHF should be stored between 20 and 24ºC; Fresh Frozen Plasma, Plasma Frozen within 24 hours after Phlebotomy, and Cryoprecipitated AHF should be stored at -18ºC or colder.

Facilities that provide transfusion services (not certified for the specialty of Immunohematology) and perform nonwaived testing are held to the requirements for the storage and distribution of blood and blood products. The laboratory providing the blood or blood products may supply these facilities with the following:

- Policies for the proper storage and transportation of blood or blood products;

- Procedures to alert the laboratory of blood storage problems;
- Policies to ensure the positive identification of a blood or blood product recipient (use D3023);
- Procedures to identify a possible transfusion reaction (use D3025); and
- Procedures to notify the laboratory of a possible transfusion reaction (use D3025).

Determine how the appropriate temperatures of blood storage areas are maintained during a power failure.

Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. No expired blood should be in the routine inventory. Unacceptable units should be segregated from routine inventory.

Probes §493.1103(c)(1)

If frozen blood products are stored, how does the facility ensure products are maintained at appropriate temperatures to prevent thawing and re-freezing of the products?

D3023
(Rev.)

§493.1103 Standard: Requirements for transfusion services.

(c)(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient.

Interpretive Guidelines §493.1103(c)(2)

Review the facility's policies for ensuring positive identification of blood or blood products and the intended recipient.

When possible, observe the actual practice, including issuing the blood and blood products to the intended recipient. This includes proper verification of patient identification prior to initiation of the transfusion.

D3025
(Rev.)

§493.1103 Standard: Requirements for transfusion services.

(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as

appropriate, to Federal and State authorities.

Interpretive Guidelines §493.1103(d)

Review the procedures for preventing, identifying, and investigating transfusion reactions. Examine records of transfusion reaction investigations for completeness, promptness, and accuracy. Verify that investigations of transfusion reactions are conducted in accordance with the facility's established protocols. Also, verify that incidents such as incomplete compatibility testing or issuing the wrong unit to a specific patient are reported to the appropriate authorities. Records should include each step in the investigation and identify the reviewer.

For facilities that provide transfusion services, confirm that all transfusion reactions identified have been investigated and the Food and Drug Administration (FDA) has been notified of all transfusion related fatalities. If the FDA has not been notified, *follow* the *instructions below:*

According to the FDA

[21 C.F.R.] Section 606.170(b) states that you may report a fatality by telephone, facsimile, express mail, or electronically transmitted mail (email). We recommend that you submit the initial notification by email, if possible, and if you do so, you will receive an email confirmation receipt from us. If email is not feasible, please notify us by telephone or facsimile. We cannot access notification outside of customary working hours unless you use email or telephone. Similarly, we recommend that you submit 7-day follow up reports by email, facsimile, or express mail.

- *Email: fatalities2@fda.hhs.gov*
- *Telephone/voice-mail number: 240-402-9160*
- *Fax number: 301-837-6256, Attn: CBER Fatality Program Manager*
- *Express mail address:*
  Office of Compliance and Biologics Quality/CBER
  Attn: Fatality Program Manager
  10903 New Hampshire Ave. Bldg. 71, Rm. 3128
  Silver Spring, MD 20993-000

NOTE: Send *CMS* reports of all the fatal transfusion reactions identified. These reports are used to ensure that the facilities have properly notified the FDA of fatal transfusion reactions and that both CMS and the FDA have conducted all necessary follow-ups.

Currently, adverse reaction reporting, where there is no fatality and no manufacturing error, is not required to be reported to the FDA. Facilities may voluntarily submit adverse reaction reports through MedWatch found at the following link:

https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

Probes §493.1103(d)

Are problems detected during the course of the transfusion reaction investigation documented, and are procedures instituted to prevent a recurrence?

§493.1105 Standard: Retention requirements.

(Rev.)

(a) The laboratory must retain its records and, as applicable, slides, blocks, and tissues as follows:

Interpretive Guidelines §493.1105(a)

The regulation applies to manual as well as automated record systems, i.e., laboratory information systems (LIS). However, the regulation does not specify the mechanism or frequency for which a laboratory should evaluate its record storage and retrieval system(s). The laboratory should establish its own policies and procedures for evaluating its system(s) and maintain documentation of the evaluation.

D3027

(Rev.)

§493.1105 Standard: Retention requirements.

(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.

D3029

(Rev.)

§493.1105 Standard: Retention requirements.

(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.

D3031

(Rev.)

§493.1105 Standard: Retention requirements.

(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic

systems activities specified in §§493.1252 through 493.1289 for at least 2 years. In addition, retain the following:

Interpretive Guidelines §493.1105(a)(3)

The records must include instrument charts, graphs, printouts, transcribed data, and manufacturers' assay information sheets for control and calibration materials. If data are transcribed, ensure that the original and the transcribed copy are retained for 2 years.

Printouts from an instrument that is not directly interfaced with the laboratory information system must be retained for 2 years.

NOTE: Thermal paper or pressure sensitive paper may fade over time. Where necessary, the laboratory is expected to make an electronic or hard copy of applicable result printouts to ensure that they are retrievable and legible for at least two years.

The laboratory is responsible for retaining records of interpretive slide results of each gynecologic and nongynecologic cytology case that each cytotechnologist examined or reviewed for at least five years.

D3033
(Rev.)

§493.1105 Standard: Retention requirements.

(a)(3)(i) Records of test system performance specifications that the laboratory establishes or verifies under §493.1253 for the period of time the laboratory uses the test system but no less than 2 years.

D3035
(Rev.)

§493.1105 Standard: Retention requirements.

(a)(3)(ii) Immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d).

Interpretive Guidelines §493.1105(a)(3)(ii)

Refer to the current version of 21 CFR Part 606.160 for the specified section.

Non-transfusion related immunohematology patient testing and quality control (QC) records, such as instrument function checks, maintenance, and temperature records, must be retained for at least 2 years.

Other immunohematology patient and QC records related to transfusion testing, including but not limited to, donor processing, compatibility testing, and transfusion reaction investigations, must be retained for the time frame stated at 21 CFR §606.160(d). This also includes the visual inspection of whole blood and red blood cells during storage and immediately before distribution [21 CFR §606.160(b)(3)(ii)], record of reissue, including records of proper temperature maintenance [21CFR §606.160(b)(3)(iv)], and emergency release of blood, including signature of requesting physician obtained before or after release [21 CFR §606.160(b)(3)(v)].

D3037
(Rev.)

§493.1105 Standard: Retention requirements.

(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

Interpretive Guidelines §493.1105(a)(4)

Proficiency testing (PT) records include all information regarding the PT event including testing records, signed attestation statements, PT results and scores from the provider, documentation of review and records of any corrective actions.

D3039
(Rev.)

§493.1105 Standard: Retention requirements.

(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.

Interpretive Guidelines §493.1105(a)(5)

Quality assessment (QA) records do not need to be maintained and stored in one location. The records may be stored in the specific area or department appropriate to the monitoring and evaluation of the laboratory activities (preanalytic, analytic, and postanalytic).

D3041
(Rev.)

§493.1105 Standard: Retention requirements.

(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of

reporting. In addition, retain the following:

Interpretive Guidelines §493.1105(a)(6)

A copy, either paper or electronic, of the original report includes all information sent to recipients, and includes the name and address of the laboratory performing the test. The copy need not be paper, but may be retrieved from a computer system, microfilm or microfiche record, as long as it contains the exact information as sent to the individual ordering the test or utilizing the test results. The laboratory copy of the report should contain information that provides an accurate, complete, display of previously reported data retained or retrieved from the laboratory's record system.

A "preliminary report" means a test result that has been reported directly to the authorized person or laboratory that initially requested the test, directly or through an electronic health record provider or health information exchange **prior to the issuance of** the final test result(s). Frequently, a preliminary report will contain significant, but not definitive information (e.g., a urine culture preliminary report of >100,000 Gram-negative bacilli after 24 hours incubation or a beta subunit preliminary report of >200 miu/ml). It should be noted on the report when the result is a preliminary result and that a final report will follow.

A "partial report" means multiple tests are ordered on the same specimen or patient. If partial reports are issued for only those tests that have been completed, then the report date will be the date when all tests have been completed. However, the laboratory should be able to identify the date that each new test is appended to the report.

The laboratory must have a system for retaining copies of all reports, including original, preliminary, corrected, and final reports. This includes computer-generated reports.

Probes §493.1105(a)(6)

How has the laboratory verified that its record retrieval system functions appropriately?

What is the laboratory's procedure for record retrieval when the information system is not functioning due to a security breach, change in system, or extended downtime?

(a)(6)(i) Immunohematology reports as specified in 21 CFR 606.160(d).

Interpretive Guidelines §493.1105(a)(6)(i)

Refer to the current version of 21 CFR Part 600.160 for the specified section.

Transfusion-related Immunohematology test reports, including but not limited to, donor processing [§493.1271(b)], compatibility testing, and transfusion reaction investigations, must be retained for the time frame stated at 21 CFR §606.160(d).

All Immunohematology test reports not subject to 21 CFR §606.130(d) must be retained for at least 2 years

(a)(6)(ii) Pathology test reports for at least 10 years after the date of reporting.

Interpretive Guidelines §493.1105(a)(6)(ii)

For test reports from histopathology, oral pathology, or cytology that require personnel identifiers or an authorized signature (which may be electronic), the retained copy must include evidence of the identifiers or signature(s).

D3043
(Rev.)

§493.1105 Standard: Retention requirements.

(a)(7) Slide, block, and tissue retention--

(a)(7)(i) Slides.

(a)(7)(i)(A) Retain cytology slide preparations for at least 5 years from the date of examination (see §493.1274(f) for proficiency testing exception).

Interpretive Guidelines §493.1105(a)(7)(i)(A)

For storage and maintenance requirements use D3013.

NOTE: Cytology specimens include fine needle aspirates.

Retention of cytology slides:
Example:

A laboratory refers all cytology specimens to a reference laboratory for examination. The reference laboratory examines all slide preparations and reports results only on normal, negative, and unsatisfactory cases. At the request of the referring laboratory, the reference laboratory returns those cases that have reactive, reparative atypia (including repair), LSIL, HSIL, all invasive squamous carcinomas, adenocarcinoma, all other malignant neoplasms, and 10% of the normal or negatives cases (including reactive and reparative cases) for quality control review. The referring laboratory must maintain the slides of the cases that it examines and for which it provides diagnosis (i.e., slides exhibiting atypical including repair, LSIL, HSIL, all invasive squamous carcinomas, adenocarcinoma, all other malignant neoplasms, and slides chosen for the 10% rescreen).

The laboratory must maintain documentation to acknowledge the donation of each slide submitted to a proficiency testing program or loaned for other purposes.

Probes §493.1105(a)(7)(i)(A)

What protocol has been established to ensure prompt return of slides, when necessary?

(a)(7)(i)(B) Retain histopathology slides for at least 10 years from the date of examination.

(a)(7)(ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination.

(a)(7)(iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.

D3045

(Rev.)

§493.1105 Standard: Retention requirements.

(b) If the laboratory ceases operation, the laboratory must make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are retained and available for the time frames specified in this section.

Subpart K--Quality System for Nonwaived Testing

§493.1200 Introduction.

(Rev.)

(a) Each laboratory that performs nonwaived testing must establish and maintain written policies and procedures that implement and monitor a quality system for all phases of the total testing process (that is, preanalytic, analytic, and postanalytic) as well as general laboratory systems.

(b) The laboratory's quality systems must include a quality assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates and resolves problems.

(c) The various components of the laboratory's quality system are used to meet the requirements in this part and must be appropriate for the specialties and subspecialties of testing the laboratory performs, services it offers, and clients it serves.

Interpretive Guidelines §493.1200(c)

Tests or procedures used to detect or identify an organism or cellular components of an organism regardless of test methodology, are categorized in the appropriate subspecialty. For example, tests or procedures for identifying Group A Streptococcus are categorized in Bacteriology.

D5002

(Rev.)

§493.1201 Condition: Bacteriology.

If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1261, and §§493.1281 through 493.1299.

D5004

(Rev.)

§493.1202 Condition: Mycobacteriology.

If the laboratory provides services in the subspecialty of Mycobacteriology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1262, and §§493.1281 through 493.1299.

D5006

(Rev.)

§493.1203 Condition: Mycology.

If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1263, and §§493.1281 through 493.1299.

D5008
(Rev.)

§493.1204 Condition: Parasitology.

If the laboratory provides services in the subspecialty of Parasitology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1264, and §§493.1281 through 493.1299.

Interpretive Guidelines §493.1204

Tests or procedures to detect or identify an antibody to *a* parasite are categorized in the subspecialty of General Immunology.

D5010
(Rev.)

§493.1205 Condition: Virology.

If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1265, and §§493.1281 through 493.1299.

Interpretive Guidelines §493.1205

Tests or procedures to detect *or identify an* antibody to *a virus* are categorized in the subspecialty of General Immunology.

D5012
(Rev.)

§493.1207 Condition: Syphilis serology.

If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, and §§493.1281 through 493.1299.

D5014
(Rev.)

§493.1208 Condition: General immunology.

If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, and §§493.1281 through 493.1299.

D5016
(Rev.)

§493.1210 Condition: Routine chemistry.

If the laboratory provides services in the subspecialty of Routine chemistry, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1267, and §§493.1281 through 493.1299.

D5018
(Rev.)

§493.1211 Condition: Urinalysis.

If the laboratory provides services in the subspecialty of Urinalysis, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, and §§493.1281 through 493.1299.

D5020
(Rev.)

§493.1212 Condition: Endocrinology.

If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, and §§493.1281 through 493.1299.

D5022
(Rev.)

§493.1213 Condition: Toxicology.

If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, and §§493.1281 through 493.1299.

D5024
(Rev.)

§493.1215 Condition: Hematology.

If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1269, and §§493.1281 through 493.1299.

D5026
(Rev.)

§493.1217 Condition: Immunohematology.

If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1271, and §§493.1281 through 493.1299.

D5028
(Rev.)

§493.1219 Condition: Histopathology.

If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1273, and §§493.1281 through 493.1299.

D5030
(Rev.)

§493.1220 Condition: Oral *p*athology.

If the laboratory provides services in the subspecialty of Oral pathology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, and §§493.1281 through 493.1299.

D5032
(Rev.)

§493.1221 Condition: Cytology.

If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1274, and §§493.1281 through 493.1299.

D5034
(Rev.)

§493.1225 Condition: Clinical *c*ytogenetics

If the laboratory provides services in the specialty of Clinical cytogenetics, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1276, and §§493.1281 through 493.1299.

D5040
(Rev.)

§493.1226 Condition: Radiobioassay.

If the laboratory provides services in the specialty of Radiobioassay, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, and §§493.1281 through 493.1299.

D5042
(Rev.)

§493.1227 Condition: Histocompatibility.

If the laboratory provides services in the specialty of Histocompatibility, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1278, and §§493.1281 through 493.1299.

GENERAL LABORATORY SYSTEMS

D5200
(Rev.)

§493.1230 Condition: General laboratory systems.

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in §§493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in §493.1239 for each specialty and subspecialty of testing performed.

Interpretive Guidelines §493.1230

Significant deficiencies cited under this condition may indicate deficiencies under personnel responsibilities. Use D5200 when significant deficiencies are identified that have the potential to adversely affect patient testing, are systemic and pervasive throughout the laboratory, and are not limited to any one specialty or subspecialty.

The requirements in this section address those general operational functions that are not specific to any one specialty or subspecialty.

D5201
(Rev.)

§493.1231 Standard: Confidentiality of *p*atient *i*nformation.

The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.

Probes §493.1231

How does the laboratory "control" visitor access to the laboratory areas where patient information may be easily viewed (e.g., computer terminals, facsimile machines, worksheets*, specimen testing locations*)?

Are there safeguards in place to ensure confidentiality of patient information and test reports? For example, are unauthorized users prohibited from gaining entry?

How does the laboratory ensure confidentiality of patient information for their Laboratory Information System (LIS)? For example, does the LIS require the authorized user to enter a user identification and password to access the patient records and LIS?

How does the laboratory ensure its record storage system(s) is secure?

D5203
(Rev.)

§493.1232 Standard: Specimen identification and integrity.

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

Interpretive Guidelines §493.1232

The regulation provides laboratories the flexibility to establish a system that ensures positive patient identification through specimen collection, labeling, accessioning, processing, (e.g., *aliquoting*), storage, testing, and reporting of results. Review the laboratory's system (policy and practices) for ensuring positive patient identification from specimen collection through reporting of results.

Optimum integrity of a patient's specimen *is* determined according to the test methodology utilized by the laboratory *and the manufacturer's instructions*. Review *the* manufacturer's instructions for performance of each test method to ensure the specimen is appropriate for the test system, is stored and preserved properly (e.g., maintained at room temperature, kept on ice, separated and frozen or refrigerated), and analyzed within the limitations of the test methodology. For specimen integrity problems in the preanalytic system, see also D5311.

The laboratory must have a procedure to ensure that special handling of specimens is maintained throughout the testing process when necessary (e.g., GC cultures and GC/Chlamydia probes, blood gas specimens, and DNA probes).

Probes §493.1232

How does the laboratory ensure positive identification of patient specimens through all phases of testing, especially when similar patient identification information (e.g., address, sex, names, timed specimens, and birth dates) exists?

How does the laboratory ensure that special handling of specimens (as specified in the laboratory's procedure manual) is maintained throughout the testing process?

Does the laboratory process patient specimens using separate (distinct) or unique identifiers in order to avoid mislabeling, specimen mix-ups, incorrect test request entry, *incorrect entry of test results in the Laboratory Information System (LIS),* and incorrect reporting of results?

D5205
(Rev.)

§493.1233 Standard: Complaint investigations.

The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

Interpretive Guidelines §493.1233

Verify that the laboratory documents all complaints and problems reported to the laboratory, and that it has a mechanism to determine which complaints require investigation.

Probes §493.1233

What mechanism does the laboratory have that allows individuals to report complaints or problems to the laboratory?

How does the laboratory inform laboratory personnel of mechanisms to anonymously report complaints about laboratory quality to outside agencies, e.g. State survey agencies?

D5207
(Rev.)

§493.1234 Standard: Communications.

The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.

Interpretive Guidelines §493.1234

Such communication could entail problems with the descriptions they have provided to authorized individuals about proper specimen collection or shipment. For example, the laboratory's system for identifying and documenting communication problems should be able to capture instances in which there is a need to request additional information concerning patient specimens. If the laboratory does not receive the appropriate specimen or patient information needed to perform the tests, the laboratory should assess whether the information that is currently being made available to authorized individuals concerning patient preparation*, specimen collection,* and specimen handling requirements is adequate.

The laboratory's system for identifying and documenting communications problems

should be able to capture instances where testing was affected. These instances could be due to the lack of necessary patient information from the authorized person, improper specimen collection, improper handling and transport of the specimens to the laboratory, etc. If the appropriate specimen(s) and/or patient information needed to perform the requested tests is not being received by the laboratory, an assessment should be made to determine whether the information that is currently made available to authorized persons concerning patient preparation, specimen collection*, and specimen* handling requirements, is adequate.

D5209
(Rev.)

§493.1235 Standard: Personnel competency assessment policies.

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

Interpretive Guidelines §493.1235

Refer to §§493.1413(b)(8) and 493.1451(b)(8) for specific testing personnel competency requirements and refer to §493.1407(e)(12) and §493.1445(e)(13) for establishing policies to monitor each individual's competency and identify remedial training or continuing education needs.

Cite *D5209* when the laboratory has developed but is not following personnel competency policies and procedures. Competency assessment applies to all persons that perform patient testing and/or report patient test results, including but not limited to technical and clinical consultants, technical supervisors, general supervisors, and other laboratory staff.

NOTE: If the laboratory director *(LD)* is the only individual *performing patient* testing and/or reporting *patient* test results, they must establish and document a minimal level of proficiency in order to ensure that they maintain the required competency for accurate and reliable testing and reporting. *C*ite *D5209* when the laboratory has developed, but is not following, personnel competency policies and procedures for the LD.

Competency Assessment Guidelines

Technical consultant, clinical consultant, technical supervisor, general supervisor

Documented competency assessment is required for the following named positions on the Form 209: technical consultant, clinical consultant, technical supervisor, *and* general supervisor. The laboratory must have policies and procedures to assess competency based on the position responsibilities listed in Subpart M and these assessments must be performed at a frequency determined by the laboratory. Cite D5209 (§493.1235). If these

people perform testing on patient specimens, they are required to have the six required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities (see §493.1413(b)(8) / §493.1451(b)(8)).

Testing personnel in laboratories with a PPM certificate

*A laboratory with a **Certificate for Provider-performed Microscopy (PPM) Procedures** must establish and follow written policies for competency assessment, as required in 42 CFR §493.1235. An educational module with a quiz and photos may be used to assess testing personnel competency. The laboratory must have a mechanism for assessing testing personnel competency. Competency assessment is the laboratory director's responsibility as outlined at §493.1359. Participation in an external PT program may or may not suffice to meet the competency assessment requirement, depending on the unique circumstances in the PPM laboratory.*

The laboratory director should consider whether the assessment evaluates:

- *Training and specific skills for test performance*
- *Proficiency in using a microscope*
- *Ability to detect and identify cellular elements present in a specimen*
- *Ability to differentiate significant elements in the specimen from debris or artifacts*

KEY POINT: In situations in which more than one citation may be used, choose the one that is most specific to the situation. This will best allow the laboratory to understand the problem and correct it.

Probes §493.1235

How does the laboratory evaluate the competency of its employees?

If the laboratory uses non-testing personnel to perform preanalytic functions how does it ensure their competency?

If a laboratory utilizes a consultant, how does the laboratory determine if the consultant is competent? Does the laboratory have a policy/procedure to determine consultant competency? Use D6030 or D6103.

How does the laboratory evaluate personnel for consistency in slide review (e.g., ANA, manual differential, urine sediment)?

D5211
(Rev.)

§493.1236 Standard: Evaluation of *p*roficiency *t*esting *p*erformance.

§493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

Probes §493.1236(a)

Is there evidence of review and evaluation of the laboratory's proficiency testing (PT) results?

D5213
(Rev.)

§493.1236 Standard: Evaluation of proficiency testing performance.

(b) The laboratory must verify the accuracy of the following:

(b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

Interpretive Guideline §493.1236(b)(1)

NOTE: An analyte submitted to a PT program for evaluation generally may not be evaluated or scored by the PT program if there are less than 10 participants in a particular peer group (§§493.909 – 493.959).

D5215
(Rev.)

§493.1236 Standard: Evaluation of proficiency testing performance.

(b)(2) Any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

Interpretive Guidelines §493.1236(b)(2)

The laboratory must have a *process* for, and documentation of, routine review of its proficiency testing results that are evaluated by its PT providers. This includes a review of its *reported* PT results against the PT provider's participant summary results for the particular PT event and when any of the following occur:

- The PT program assigned an artificial score of 100% (e.g., results not evaluated or scored);

- A zero score for nonparticipation; if the laboratory did not test the specimen, it must document what other means were used to assess the accuracy of the test for the PT event that was missed; or

- The PT provider notifies the laboratory that its results were not evaluated (given a score of "0") due to missing the return deadline.

NOTE: *Refer to §493.1239(a)-(d)*

Probes §493.1236(b)(2)

Has the laboratory reviewed its test menu to determine if it tests any analyte(s) that are not listed in subpart I?

§493.1236(c) At least twice annually, the laboratory must verify the accuracy of the following:

D5217
(Rev.)

§493.1236 Standard: Evaluation of proficiency testing performance.

(c)(1) Any test or procedure it performs that is not included in subpart I of this part.

Interpretive Guidelines §493.1236(c)(1)

Refer to subpart I, Proficiency Testing Programs for Nonwaived Testing. Subpart I includes those specialties, subspecialties, analytes and tests that are considered regulated tests. For those tests not listed in subpart I (not regulated), the laboratory must verify the accuracy of the test or procedure twice annually, including the accuracy of calculated results, if applicable.

For those tests not listed under Subpart I, the laboratory may enroll in a PT program to verify the accuracy of their test or procedure. However, under no circumstances may these PT samples be referred (or results communicated) to another laboratory for any reason prior to the PT testing event cut-off date. The PT referral consequences (loss of certificate and bar on owner/operator) apply equally to all PT testing samples and results. (See D2013).

If the laboratory is using multiple test platforms to test an analyte, it must choose one primary method per analyte and use that method to test for all samples in a Proficiency Testing (PT) challenge.

For a PPM laboratory performing testing not included in subpart I, the laboratory must verify accuracy at least twice annually.

D5219
(Rev.)

§493.1236 Standard: Evaluation of proficiency testing performance.

(c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

Interpretive Guidelines §493.1236(c)(2)

Laboratory tests or procedures *for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program* may include new or emerging technologies.

For PPM testing that is included in Subpart I, generally, CMS-approved PT programs are unavailable and therefore the laboratory must verify accuracy at least twice annually.

Probes §493.1236(c)(2)

How does the laboratory verify accuracy of tests not included under subpart I or tests for which compatible PT samples are not available (e.g., blind testing of materials with known values, other external assessment programs, split samples with another laboratory instrument or method, comparison with *photomicrograph* slides from a reference source)?

D5221
(Rev.)

§493.1236 Standard: Evaluation of proficiency testing performance.

(d) All proficiency testing evaluation and verification activities must be documented.

Interpretive Guidelines §493.1236(d)

Documentation must include review of all unsatisfactory scores and the corrective action taken.

D5291
(Rev.)

§493.1239 Standard: General laboratory systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at §§493.1231 through 493.1236.

Interpretive Guidelines §493.1239(a)

Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, other laboratories ordering tests, and the other non-laboratory areas of the facility of which it is a part.

When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves *investigation,* identification, and resolution of the problem, *followed by* development of policies that will prevent recurrence.

The laboratory should:

- *Establish and/or revise written policies and procedures to prevent recurrence of the problems identified;*
- *Communicate the established and/or revised policies to the laboratory personnel and other staff, clients, etc., as appropriate; and*
- *Document that the established and/or revised policies and procedures to prevent recurrence have been followed.*

Over time, the laboratory must *document* monitor*ing of* the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem.

All pertinent laboratory staff must be involved in the assessment process through discussions or active participation.

QA of the General Laboratory System includes assessing practices/issues related to:

- Patient confidentiality;
- Specimen identification and integrity;
- Complaint investigations;
- Communications;

- Personnel competency; and
- Proficiency testing performance.

Probes §493.1239(a)

Does the laboratory have a system in place for monitoring and evaluating confidentiality of patient information?

How does the laboratory ensure that an individual who had problems in performance is competent after appropriate retraining and technical assistance is completed?

How does the laboratory determine which complaints require investigation and which do not?

D5293
(Rev.)

§493.1239 Standard: General laboratory systems quality assessment.

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff.

Interpretive Guidelines §493.1239(b)

Review assessment policies, procedures and reports to verify that the laboratory has a system in place to ensure continuous improvement. Corrective action reports are one indication that the laboratory is monitoring and evaluating laboratory performance and the quality of services.

Probes §493.1239(b)

When problems are identified in personnel competency, what corrective actions are instituted to improve employee performance?

When the laboratory identifies a problem, are corrective actions taken? Are these actions documented and monitored for effectiveness?

How does the laboratory prevent reoccurrences of problems?

How does the laboratory identify and document potential communication problems and any corrective actions that are taken (e.g., with staff, referral laboratories)?

Have the corrective actions that were taken as a result of failures in proficiency testing (PT) and/or verification of accuracy testing (as required under subpart H) improved performance?

(c) The laboratory must document all general laboratory systems quality assessment activities.

Interpretive Guidelines §493.1239(c)

Laboratories must document the steps taken to identify and correct problems, and any efforts to prevent recurrences. This includes laboratory policies amended due to QA activities.

PREANALYTIC SYSTEMS

D5300
(Rev.)

§493.1240 Condition: Preanalytic systems.

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in §§493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in §493.1249 for each specialty and subspecialty of testing performed.

Interpretive Guidelines §493.1240

Preanalytic refers to all steps taken prior to the actual testing of a patient specimen from the test request to the actual testing of the specimen. The preanalytic systems requirements fall into three distinct standards: test requests; specimen submission, handling, and referral; and preanalytic systems quality assessment.

Significant deficiencies cited under this condition may indicate deficiencies under personnel responsibilities. Use D5300 when deficiencies are identified that have the potential to, or are adversely affecting patient testing, or when they are systemic and pervasive throughout the laboratory, and are not limited to any one specialty or subspecialty.

To determine which tests are categorized as waived or nonwaived testing (i.e., moderate and high complexity tests), refer to the following web link for the FDA categorization database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm?sAN=0). Test systems, assays and examinations not included in this listing (i.e., not yet categorized) are considered high complexity.

D5301
(Rev.)

§493.1241 Standard: Test request.

(a) The laboratory must have a written or electronic request for patient testing from an authorized person.

Interpretive Guidelines §493.1241(a)

An "authorized person" means an individual authorized under State law to order tests or receive test results, or both. See 42 CFR §493.2 (definition of "authorized person"). See D5305 for specific guidance on the CLIA requirements for the test requisition process.

To ensure that an authorized person is ordering the test, a laboratory using electronic test requests may issue passwords.

Written policies should cover the use of standing orders. Such policies should clearly define which tests may be covered by standing orders and at what interval standing orders should be reconfirmed.

D5303
(Rev.)

§493.1241 Standard: Test request.

(b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.

Interpretive Guidelines §493.1241(b)

Review the laboratory's policy for requesting written orders within 30 days of the oral requests. If no written order was received, verify the laboratory has documentation showing the attempt.

D5305
(Rev.)

§493.1241 Standard: Test request.

(c) The laboratory must ensure the test requisition solicits the following information:

(c)(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values.

Interpretive Guidelines §493.1241(c)(1)-(c)(8)

The test requisition must provide the information necessary to identify and send test results to the individual who ordered the test (the authorized person), or, where applicable, to the authorized person's representative. An authorized person may also use

the test requisition to designate additional individuals/entities that will be responsible for using the test results to provide care to the subject individual.

The address(es) to which test results should be sent may include a postal address (street, city or town, state and ZIP code), a fax number, and/or the information necessary for electronic transmission. When appropriate, a telephone number or other mechanism to contact the individual responsible for using the test results should be provided to the laboratory on the requisition.

Verify that test requisitions solicit all information necessary for the proper interpretation of results. This may include patient's age, sex, date, fasting status, time of collection, specimen type (e.g., plasma, urine, spinal fluid), diagnosis, and date of last menstrual period (LMP) for Papanicolaou (PAP) smears. Verify that the instructions to clients are clear and specify the items that must be completed.

Laboratories must have policies that guide staff on what to do if/when they receive a requisition or patient medical chart or record that is missing required information. Laboratories must either obtain the missing information, or report results and indicate on the test report, medical record or chart any limitations of test results due to the omission of patient information. If the missing information is essential (such as the family history for certain genetic tests) for accurate test results, it must be obtained prior to reporting patient test results.

(c)(2) The patient's name or unique patient identifier.

(c)(3) The sex and age or date of birth of the patient.

(c)(4) The test(s) to be performed.

(c)(5) The source of the specimen, when appropriate.

(c)(6) The date and, if appropriate, time of specimen collection.

(c)(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.

(c)(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

Interpretive Guidelines §493.1241(c)(8)

This may include such items as preventative or therapeutic medications, or family history.

Probes §493.1241(c)(1)-(c)(8)

How does the laboratory uniquely identify patient specimens that share the same or similar name, birth date, address or sex?

How does the requisition provide for inclusion of additional information when necessary (e.g., specimen type or source)?

D5307
(Rev.)

§493.1241 Standard: Test request.

(d) The patient's chart or medical record may be used as the test requisition or authorization but must be available to the laboratory at the time of testing and available to CMS or a CMS agent upon request.

Probes §493.1241(d)

When the patient's chart or medical record is used as the test requisition does it provide all the information necessary to ensure accurate testing and reporting of results?

D5309
(Rev.)

§493.1241 Standard: Test request.

(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

Interpretive Guidelines §493.1241(e)

The laboratory must have an ongoing mechanism to ensure the accuracy of manual entries by personnel into an LIS.

How does the laboratory ensure that all individuals who enter data including clerical staff correctly match patient information?

D5311
(Rev.)

§493.1242 Standard: Specimen submission, handling, and referral.

(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable:

(a)(1) Patient preparation.

Probes §493.1242(a)(1)

How does the laboratory ensure that all staff, including phlebotomists, gives appropriate instructions for patient preparation when needed?

Does the laboratory provide instructions directly to patients or to the client when proper patient preparation is required for optimal specimen collection? For example:

- Proper preservation (temperature) and transportation time of semen specimens;
- Fasting instructions for lipid profile testing;
- Dietary restrictions prior to occult blood testing;
- Twenty-four hour urine collection for specific tests; and
- Fasting and two hour post-prandial glucose collections.

If a patient has special communication needs (hearing impaired, not fluent in English etc.), are resources available to the client or to the patient, as appropriate, to ensure that instructions for specimen collection, preservation, and transportation to the laboratory, are properly understood?

Has the laboratory provided to its staff and/or individuals external to the laboratory who collect specimens, written procedures to ensure that patient preparation requirements have been followed?

(a)(2) Specimen collection.

Interpretive Guidelines §493.1242(a)(2)

Verify that procedures are available to the appropriate staff responsible for collecting the correct specimen, that personnel are using the appropriate collection technique (order and site of draw) and proper containers (e.g., acceptable anti-coagulant, sterile containers for culture specimens, dacron swabs vs. cotton swabs).

(a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source.

Interpretive Guidelines §493.1242(a)(3)

If the laboratory receives two specimens simultaneously with the same first and last name or birth date, the laboratory must have a system in place to process these specimens using

distinct identifying indicators in order to distinguish between the specimens. This also pertains to personnel collecting and labeling specimens. This may include a system that involves labeling the specimen container and request slip (or the patient's medical record or chart) with a unique patient identification number, but does not preclude the use of other mechanisms to assist in patient identification and tracking of specimens throughout the collection, accessioning, testing, and reporting processes.

(a)(4) Specimen storage and preservation.

Interpretive Guidelines §493.1242(a)(4)

Review manufacturer's instructions for performance of each test method to ensure that specimens are properly stored (e.g., maintained at room temperature, kept refrigerated after separation, separated and frozen).

Probes §493.1242(a)(4)

What instructions are provided for specimen preservation and transportation, when applicable? For example:

- Sputum for Cytology;
- Specimens for parathyroid hormone;
- Specimens for blood gas analysis;
- Specimens for urine culture and colony count; and
- Specimens for 24-hour urine collections requiring preservatives.

(a)(5) Conditions for specimen transportation.

Probes §493.1242(a)(5)

Does the laboratory follow the manufacturer's or the referral laboratory's instructions, as appropriate, for transport of specimens?

(a)(6) Specimen processing.

Interpretive Guidelines §493.1242(a)(6)

Specimen processing may include receiving the specimen, accessioning the specimen, preparing the specimen for in-house analysis, preparation to send to a reference laboratory, preparing slides, and inoculating primary culture media, etc. Specimen processing also includes: Parasitology: the fixation and concentration of specimens; Virology: the pretreatment of specimens with antibiotics, the manipulation of cell culture

tubes and inoculation of the cell cultures prior to incubation; Mycobacteriology: performing digestion-decontamination and concentration procedures on clinical specimens; and Histopathology: specimen accession with or without fixation, embedding the paraffin block, cutting the paraffin block, mounting the embedded cut tissue to a slide, preparing the slide for staining, staining and cover slipping the slide, or any other slide preparation procedures that do not involve examination resulting in diagnostic interpretation.

NOTE: for histopathology specimens, specimen processing does not constitute a CLIA test. Only gross examinations (including weighing, measuring, describing color, specific orientation for diagnostic interpretation, and other characteristics of the tissue, or performing other mechanical procedures including dissection, inking, and marking) require a CLIA certificate. Microscopic examinations of tissue with diagnostic interpretation and reporting is a Histopathology test and requires CLIA certification.

Probes §493.1242(a)(6)

What policies or systems does the laboratory have in place to differentiate specimens that have similar names or identification information?

How does the laboratory recognize and process timed patient specimens (e.g., peaks and troughs)?

(a)(7) Specimen acceptability and rejection.

Interpretive Guidelines §493.1242(a)(7)

Criteria for specimen acceptability and rejection must include the disposition of the rejected specimen(s). Use D5805. The laboratory should promptly notify the authorized person when a specimen meets its rejection criteria and is unsuitable for testing.

(a)(8) Specimen referral.

Interpretive Guidelines §493.1242(a)(8)

Ensure that the laboratory has a current service manual available for each reference laboratory that it uses that contains the reference laboratory's specimen requirements for the test to be performed.

Probes §493.1242(a)(8)

Are laboratory personnel familiar with procedures to prepare and/or submit specimens to the appropriate reference laboratory?

How does the laboratory ensure the security and preservation of specimens submitted to their reference laboratory (e.g., if the office closes before the arrival of the reference

laboratory's courier)? How does the laboratory ensure a timely pick-up of specimens to be performed at the referral laboratory?

D5313
(Rev.)

§493.1242 Standard: Specimen submission, handling, and referral.

(b) The laboratory must document the date and time it receives a specimen.

Interpretive Guidelines §493.1242(b)

When a sample is collected and a test is performed during the course of a patient's visit, the date and time recorded in the patient "sign-in" log may be used as the date and time of receipt into the laboratory.

D5315
(Rev.)

§493.1242 Standard: Specimen submission, handling, and referral.

(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

Interpretive Guidelines §493.1242(c)

Some examples of laboratories meeting equivalent requirements are those of the Veterans Administration (VA), the Department of Defense (DOD) facilities, and CLIA-exempt laboratories.

Probes §493.1242(c)

How does the laboratory ensure that the reference laboratory has and maintains a current CLIA certificate?

D5317
(Rev.)

§493.1242 Standard: Specimen submission, handling, and referral.

(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

Interpretive Guidelines §493.1242(d)

Ensure the laboratory has provided written instructions to each client that sends specimens/test requests. The instructions may contain information on specimen handling (e.g., collection, preservation, storage, transport, testing schedule times and how to obtain additional assistance for unusual circumstances).

D5391
(Rev.)

§493.1249 Standard: Preanalytic systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at §§493.1241 through 493.1242.

Interpretive Guidelines §493.1249(a)-(c)

Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, other laboratories ordering tests, and the other non-laboratory areas of the facility of which it is a part.

When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves *investigation,* identification, and resolution of the problem, *followed by* development of policies that will prevent recurrence.

The laboratory should:

- *Establish and/or revise written policies and procedures to prevent recurrence of the problems identified;*
- *Communicate the established and/or revised policies to the laboratory personnel and other staff, clients, etc., as appropriate; and*
- *Document that the established and/or revised policies and procedures to prevent recurrence have been followed.*

Over time, the laboratory must *document* monitor*ing of* the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem.

All pertinent laboratory staff must be involved in the assessment process through discussions or active participation.

QA of the **Preanalytic System** includes assessing practices/issues related to test requests,

specimen submission, handling and referral.

Some examples include: monitoring the frequency of specimen handling problems (such as the use of an improper blood collection tube, inadequate mixing of blood specimens with anticoagulant after collection), and delays in specimen transport; identifying clients who repeatedly refer unacceptable specimens or improperly complete requisition forms and documentation of the laboratory's efforts to reduce the recurrence of these problems.

Review assessment policies, procedures and reports to verify that the laboratory has a system in place to ensure continuous improvement. Corrective action reports are one indication that the laboratory is monitoring and evaluating laboratory performance and the quality of services.

Probes §493.1249(a)-(c)

When a laboratory uses off-site drawing facilities, what policies or procedures does the laboratory use to ensure proper accountability or tracking of patient specimens from *the* time of collection to receipt by the laboratory performing the tests?

Does the laboratory *routinely* perform *a review of systems* for accurate transfer of information (e.g., manual entries by personnel from test orders to test requisition or into a LIS)? For referral specimens, how does the laboratory check for transcription errors when patient test information is transcribed from the laboratory's original requisition form to the reference laboratory's requisition?

What actions does the laboratory take if test requisitions from one or more clients are consistently incomplete, illegible, or contain incorrect information?

What actions does the laboratory take if specimens received from one client are consistently unsatisfactory for testing (e.g., specimens for Cytology)? Has the laboratory's efforts to reduce the recurrence of these problems been documented and effective?

D5393
(Rev.)

§493.1249 Standard: Preanalytic systems quality assessment.

(b) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff.

§493.1249(c) The laboratory must document all preanalytic systems quality assessment activities.

Interpretive Guidelines §493.1249(c)

The steps taken by the laboratory to identify and correct problems and prevent their recurrence must be documented. All laboratory policies amended due to its QA activities must also be noted.

ANALYTIC SYSTEMS

D5400
(Rev.)

§493.1250 Condition: Analytic systems.

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in §§493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in §493.1289 for each specialty and subspecialty of testing performed.

Interpretive Guidelines §493.1250

Significant deficiencies cited under this condition may indicate deficiencies under personnel. Use D5400 when deficiencies are identified that are significant and have the potential to, or adversely affect patient testing, are systemic and pervasive throughout the laboratory, and are not limited to any one specialty or subspecialty.

Refer to §§493.1261 - 493.1278 for additional requirements for Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Routine Chemistry, Hematology, Immunohematology, Histopathology, Cytology, Clinical Cytogenetics, and Histocompatibility.

D5401
(Rev.)

§493.1251 Standard: Procedure manual.

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

Interpretive Guidelines §493.1251(a)

Procedures may be organized in the form of paper-based manuals, or a manual that is stored in and accessed through computers and/or card files. Use D5403, if the procedure manual lacks any of the applicable information as specified in §493.1251(b)(1)-(14). If the laboratory has procedures that are not used for test performance, but are used for reference purposes, they may be placed in a reference section. You need not review reference procedures unless problems are identified with patient test results.

Centers for Disease Control and Prevention (CDC) manuals, manufacturer's operating instructions, and package inserts, are acceptable provided the policies and procedures are available, and the methods in use are clearly indicated. If the laboratory modifies any procedure, the modification must be documented and verified/established as specified in §493.1253.

Probes §493.1251(a)

How does the laboratory ensure that personnel follow the procedures in the procedure manual? How are changes in procedures communicated to laboratory personnel? For competency issues, use D6030 or D6103 as applicable.

D5403

(Rev.)

§493.1251 Standard: Procedure manual.

(b) The procedure manual must include the following when applicable to the test procedure:

(b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242.

Interpretive Guidelines §493.1251(b)(1)

If testing is delayed or not performed daily, specimens must be preserved or stored in accordance with the laboratory's procedures to ensure specimen integrity.

Determine if the laboratory has a procedure for handling and identifying aliquoted specimens; e.g., sputum sent for Mycobacteriology and Cytology examinations; stool specimens for occult blood, routine culture, parasitology and C. difficile toxin assay; and cerebrospinal fluids for cell count, culture, glucose and protein.

(b)(2) Microscopic examination, including the detection of inadequately prepared slides.

(b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

(b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.

(b)(5) Calibration and calibration verification procedures.

Interpretive Guidelines §493.1251(b)(5)

Calibration and calibration verification procedures must be established in accordance with §493.1255.

(b)(6) The reportable range for test results for the test system as established or verified in §493.1253.

(b)(7) Control procedures.

Interpretive Guidelines §493.1251(b)(7)

Determine if the laboratory's quality control procedures include the following:

- Type of control (e.g., manufacturer or in-house, electronic);
- Identity (e.g., normal, abnormal, level I, II, patient or a control);
- Number and frequency of testing controls;
- Control limits established in accordance with §§493.1253 and 493.1256; and
- Criteria to determine acceptable control results.

(b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.

Interpretive Guidelines §493.1251(b)(8)

Ensure that corrective action procedures are established in accordance with §493.1282(b)(2).

(b)(9) Limitations in the test methodology, including interfering substances.

(b)(10) Reference intervals (normal values).

(b)(11) Imminently life-threatening test results, or panic or alert values.

(b)(12) Pertinent literature references.

(b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values.

Interpretive Guidelines §493.1251(b)(13)

Ensure the procedure manual provides instructions for reporting the patient's test results

in the appropriate units or terminology. *See also* D5805.

Probes §493.1251(b)(13)

Do laboratory procedures address the process for reporting (oral and written) results on patients with multiple laboratory encounters to ensure that the exact name, date, time and identification of specimen is conveyed to the authorized person?

(b)(14) Description of the course of action to take if a test system become inoperable.

Interpretive Guidelines §493.1251(b)(14)

Laboratory information systems (LIS) procedures must be available to *laboratory personnel*. Instructions should identify the individual(s), *or Point-of-Contact*, to notify if the LIS goes down or if a system error occurs. *The laboratory should have a procedure outlining how results will be reported if the test system (e.g., instrument, LIS) becomes inoperable.*

Probes §493.1251(b)(14)

When the primary testing system is inoperable, what procedure does the laboratory use to bring the backup system on line?

Does the laboratory have a plan if a test system becomes inoperable for either a short or extended time (e.g., several hours, several months, or permanently)?

D5405
(Rev.)

§493.1251 Standard: Procedure manual.

(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

D5407
(Rev.)

§493.1251 Standard: Procedure manual.

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

Interpretive Guidelines §493.1251(d)

Verify that the methods in the procedure manual are current for tests offered by the laboratory (e.g., reagent test kits and instruments used in the laboratory correlate with methods in the procedure manual).

All laboratory procedures including CDC manuals, manufacturer's operator manuals, and package inserts must reflect the director's review and approval including any modifications in the procedure.

Approval of procedures and changes to procedures is the responsibility of the laboratory director. This responsibility cannot be delegated. A coversheet may be used for the director to approve the manual. Annual review of procedures is not required.

D5409
(Rev.)

§493.1251 Standard: Procedure manual.

(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in §493.1105(a)(2).

D5411
(Rev.)

§493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies.

(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under §493.1253.

Interpretive Guidelines §493.1252(a)

The laboratory must meet any and all regulatory requirements and comply with the manufacturer's requirements to the extent that the manufacturer's requirements do not conflict with any regulatory requirements. We encourage laboratories to also comply with the manufacturer's recommendations for testing to the extent that the manufacturer's recommendations do not conflict with any regulatory requirements.

These include, but are not limited to:

- Handling reagents, materials, and supplies;
- Adhering to conditions for storage and testing; and
- Performing equipment maintenance and function checks

For International Normalized Ratio (INR) calculation, ensure the laboratory:

- Verifies that the normal patient Prothrombin mean study has been performed according to the manufacturer's instructions;
- Periodically verifies, for each thromboplastin lot number in use, the correct normal patient Prothrombin time mean and the International Sensitivity Index (ISI) value are being used for calculating the INR value; and
- Periodically verifies the accuracy of the INR calculation (manual, instrument or LIS).

To verify Prothrombin time testing with INR calculations:

- Check the accuracy of normal Prothrombin time mean calculation (manual, instrument or LIS).
- Verify the ISI used in the calculation correlates with the ISI specified in the reagent package insert. Select an abnormal low or abnormal high Prothrombin time result and verify the calculation.

For Immunology tests such as Syphilis Serology, check for the following parameters:

- Antigen volume;
- Incubation time and temperature;
- Light source;
- Rotator speed and circumference; and
- Conjugate titer.

Probes §493.1252(a):

Are instruments with adjustable settings appropriately set for each substance or cell to be analyzed (e.g., gamma counters, flow cytometry)?

D5413

(Rev.)

§493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies.

(b) The laboratory must define criteria for those conditions that are essential for

proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following:

(b)(1) Water quality.

Interpretive Guidelines §493.1252(b)(1)

Water quality is classified by several different organizations into different reagent grades dependent on microbial content, resistivity, silicate content, and particulate matter. Each laboratory is expected to use the appropriate water quality as required for each instrument, kit, or test system. Laboratories producing water should consider parameters such as pH, silicate content, particulate matter, and bacterial and organic content in assessing water quality. These parameters vary by test system. The laboratory should assess each test system to determine the parameters of water appropriate for that system and to develop monitoring procedures to ensure the water remains within those parameters. Laboratories purchasing water that has already been classified are not expected to evaluate the above parameters unless specified by the manufacturer or by the laboratory in its procedure manual.

(b)(2) Temperature.

(b)(3) Humidity.

Interpretive Guidelines §493.1252(b)(2)-(b)(3)

Corrective action is needed when acceptable temperature and/or humidity ranges are exceeded. Use D5781 when corrective action not documented.

Continuous monitoring of temperatures by a recording thermograph or computer is acceptable provided the data and time of use are annotated or otherwise electronically recorded. The charts must be retained for at least two years unless otherwise specified to document that temperatures were within the limits established by the laboratory. Refer to D3035 for additional information on record retention.

It is also acceptable for temperatures to be maintained and monitored internally by the instrument, provided (1) test results are either flagged or not generated when the temperature range for test performance is exceeded, and (2) the laboratory retains the instrument's temperature readings for at least two years. If the instrument is not capable of recording and maintaining its readings, the lab will need to manually record the readings and retain those records for at least two years to comply with § 493.1105(a)(3) and § 493.1289.

(b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

Probes §493.1252(b)(1)-(b)(4)

How does the laboratory provide special conditions when required for specimen or reagent storage?

How is room temperature and humidity monitored when necessary for test performance, proper operation of reagents, instruments, equipment, or laboratory computer systems? When temperatures and/or humidity are outside acceptable limits, how does the laboratory rectify the problem?

How does *a* laboratory that moves from testing site to testing site demonstrate that the conditions necessary for quality testing are maintained?

When mobile laboratory or temporary testing site equipment is not in use (weekends, overnight) how are instruments, reagents, stains, and other solutions protected from extreme temperature fluctuations?

D5415
(Rev.)

§493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies.

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following:

(1) Identity and when significant, titer, strength or concentration.

(2) Storage requirements.

(3) Preparation and expiration dates.

Interpretive Guidelines §493.1252(c)(3)

Expiration dates for test kits and/or reagents may differ due to date opened or storage conditions (e.g., refrigerator, room temperature). Verify that laboratory personnel are aware of these differences and document the appropriate expiration date.

(4) Other pertinent information required for proper use.

D5417
(Rev.)

§493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies.

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

Interpretive Guidelines §493.1252(d)

In citing deficiencies, for outdated or deteriorated materials, indicate whether these materials have been used for patient testing. Also, look for contamination, drying or other signs of deterioration. This is as important as checking expiration dates.

D5419
(Rev.)

§493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies.

(e) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.

Interpretive Guidelines §493.1252(e)

"Kit" means all components of a test that are packaged together.

§493.1253 Standard: Establishment and verification of performance specifications.

(a) Applicability. Laboratories are not required to verify or establish performance specifications for any test system used by the laboratory before April 24, 2003.

Interpretive Guidelines §493.1253(a)

The requirements of §493.1253 apply to each nonwaived test system (i.e., moderate and high complexity) introduced into the laboratory on or after April 24, 2003. This includes the following:

- A test system that is introduced into the laboratory for the first time to measure an analyte that the laboratory has not previously measured;
- A test system introduced for the first time into the laboratory for a test that the laboratory currently performs on an alternative test system (e.g., instrument A has been used to perform cholesterol testing, now instrument B will be used);
- An analyte added to a test system that can measure multiple analytes which the laboratory has been using for patient testing but has not previously reported

patient results for this particular analyte; and

- A modification to a test system that the laboratory has been using for patient testing (e.g., the laboratory reduces the specimen and/or reagent volumes).

When multiple instruments (including the same make and model, e.g., point-of-care instruments) are used to perform the same test, the laboratory must verify or establish, as applicable, performance specifications for each instrument.

Refer to requirements in subpart M, for training and competency of personnel.

Specific information regarding testing for agents of emergent public health significance and alternative methods/procedures for establishing performance specifications may be found at www.aphl.org.

NOTE: Public health testing performed on environmental (non-human) samples is not subject to CLIA.

D5421
(Rev.)

§493.1253 Standard: Establishment and verification of performance specifications.

(b)(1) Verification of performance specifications. Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results:

Interpretive Guidelines §493.1253(b)(1)

The laboratory is responsible for verifying the performance specifications of each nonwaived unmodified FDA-cleared or approved test system that it introduces, prior to reporting patient test results. The verification of method performance should provide evidence that the accuracy, precision, and reportable range of the procedure are adequate to meet the clients' needs, as determined by the laboratory director and clinical consultant. A laboratory may use the manufacturer's performance specifications as a guideline, but is responsible for verifying the manufacturer's analytical claims before initiating patient testing. *Refer to CLIA Brochure - Verification of Performance Specifications (PDF).*

If a method was verified by someone other than the laboratory staff (e.g., manufacturer representative), the laboratory must demonstrate that this verification correlates with its in-house test performance. This may be accomplished by the laboratory testing "known" samples.

For some qualitative tests, the laboratory may verify the manufacturer's specifications by

testing known positive and negative samples to ensure that the expected results are obtained. (Specimens of known quantitative value may be used to verify the accuracy of a qualitative test.)

Prior to introducing a test for routine patient testing, the laboratory must review and evaluate the verification data.

Each laboratory is responsible for determining that its performance specifications for each test system are not affected by the relocation of the laboratory or test system. (See manufacturer's package insert regarding critical requirements such as set-up, limitations, environmental conditions, etc.) When a temporary replacement (loaner) instrument is received which is identical (i.e., same make and model, and method for the same analyte) to the instrument which is being replaced, the laboratory must verify performance specifications.

If calibration material is used to verify method performance specifications, the laboratory must demonstrate that there is a minimal matrix effect and the calibration material is appropriate for verifying test system performance specifications.

If the LIS performs any calculations to determine a laboratory result, the calculations must be verified immediately after the LIS is programmed and prior to initial calculation of patient results.

"Less than" is used for reporting test results that are below the laboratory's detection limits for an analyte. (Detection limits must be established through method verification.) "Equivalent designation" is used to report test results for those methods that yield results below a clinically significant level (e.g., for a quantitative immunology test, patient results may be clinically negative at a 1:8 titer and test results may be reported as "1:8 negative"). (The normal value is 1:8 or less.) "Greater than" is used for reporting test results that are above the laboratory's detection limits for an analyte. If patient test results exceed the laboratory's reportable range, the laboratory must report the result as greater than the highest detection limit, re-assay a diluted patient specimen and report the calculated result, or send the specimen to a reference laboratory.

CDC Developed Assays and Non-CDC Developed Assays:

Laboratories are required to verify performance specifications for CDC developed EUA assays per 42 CFR 493.1253(b)(1). In general, CDC developed test kits provide an initial set of samples for verifying performance specifications and instructions for their use. Laboratories using a CDC developed assay authorized for emergency use should follow any and all instructions provided for verifying performance specifications.

As with CDC developed EUA assays, laboratories are required to verify performance specifications for other, non-CDC developed EUA assays per 42 CFR 493.1253(b)(1). Laboratories are required to verify performance specifications according to the performance specifications established by the manufacturer and the manufacturer's

reference intervals. In accordance with 42 CFR §493.1252(a), any manufacturer's instructions for verification must be followed, if provided. The surveyor should confirm that the laboratory has followed its procedures for verification.

Refer to CMS QSO-18-19-CLIA, Performance Specification Verification of Assays Authorized Under Emergency Use (EUA) for additional information.

Probes §493.1253(b)(1)

How does the laboratory determine if a new or revised LIS program (whether purchased or developed in-house) performs acceptably before it is integrated into routine operation?

(b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics:

Interpretive Guidelines §493.1253(b)(1)(i)

Laboratories may simultaneously verify multiple performance specifications by choosing appropriate samples; e.g., repeatedly test (precision) samples with known (accuracy) high and low values (reportable range). This testing should be performed among all operators on different days. In addition, for test systems of the same make and model, consider verifying performance specifications of these devices at the same time.

§493.1253 Standard: Establishment and verification of performance specifications.

(b)(1)(i)(A) Accuracy.

Interpretive Guidelines §493.1253(b)(1)(i)(A)

Accuracy- The laboratory is responsible for verifying that the method produces correct results. Verification of accuracy may be accomplished by:

- Testing reference materials;
- Comparing results of tests performed by the laboratory against the results of a reference method; or
- Comparing split sample results with results obtained from another method, which has already been shown to provide accurate results.

For qualitative methods, the laboratory must verify that a method will identify the presence/absence of the analyte.

§493.1253 Standard: Establishment and verification of performance

specifications.

(b)(1)(i)(B) Precision.

Interpretive Guidelines §493.1253(b)(1)(i)(B)

Precision (Reproducibility) - The laboratory is responsible for verifying the precision of each test system by assessing day-to-day, run-to-run, and within-run variation, as well as operator variance. This may be accomplished by:

- Repeat testing of known patient samples over time;
- Testing QC material in duplicate and over time; or
- Repeat testing of calibration materials over time.

EXCEPTION: For fully automated systems that are not user dependent, operator variance does not need to be evaluated.

(b)(1)(i)(C) Reportable range of test results for the test system.

Interpretive Guidelines §493.1253(b)(1)(i)(C)

Reportable Range- The laboratory is responsible for verifying the reportable range of patient test results for each test system. Verification of reportable range may be accomplished by:

- Assaying low and high calibration materials or control materials; or
- Evaluating known samples of abnormal high and abnormal low values.

Hematology whole blood high range calibration materials are not generally available. Therefore, laboratories may use patient specimens with verified elevated cell counts to verify the upper limit of the reportable range.

Probes §493.1253(b)(1)(i)(C)

If a dilution procedure is used when patient results exceed the test system's reportable range, how does the laboratory ensure the appropriate diluent is used for each type of specimen?

How does the laboratory verify and document the accuracy of the results for diluted specimens?

§493.1253 Standard: Establishment and verification of performance specifications.

(b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

Interpretive Guidelines §493.1253(b)(1)(ii)

Reference Range (Normal Values) - The laboratory may use the manufacturer's reference range provided it is appropriate for the laboratory's patient population (i.e., a normal range that reflects the type of specimen and demographic variables such as age and sex, as applicable). If the manufacturer has not provided reference ranges appropriate for the laboratory's patient population, the laboratory may use published reference range(s). The laboratory must evaluate an appropriate number of specimens to verify the manufacturer's claims for normal values or, as applicable, the published reference ranges.

D5423
(Rev.)

§493.1253 Standard: Establishment and verification of performance specifications.

(b)(2) Establishment of performance specifications. Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as textbook procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable:

Interpretive Guidelines §493.1253(b)(2)

Prior to reporting patient test results, the laboratory is responsible for establishing the performance specifications for each modified FDA-cleared or approved test system, each test system not subject to FDA clearance or approval, and each test system for which the manufacturer does not provide performance specifications. The establishment of method performance specifications should provide evidence that the accuracy, precision, analytical sensitivity, and analytical specificity of the procedure is adequate to meet the clients' needs as determined by the laboratory director and clinical consultant.

"Modified by the laboratory" means any change to the assay that could affect its performance specifications for sensitivity, specificity, accuracy, or precision, etc. Laboratory modification of the manufacturer's instructions that could affect performance specifications include but are not limited to:

- Change in specimen handling instructions;
- Change in incubation times or temperatures;

- Change in dilution of specimen or reagent;
- Using a different calibration material or reference material, or changing the manufacturer's set-points;
- Introducing a different antibody (source, monoclonal-vs.-polyclonal);
- Change or elimination of a procedural step;
- Change or addition of detector (conjugate) or substrate;
- Change in the solid phase;
- Change in the cutoff or method of calculating the cutoff for semi-quantitative assays;
- Change in the endpoint or calculation of the endpoint;
- Addition of adsorbent; and
- Change in the strain of antigen in serologic assays.

A modified moderate complexity test (including modifications in its intended use) is considered uncategorized for CLIA and therefore becomes a high complexity test.

EXCEPTIONS: Use of a manufacturer's reagents that are exempt from the premarket notification procedures in 21 CFR §807 for an instrument produced by another manufacturer is **not** considered a method modification. If the FDA has cleared a manufacturer's reagents and/or calibration materials for use with an instrument produced by another manufacturer, the use of these reagents/materials is **not** considered a method modification and does not require establishment of performance specifications. However, the laboratory must **verify** performance specifications as required under §493.1253(b)(1). Reverification of performance specifications is required if reagents are changed to those of another manufacturer.

"Modified by the laboratory" also means any change in **intended use** that could affect test system performance specifications for sensitivity, specificity, accuracy, and precision, etc., and the clinical utility of the test system. Changes in intended use are considered "off-label" use of a commercial test system. CAUTION: "Off-label" use is not supported by the manufacturer's clinical data.

Examples of changes in intended use are:

- Using a different sample matrix (plasma vs. urine);

- Using or promoting the test for another purpose (screening vs. diagnostic); and
- Changing the type of analysis (qualitative results reported as quantitative).

NOTE: The laboratory is responsible for establishing performance specifications for test systems using analyte specific reagents (ASR).

For automated or semi-automated analyzers, the use of reprocessed (reconditioned) rotors/cuvettes which have passed quality control inspection criteria of the reprocessing company, are not considered a method modification if/when they are returned to the same laboratory that sent them for cleaning and re-use.

Specimens of known quantitative value may be used to determine the laboratory's performance specifications for a qualitative test.

Each laboratory is responsible for determining that its performance specifications for each test method are not affected by the relocation of the laboratory or test system. (See manufacturer's package insert regarding critical requirements such as set-up, limitations, environmental conditions, etc.)

If calibration material is used to establish method performance specifications, the laboratory must demonstrate that there is a minimal matrix effect and the calibration material is appropriate for establishing test system performance specifications.

If the LIS performs any calculations to determine a laboratory result, the calculations must be verified immediately after the LIS is programmed and prior to initial calculation of patient results.

NOTE: Public health testing performed on environmental (non-human) samples is not subject to CLIA.

Probes §493.1253(b)(2)

How does the laboratory determine if a new or revised LIS program (whether purchased or developed in-house) performs acceptably before it is integrated into routine operation?

§493.1253 Standard: Establishment and verification of performance specifications.

(b)(2)(i) Accuracy.

Interpretive Guidelines §493.1253(b)(2)(i)

Accuracy - The laboratory is responsible for establishing that the method produces correct results. Establishment of accuracy may be accomplished by:

- Testing reference materials or comparing results of tests performed using an established reference method; or

- Comparing split sample results with results obtained from another method, which has already been shown to provide accurate results.

For qualitative methods, the laboratory is responsible for establishing that a method will identify the presence/absence of the analyte.

In establishing a test system for a new analyte, research results may be used to document the accuracy of the test by correlation with the clinical presentation. In addition, the laboratory needs to determine the test system's precision and have mechanisms for determining analytical specificity, analytical sensitivity, and interfering substances.

§493.1253 Standard: Establishment and verification of performance specifications.

(b)(2)(ii) Precision.

Interpretive Guidelines §493.1253(b)(2)(ii)

Precision (Reproducibility) - The laboratory is responsible for establishing the precision of each test system by assessing day-to-day, run-to-run, and within-run variation, as well as operator variance.

This may be accomplished by:

- Repeat testing of known patient samples over time;

- Testing QC material in duplicate **and** over time; or

- Repeat testing of calibration materials over time.

EXCEPTION: For fully automated systems that are not user dependent, operator variance does not need to be evaluated.

§493.1253 Standard: Establishment and verification of performance specifications.

(b)(2)(iii) Analytical sensitivity.

Interpretive Guidelines §493.1253(b)(2)(iii)

Analytical Sensitivity - The laboratory is responsible for determining the lowest concentration or amount of the analyte or substance that can be measured or distinguished from a blank, i.e., minimum detection limits or how much of the analyte

must be present to be measured.

For modified test systems, the laboratory may use the lower limit of the manufacturer's reportable range if it has demonstrated that the modification has not affected the lower limit.

§493.1253 Standard: Establishment and verification of performance specifications.

(b)(2)(iv) Analytical specificity to include interfering substances.

Interpretive Guidelines §493.1253(b)(2)(iv)

Analytical Specificity - The laboratory must determine the extent to which the method measures the analyte for which it is reporting results.

Interfering Substances - The laboratory must document information regarding interfering substances from product information, literature, or its own testing. These may include: specimen hemolysis, anticoagulant, lipemia, and turbidity; patients' clinical conditions, disease states, and medications.

§493.1253 Standard: Establishment and verification of performance specifications.

(b)(2)(v) Reportable range of test results for the test system.

Interpretive Guidelines §493.1253(b)(2)(v)

Reportable Range- The laboratory is responsible for establishing the upper and lower limits of the test system.

§493.1253 Standard: Establishment and verification of performance specifications.

(b)(2)(vi) Reference intervals (normal values).

Interpretive Guidelines §493.1253(b)(2)(vi)

Reference Range (Normal Values) - The laboratory must establish a reference range that is appropriate for the laboratory's patient population (i.e., a normal range that reflects the type of specimen and demographic variables such as age and sex, as applicable).

§493.1253 Standard: Establishment and verification of performance specifications.

(b)(2)(vii) Any other performance characteristic required for test performance.

D5425
(Rev.)

§493.1253 Standard: Establishment and verification of performance specifications.

(b)(3) Determination of calibration and control procedures. The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

Interpretive Guidelines §493.1253(b)(3)

Through the verification/establishment process, the laboratory defines the frequency for calibration and control performance as well as the type, number, and concentration of calibration and control materials used to monitor, detect error, and evaluate method performance. The frequency for calibration and control performance must not be less than the frequency specified in the manufacturer's instructions.

In establishing the calibration and quality control frequency, the laboratory must consider:

- Test system instrument/reagent stability, including relocation;
- Frequency with which the test is performed;
- Technique dependence of the method;
- Frequency of quality control failures; and
- Training, experience, and competency of technical personnel.

For additional criteria in determining calibration and quality control frequency refer to §§493.1255 and 493.1256.

D5427
(Rev.)

§493.1253 Standard: Establishment and verification of performance specifications.

(c) Documentation. The laboratory must document all activities specified in this section.

Interpretive Guidelines §493.1253(c)

The actual measurement(s) taken, reactions and/or observations must be recorded.

Acceptable formats for documentation may vary.

§493.1254 Standard: Maintenance and function checks.

§493.1254(a) Unmodified manufacturer's equipment, instruments, or test systems. The laboratory must perform and document the following:

Interpretive Guideline §493.1254(a)

When a laboratory introduces a new test system, the laboratory may determine, depending on the outcome of the performance specifications, that additional measures are necessary in order to ensure accurate and reliable test results.

D5429
(Rev.)

§493.1254 Standard: Maintenance and function checks.

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

Interpretive Guidelines §493.1254(a)(1)

"As defined by the manufacturer" means that the laboratory must comply with the maintenance required in package inserts and/or instrument operator manuals for each piece of equipment/instrument it uses, including those that are peripherally involved in patient testing (e.g., incubators, centrifuges, safety cabinets, autoclaves and microscopes). We encourage laboratories to also comply with the manufacturer's maintenance recommendations.

A laboratory's maintenance program is *categorized* into two parts:

- Unscheduled repairs when needed; and
- Scheduled preventive maintenance (PM), which *includes maintenance by the laboratory (e.g., daily, weekly, monthly, etc.),* is performed to prevent breakdowns or malfunctions, to prolong the life of an instrument and to maintain optimum operating characteristics.

The laboratory is responsible to ensure the performance of all manufacturer-required maintenance regardless of any service contract.

A service contract for PM from an outside source is acceptable provided that for each instrument or piece of equipment, there is a description of the service to be performed and frequency of service.

Acceptable performance parameters (if applicable) must be documented.

The laboratory must perform and document maintenance as specified by the manufacturer for the LIS computer and devices such as monitors, printers and modems. All devices must be maintained to ensure accurate, clear, and interference-free transmission.

Probes §493.1254(a)(1)

Are LIS system components (e.g., server, hard drives, disk packs) maintained according to the manufacturer's instructions?

When downtime is required to perform maintenance on LIS equipment, how are LIS users notified?

How does the laboratory's maintenance program ensure that instruments and equipment maintain optimum operating characteristics and minimize breakdowns?

D5431
(Rev.)

§493.1254 Standard: Maintenance and function checks.

(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

Interpretive Guidelines §493.1254(a)(2)

Function checks refer to those activities performed to evaluate critical operating characteristics (e.g., stray light, zeroing, electrical levels, optical alignment, background counts, counting efficiency) according to the accepted method of operation for each type of device or instrument. Daily quality control activities and function checks are performed prior to patient testing to ensure that an instrument is functioning correctly and is properly calibrated (Checking electrical, mechanical, and operational functions may be independent of the procedure). The performance of daily quality control activities may serve as an additional instrument function check, since analysis of external control samples check the operating characteristics of a test system, including instrument stability and calibration.

The laboratory must follow and document the required functions checks as stated by the

laboratory information system (LIS) manufacturer for the LIS computer and devices such as monitors, printers and modems.

For instruments that automatically perform function checks and flag problems, the laboratory is required to document the corrective actions in response to the flagged problems. Use D5793 for deficiencies related to documenting corrective actions in response to the flagged problems.

Flow Cytometry:

A fluorescence standard(s) for each fluorochrome should be used each day of patient testing to ensure:

- Proper alignment of the optical system;
- Standardization of the fluorescence detectors;
- Resolution of dimly-stained particles; and
- Appropriate compensation for spectral overlap of the fluorochromes.

Fluorescence standards should have the same fluorochromes as are used for the test, and with the exception of alignment standards, should have similar fluorescence intensities as found in the test specimens. The laboratory must have an acceptable range of performance for all procedures.

Probes §493.1254(a)(2)

For those methods in which the centrifugation is a critical portion of the test, does the laboratory check the RPM's and timing periodically (e.g., urine sediments)?

Do the records of a laboratory that moves from testing site to testing site demonstrate the performance of function checks as necessary?

In immunofluorescent test procedures, how does the laboratory ensure that the bulb is emitting ultraviolet light at the correct wavelength?

How does the laboratory ensure that the fluorescent light source has not exceeded the manufacturer's established optimal timeframe?

For procedures or test systems that require pipetting or dilution of patient specimens separately from controls or calibrators, how are autodiluters, microdiluters, and/or pipettors checked for adequate and consistent delivery?

For those systems that perform simultaneous fluid delivery to multi-well plates or tubes, how does the laboratory ensure uniform delivery of reagents or washing solutions to all

wells or tubes?

§493.1254 Standard: Maintenance and function checks.

(b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

Interpretive Guidelines §493.1254(b)

The laboratory must establish and follow procedures for performing maintenance and function checks on each piece of equipment/instrument it uses, including those that are peripherally involved in patient testing (e.g., incubators, centrifuges, safety cabinets, autoclaves and microscopes).

A manufacturer's instructions may not require maintenance and function checks. However, if the laboratory determines that a maintenance and/or function check protocol is necessary in order to ensure accurate and reliable test results, the laboratory must establish a maintenance and/or function check protocol and perform and document the described activities as they are carried out over time.

D5433
(Rev.)

§493.1254 Standard: Maintenance and function checks.

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

Interpretive Guidelines §493.1254(b)(1)*(i)-(1)(ii)*

NOTE: *Refer to §493.1254(a)(1)*

Probes §493.1254(b)(1)*(i)-(1)(ii)*

How does the laboratory's maintenance program ensure that instruments and equipment maintain optimum operating characteristics and minimize breakdowns?

Has the laboratory evaluated whether any modifications it has made to a manufacturer's instrument or piece of equipment has resulted in the need for additional maintenance or function checks, and, if so, have the additional procedures been established and

implemented?

D5435
(Rev.)

§493.1254 Standard: Maintenance and function checks.

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

Interpretive Guidelines §493.1254(b)(2)(i)-(b)(2)(ii)

The laboratory must establish and follow procedures for performing function checks on each piece of equipment/instrument it uses, including those that are peripherally involved in patient testing (e.g., incubators, centrifuges, safety cabinets, autoclaves).

Function checks refer to those activities performed to evaluate critical operating characteristics (e.g., stray light, zeroing, electrical levels, optical alignment, background counts, counting efficiency) according to the accepted method of operation for each type of device or instrument. Daily quality control activities and function checks are performed prior to patient testing to ensure that an instrument is functioning correctly and is properly calibrated. Checking electrical, mechanical, and operational functions may be independent of the procedure. The performance of daily quality control activities serves as an additional instrument function check. Analysis of external control samples check the operating characteristics of a test system, including instrument stability and calibration.

When function checks are critical to test performance, the laboratory must have a mechanism in place to monitor such items as:

- Rotator speed and circumference;
- Timers;
- Anaerobic chambers;
- Cell washers;
- Radioactive particle counters;

- Blood cell counters; and
- Nucleic acid amplification equipment.

Flow Cytometry:

A fluorescence standard(s) for each fluorochrome must be used each day of patient testing to ensure:

- Proper alignment of the optical system;
- Standardization of the fluorescence detectors;
- Resolution of dimly-stained particles; and
- Appropriate compensation for spectral overlap of the fluorochromes.

Fluorescence standards must have the same fluorochromes incorporated into them as are used for the test, and with the exception of alignment standards, must have similar fluorescence intensities as found in the test specimens. The laboratory must have an acceptable range of performance for all procedures.

For flow cytometers with air-cooled lasers, the laser should be tested each day patients are tested by peaking the laser signal and monitoring the current input (amps) to laser light output (milliwatts) to determine whether the brewster windows are in need of cleaning.

Probes §493.1254(b)(2)

For those methods in which the centrifugation is a critical portion of the test, how has the laboratory checked the established RPM's and timing as necessary?

In immunofluorescent test procedures, how does the laboratory ensure that the bulb is emitting ultraviolet light at the correct wavelength?

If function checks are not required or recommended by the manufacturer, how does the laboratory establish the performance criteria of its equipment and instruments?

For RIA testing, are backgrounds or baselines measured for each setting? For example, if the laboratory uses more than one type of isotope, at what window setting are background counts performed and recorded?

When performing flow cytometry analysis using two or more fluorochromes simultaneously, how does the laboratory identify and adjust for "spill over" into the other fluorescence detectors?

§493.1255 Standard: Calibration and calibration verification procedures.

Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test system throughout the laboratory's reportable range of test results for the test system. Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following:

Interpretive Guidelines §493.1255

For definitions of calibration and calibration verification, refer to §493.2.

For calibration and calibration verification of blood gas analysis, see §493.1267(a) through (d).

In many instances, the performance of method calibration serves to satisfy the requirement for instrument calibration. Calibration procedures are not to be confused with instrument/equipment function checks at §493.1254.

D5437
(Rev.)

§493.1255 Standard: Calibration and calibration verification procedures.

(a) Perform and document calibration procedures -

(a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer;

(a)(2) Using the criteria verified or established by the laboratory as specified in §493.1253(b)(3)--

(a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and

(a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and

(a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

Interpretive Guidelines §493.1255(a)

Laboratories must follow the manufacturer's instructions on carrying out the calibration

and must follow or exceed the manufacturer's frequency recommendations for calibration. *However, if a calibration system proves less stable than expected by the manufacturer, additional calibration materials and/or more frequent calibration may be required, as established or verified by the laboratory under §493.1253(b)(3).*

The calibration requirement does not apply to a variety of procedures, which include, but are not limited to:

- Manual procedures not involving an instrument (e.g., microbiology cultures, Kirby-Bauer disk susceptibility tests, tilt-tube prothrombin time test systems, ABO group and D (Rho) typing);

- Microscopic procedures (e.g., KOH preparations, pinworm preparations, urine sediment analysis, all manual differential procedures, manual cytology screening procedures); and

- Test systems which include instruments that cannot be adjusted or calibrated because they are factory or manufacturer calibrated (e.g. unit use devices). This would include prothrombin time procedures on a fibrometer, or instruments that utilize a whole blood specimen and single unit use cartridge (PT/INR, Activated Clotting Time).

The term "calibration material" has generally replaced "standard" since many instruments now use serum-based reference materials. "Calibration material" means a solution that has a known amount of analyte weighed in or has a value determined by repetitive testing using a reference/definitive test method or is traceable to a National Institute for Standards and Technology (NIST) Standard, if possible.

The actual measurement(s) taken, reactions, and/or observations must be recorded.

Probes §493.1255(a)

If the laboratory calculates values for one or more calibration materials, are the calculations correct, and do the records reflect that the measured values are within the laboratory's established limits for the calibration materials?

D5439
(Rev.)

§493.1255 Standard: Calibration and calibration verification procedures.

(b) Perform and document calibration verification procedure -

(b)(1) Following the manufacturer's calibration verification instructions;

(b)(2) Using the criteria verified or established by the laboratory under §493.1253(b)(3)--

(b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and

(b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and

(b)(3) At least once every 6 months and whenever any of the following occur:

(b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.

(b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance.

(b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.

(b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

Interpretive Guidelines §493.1255(b)

The calibration verification requirements may be met by verifying the procedure using a high-level material such as a control, calibration material, or patient specimen and diluting it to cover the reportable range if allowed by the manufacturer.

Control activities routinely used to satisfy the requirement for §493.1256 do **not** satisfy the calibration verification requirements.

EXCEPTIONS:

1. Laboratories must perform and document calibration procedures following the manufacturer's test system instructions, using calibration materials provided or specified, and at a frequency that is recommended by the manufacturer. Where the manufacturer does not provide such instruction, the laboratory may calibrate using 3 or more levels of calibration materials that include a low, mid, and high value at least every 6 months.

2. If the laboratory performs a calibration protocol using 3 or more levels of calibration materials that include a low, mid, and high value at least every 6 months, the calibration

verification requirement is met.

3. For automated cell counters, the calibration verification requirements are considered met if the laboratory follows the manufacturer's instructions for instrument operation and tests 2 levels of control materials each day of testing provided the control results meet the laboratory's criteria for acceptability. This exception does not apply to centrifugal hematology test systems.

4. For automated chemistry analyzers, the calibration verification requirements are considered met if the laboratory follows the manufacturer's instructions for instrument operation and routinely tests three levels of control materials (lowest level available, mid-level, and highest level available) more than once each day of testing, the control material results meet the laboratory's criteria for acceptability and the control materials are traceable to National Institute of Standards and Technology (NIST) reference materials.

Calibration materials, proficiency testing samples with known results, or control materials with known values may be used to perform calibration verification. For these materials, the laboratory must define acceptable limits for the difference between the measured value obtained, versus the actual concentration of the materials.

NOTE: PT samples can only be used after the event cut-off date.

"Calibration material" means a solution that has a known amount of analyte weighed in, has a value determined by repetitive testing using a reference/definitive test method or is traceable to National Institute of Standards and Technology (NIST) reference material, if possible.

If a manufacturer provides reagents for a test where all of the reagents for a test are packaged together, calibration verification is not required for each additional reagent package with the same lot number that is received in the same shipment. For example, if the laboratory receives 12 packs of reagents and the laboratory has verified calibration for at least one of the 12 packs of reagents, then the laboratory does not have to verify calibration for the remaining 11 packs of reagents provided that all 12 packs of reagents have the same lot number and were received on the same shipment to the laboratory. However, this exception does not override the requirement to perform calibration verification as specified at 493.1255(b)(3).

5. Calibration verification is not required on:
   - Instruments that are factory or manufacturer calibrated and/or
   - Tests that are considered non-quantitative (e.g., Prothrombin time and Activated Clotting Time, which are measured in units of time)

When reviewing the laboratory's maintenance and function check records as required in §493.1254, determine whether the laboratory performed calibration verification when major maintenance occurred or critical parts were replaced.

The actual measurement(s) taken, reactions and/or observations must be recorded.

Probes §493.1255(b)

If a laboratory does not perform calibration verification after a complete change of reagents, what data does the laboratory have to document that changing reagent lot numbers does not affect the reportable range of patient test results, and does not adversely affect control results?

D5441
(Rev.)

§493.1256 Standard: Control procedures.

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process.

(b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in §493.1253(b)(3).

(c) The control procedures must--

(c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance.

(c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

Interpretive Guidelines §493.1256(a)-(c)

For each test system, the laboratory is responsible for monitoring the accuracy and precision of each phase of the analytic testing process by using control procedures that will detect immediate errors and errors occurring over time. Errors may occur due to test system failure, change in environmental conditions, and operator performance.

TEST SYSTEM

Test system failures may result from reagent contamination or deterioration, reagent lot variation, reaction temperature fluctuations, inadequate sampling, improper or loss of calibration, electronic or mechanical failure, power supply variances, etc.

ENVIRONMENT

Environmental conditions that may affect test system performance include temperature,

airflow, light intensity, humidity, altitude, etc.

OPERATOR (TESTING PERSONNEL)

Operator (testing personnel) performance that may affect testing includes improper specimen preparation and handling, incorrect test interpretation, failure to follow the manufacturer's test system instructions, etc. Operator training prior to testing is critical and competency assessment over time is necessary to ensure continued appropriate test performance. (See subpart M.)

Interpretive Guidelines §493.1256(c)

Control materials are referenced throughout the CLIA regulations. For §§493.1256(d)(3)(iv)-(v), (4)-(10), and (e)-(h); also §§493.17, 19, 1252, 1255, 1267, 1269, and 1278 (all mentioning the term "control material"), specific control materials are not specified by the regulation. §493.1264 and §493.1265 specify the control material to be used.

Acceptable control materials

Control materials that go through all elements of the analytic process must be run for each procedure per §493.1256(d)(3)(i)-(iii). With the advances in technology, certain instruments have introduced the use of on-board controls, that is, ampules or cartridges containing the same QC material that would traditionally be considered as external QC. For example, on-board control materials that have a similar matrix to that of patient specimens, are treated in the same manner as patient specimens, and go through all elements of the analytic process as applicable, will be considered acceptable to meet the regulatory requirement for control materials.

When the manufacturers' instructions do not address quality control or those instructions are less stringent than the regulatory control procedures for Analytic Systems (see Table 1 under IQCP, 493.1256(d)), the laboratory needs to follow the regulatory requirements or develop an IQCP. The laboratory director is responsible for the determination of what control materials to use in his/her laboratory.

Control activities that are not considered to be acceptable as control materials to meet the regulatory requirements.

Function checks, instrument/electronic checks, and procedural controls do not fulfill the regulatory requirements for testing control materials. These types of checks only verify the electronic components and detection function of the instrument and may only monitor a portion of the analytic process, such as sample addition, instrument/reagents interaction, or test completion, not the performance of the entire test system. Accordingly, they do not go through all elements of the analytic process as applicable.

Surveyors will ensure that the laboratory is following its own established policies,

specifically its QC procedures, in the context of the Outcome Oriented Survey Process.

CONTROL PROCEDURES

In determining the control procedures, including the frequency of testing controls that detect immediate errors and monitor test performance over time, the laboratory needs to consider the following:

- Control procedures specified by the test system's manufacturer;
- Test system instrument reliability and reagent stability (e.g., relocation);
- Frequency and volume of test performance;
- Technique dependence of the method;
- Frequency of quality control failures; and
- Training, experience, and competency of person(s) performing the test.

Traditionally, laboratories have tested two levels of external control materials daily to monitor the accuracy and precision of the analytic test system components. External control materials having a similar matrix to that of patient specimens, are treated in the same manner as patient specimens, and go through all analytic phases of testing as applicable. External control materials may be provided as part of the test system, provided separately or prepared in-house. Testing external controls meets the requirement for monitoring test system components, environment, and operator performance. External control materials may be:

- Commercially or in-house prepared controls;
- Proficiency testing specimens for which results have been confirmed;
- Reference or control strains of microorganisms;
- Calibrators of different lot numbers and concentration than those used to calibrate the system; or
- Previously tested patient specimens provided the laboratory determines the acceptable performance level for the patient specimens.

D5445
(Rev.)

§493.1256 Standard: Control procedures.

(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--

(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at §§493.1261 through 493.1278.

(d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section.

(d)(3) At least once each day patient specimens are assayed or examined perform the following for:

Interpretive Guidelines §493.1256(d)

INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)

INTRODUCTION

§493.1250 provides for HHS' approval of a procedure that provides equivalent quality testing as an alternative to meeting the Analytic Systems requirements in §493.1251 - §493.1283. CMS has *approved* use of an equivalent quality control procedure, which permits laboratories to develop and customize laboratory-specific quality control procedures for their healthcare setting(s). This procedure is termed Individualized Quality Control Plan (IQCP).

An IQCP is composed of three parts: a Risk Assessment (RA), a Quality Control Plan (QCP), and a Quality Assessment (QA) plan. The RA is the identification, evaluation, and documentation of potential failures and errors in a testing process. The QCP documents a laboratory's standard operating procedure that describes the practices, resources, and procedures to control the quality of a test process. The QA consists of the laboratory's written policies and procedure for the ongoing monitoring of the effectiveness of their IQCP.

IQCP is only available for select quality control requirements, which are identified below in Table 1 "Eligibility for IQCP."

When the manufacturers' instructions do not address quality control or those instructions are less stringent than the regulatory control procedures for Analytic Systems (see Table 1), the laboratory needs to follow the regulatory requirements or develop an IQCP. Laboratories have the flexibility to follow all regulatory requirements as written or customize their control procedures using the IQCP procedure. Whichever option is selected laboratories are not permitted to establish quality control procedures that are less stringent than those specified by the manufacturer of the test system.

LABORATORY DIRECTOR RESPONSIBILITIES

Under subpart M, the laboratory director is responsible for ensuring that quality control (use D6020 or D6093 as appropriate) and quality assessment programs are established and maintained to assure the quality of laboratory services, including the identification of failures in quality as they occur.

The laboratory director is responsible for deciding whether a laboratory will seek to meet its CLIA quality control obligations through IQCP, and if the laboratory director decides to do so, the laboratory director is also responsible for ensuring that the QCP the laboratory develops meets the IQCP requirements.

The laboratory director must consider the laboratory's clinical and legal responsibility for providing accurate, reliable and timely patient test results (§493.1407 or §493.1445) prior to implementing a QCP that is less stringent than the applicable Analytic Systems control regulations listed in Table 1, Eligibility for IQCP.

REGULATORY CONSIDERATIONS WHEN USING IQCP

All CLIA regulations, other than those specifically designated as eligible for IQCP in Table 1, Eligibility for IQCP, continue to be in force and must be followed.

Table 1, Eligibility for IQCP, lists those specialties/subspecialties and general regulations which are designated as "eligible" for IQCP, that is, those specialties/subspecialties and general regulations for which the laboratory has the flexibility to develop control procedures using the IQCP procedure. Table 1 also lists those specialties/subspecialties and specialty/subspecialty regulations which are not eligible for IQCP.

- The first column lists the CLIA specialties/subspecialties: Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Syphilis Serology, General Immunology, Routine Chemistry, Urinalysis, Endocrinology, Toxicology, Hematology, Immunohematology, Clinical Cytogenetics, Radiobioassay, Histocompatibility, Pathology, Histopathology, Oral Pathology and Cytology.

- The second column indicates whether or not each specialty/subspecialty is eligible for IQCP. The specialties/subspecialties eligible for IQCP are; Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Syphilis Serology, General Immunology, Routine Chemistry, Urinalysis, Endocrinology, Toxicology, Hematology, Immunohematology, Clinical Cytogenetics, Radiobioassay and Histocompatibility. The specialties/subspecialties not eligible for IQCP are Pathology, Histopathology, Oral Pathology and Cytology.

- The third column lists the general regulations that *are eligible for IQCP* and may be applied to the eligible specialty/subspecialties listed in column one: §493.1256(d)(3)-(5) and §493.1256(e)(1)-(4).

- The fourth column lists the specialty/subspecialty regulations that are eligible for IQCP: §493.1261, §493.1262, §493.1263, §493.1264, §493.1265, §493.1267(b), (c), §493.1269, and §493.1278(b)(6), (c), (d)(6), (e)(3).

- The fifth column lists the specialty/subspecialty regulations that are not eligible for IQCP: §493.1267(a), (d), §493.1271, §493.1276, §493.1278(a), (b)(1-5), (d)(1-5), (d)(7), (e)(1-2), (f), (g), §493.1273 and §493.1274.

Table 1: Eligibility for IQCP

CLIA Specialty/ Subspecialty	**Eligible for IQCP?**	**General Regulations Eligible for IQCP**	**Specialty/ Subspecialty Regulations Eligible for IQCP**	**Specialty/ Subspecialty Regulations NOT Eligible for IQCP**
Bacteriology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1261	N/A
Mycobacteriology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1262	N/A
Mycology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1263	N/A
Parasitology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1264	N/A
Virology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1265	N/A
Syphilis Serology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
General Immunology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Routine Chemistry	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1267(b), (c)	§493.1267(a), (d)
Urinalysis	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Endocrinology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Toxicology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Hematology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1269	N/A
Immunohematology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	§493.1271

Clinical Cytogenetics	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	§493.1276
Radiobioassay	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Histocompatibility	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1278(b)(6), (c), (d)(6), (e)(3)	§493.1278(a), (b)(1-5), (d)(1-5), (d)(7), (e)(1-2), (f), (g)
Pathology	No	None (Not eligible for IQCP)	N/A	N/A
Histopathology	No	None (Not eligible for IQCP)	N/A	§493.1273
Oral Pathology	No	None (Not eligible for IQCP)	N/A	N/A
Cytology	No	None (Not eligible) for IQCP)	N/A	§493.1274

Probe(s) §493.1256(d)

For each test system, does the laboratory perform quality control testing procedures as specified in the manufacturer's instructions? Use D5411.

If the manufacturer's instructions are less stringent than the CLIA regulatory requirements for control procedures, did the laboratory perform an IQCP or are they following the CLIA regulatory requirements for control procedures?

As stated above, an IQCP must include:

- Risk Assessment (RA)
- Quality Control Plan (QCP)
- Quality Assessment (QA)

Risk Assessment

Risk assessment is the identification and evaluation of potential failures and sources of errors in a testing process.

Risk assessments for IQCP must include, at a minimum, an evaluation of the following five components:

1. Specimen
2. Test system
3. Reagent
4. Environment
5. Testing personnel

The scope of risk assessments must encompass the entire testing process - preanalytic, analytic, and postanalytic phases - and include, at a minimum, the evaluation of the five risk assessment components listed above for each test for which the laboratory wishes to employ IQCP. Use D5445.

The laboratory director has the responsibility for ensuring that the risk assessment considers the CLIA Quality System requirements at 42 C.F.R. 493, Subpart K for accurate, reliable, and timely test results and that test result quality is appropriate for patient care. Re-evaluation of the RA must be considered by the director or his/her designee when changes occur in any of the following components: specimen, test system, reagent, environment and testing personnel.

Conducting the Risk Assessment

To conduct a risk assessment, the laboratory must identify the sources of potential failures and errors for a testing process, and evaluate the frequency and impact of those failures and sources of error on test quality.

In-house data, established by the laboratory in its own environment and by its own personnel, must be utilized to demonstrate that the stability of the test system as it is used in that laboratory supports the number and frequency of the QC documented in the QCP. Use D5425. Data from verification or establishment of performance specifications, historical (existing) QC data, and data/documentation compiled to meet other existing CLIA Quality System regulations at 42 C.F.R. 493, Subpart K can be included. Published data or data from manufacturers (e.g. package inserts) may be taken into consideration, but may not be used as the sole criteria for decision-making. The laboratory must document all activities completed for the risk assessment, including data to support their risk assessment decisions. Use D5481. *All* RA documentation must be maintained for at least two years after the corresponding QCP has been discontinued. Use D3029.

NOTE: Manufacturer-provided tools and templates, if available, may be helpful for laboratories implementing IQCP; however, laboratories will need to supplement these materials with laboratory-specific information as part of the Risk Assessment. The manufacturer information is not sufficient in and of itself.

Laboratories must assess information provided by manufacturers as part of the RA, such as the manufacturer's instructions (e.g. intended use, limitations, interferences, recommendations). If additional information is required to conduct the risk assessment, that is not available in the manufacturer's instructions, the laboratory should contact the manufacturer to request the needed information.

The following list contains additional possible sources of information for conducting a risk assessment:

- Regulatory requirements

- Manufacturer's package insert (including intended use, limitations, environmental requirements, QC frequency, specimen requirements, reagent storage, maintenance, calibration, interfering substances, etc.)
- Manufacturer's operator manual
- Troubleshooting guide
- Manufacturers' alerts and bulletins
- Verification or establishment of performance specifications
- Testing personnel qualifications, training and competency records
- QC data
- Proficiency testing data
- QA information, including corrective action
- Scientific publications
- Other information as appropriate

In laboratories with multiple identical devices (same make and model), a single risk assessment may be performed for the test system. However, differences in testing personnel and environments where the device will be used must be taken into consideration when performing the risk assessment; therefore, there may be a need to customize a QCP for each individual location and/or device.

NOTE: Multiple devices may be included in a single QCP; however, performance specifications must be established or verified for each individual device and each analyte.

Probes §493.1256(d)

Does the laboratory's RA support its procedures for testing quality control samples, including the frequency of testing? Use D5445.

Has the laboratory included all five components and all phases of testing in their risk assessment, and have they reasonably identified and evaluated the potential failures and sources of error? Use D5445.

Has the laboratory conducted a risk assessment for each location where testing is performed on multiple numbers of identical devices (i.e. same make, model)?

For example, has the laboratory conducted a risk assessment with respect to:

- Multiple laboratory/testing locations within a single CLIA number
- Point-of -care devices throughout health care/laboratory systems
- Multiple identical devices or kits in a single location
- Differences in testing personnel

Has the laboratory's RA identified the sources of potential failures and sources of error contained in the most current version of the manufacturer's instructions?

Has the laboratory documented all activities completed for the risk assessment? Does the laboratory have documentation, including data, to support their risk assessment decisions? Use D5481.

SPECIMEN

Probe §493.1256(d)

Has the laboratory identified and evaluated the potential failures and sources of error in the preanalytic phase, as applicable, for:

- Patient preparation
- Specimen collection
- Specimen labeling
- Specimen storage, preservation and stability
- Specimen transportation
- Specimen processing
- Specimen acceptability and rejection
- Specimen referral

TEST SYSTEM

The risk assessment must include consideration of the manufacturer instructions for function checks and maintenance checks. In addition, the risk assessment should take into consideration the laboratory's test volume, and intended use of the test results (i.e. screening or diagnostic).

Additional factors to consider in the risk assessment for analyte and test systems may include, but are not limited to potential failures and sources of error due to:

- Inadequate sampling
- Clot detection capabilities
- Capabilities for detection of interfering substances (e.g., hemolysis, lipemia, icterus, turbidity)
- Calibration associated issues
- Mechanical/electronic failure of test system
- Optics
- Pipettes or pipettors
- Barcode readers
- Failure of system controls and function checks
- Built-in procedural and electronic controls (internal controls)
- External or internal liquid quality control (assayed vs. unassayed)

- Temperature monitors and controllers
- Software/Hardware
- Transmission of data to Laboratory Information System
- Result reporting

REAGENT

Factors to consider in the risk assessment for reagents, quality control materials, calibrators, and similar materials may include, but are not limited to potential failures and sources of error related to:

- Shipping/Receiving
- Storage condition requirements
- Expiration Date (may vary based on storage requirements)
- Preparation

Probes §493.1256(d)

Has the laboratory assessed potential test system failures or sources of error, which may result from reagent, quality control material, and calibrator contamination or deterioration and reagent lot variation?

Has the laboratory assessed potential test system failures or sources of error due to the risk of inadvertently mixing reagents from different kits or lot numbers, if applicable?

ENVIRONMENT

Probes §493.1256(d)

Has the laboratory evaluated environmental conditions, which may affect test system performance including, but not limited to potential failures and sources of error due to:

- Temperature
- Airflow/ventilation
- Light intensity
- Noise and vibration
- Humidity
- Altitude
- Dust
- Water
- Utilities (e.g. Electrical failure/power supply variance or surge)
- Adequate space

Has the laboratory evaluated potential failures and sources of error due to the transport of instruments and reagents in a mobile laboratory?

TESTING PERSONNEL

Testing personnel must participate in the process of conducting the risk assessment. It is not necessary for all personnel to be involved.

Probe §493.1256(d)

Has the laboratory assessed the potential failures and sources of error due to testing personnel by evaluating the following:

- Training
- Competency
- Appropriate education and experience qualifications
- Adequate staffing

After the laboratory has identified the sources of potential failures and errors for a testing process and evaluated the frequency and impact of those failures and errors on test quality, the resulting risk assessment is then used to develop the Quality Control Plan (QCP).

Quality Control Plan

A QCP is a document that describes the practices, resources, and procedures to control the quality of a particular test process. The QCP must ensure accurate, reliable and timely test results, and that test result quality is appropriate for patient care. The QCP must be available to, and followed by, laboratory personnel. Use D5401.

The QCP must provide for the immediate detection of errors that occur due to test system failure, adverse environmental conditions, and operator performance. It must also monitor, over time, the accuracy and precision of test performance that may be influenced by changes in the test system, environmental conditions, or variance in operator performance. Use D5441.

The QCP must at least include the number, type, frequency of testing and criteria for acceptable result(s) of the quality control(s). Use D5441 or D5469, as appropriate.

If indicated by the evaluation of the risk assessment, the QCP may also include:

- Electronic controls
- Procedural controls
- Training and competency assessment
- Other specified quality control activities

Laboratories implementing IQCP for new tests are encouraged to perform control procedures at more frequent intervals during initial implementation, allowing the laboratory to identify performance issues that could indicate a need to adjust the QCP.

There must be documented evidence that the laboratory director has approved, signed, and dated the QCP (§493.1251(d)). The task of development and implementation of QCPs may be delegated (in writing) to a qualified individual (§493.1407(e)(14) or §493.1445(e)(15)). However, the laboratory director has the ultimate responsibility for the proper development and implementation of a QCP. (§493.1407(b) or §493.1445(b)). Use D5407. Re-evaluation of the QCP must be considered by the director or his/her designee when changes occur in any of the following components: specimen, test system, reagent, environment and testing personnel.

Probes §493.1256(d)

Does the laboratory have a written QCP for each test system, as applicable? Use D5441 or D5445, as appropriate.

Does the QCP specify the number, type, and frequency of testing of the quality control material(s)? Does the QCP provide for immediate detection of errors? Use D5441.

Does the QCP contain criteria to determine acceptable quality control results? Use D5469.

Does the QCP require that the laboratory perform QC as specified by the manufacturer's instructions? Regardless, if the laboratory is performing QC less frequently than required by the manufacturer, use D5411 or D5445, as appropriate.

Is there documented evidence of laboratory director approval of the QCP before it was put into use? Use D5407.

Quality Assessment

All IQCP Quality Assessment monitoring must be part of the laboratory's overall Quality Assessment plan. The laboratory must establish and follow written policies and procedures for the ongoing monitoring of the effectiveness of their IQCP. The monitoring *must* include, but is not limited to, the following components:

1. *Specimen*
2. *Test System*
3. *Reagent(s)*
4. *Environment*
5. *Testing Personnel*

Re-evaluation of the RA and the QCP must be considered by the director or his/her designee when changes occur in any of the above components.

Laboratories implementing IQCP for new tests are encouraged to perform monitoring activities at more frequent intervals during initial implementation, allowing the laboratory to identify performance issues that could indicate a need to adjust the QCP.

Documents to consider for QA review may include, but are not limited to:

- QC review
- Proficiency testing records (e.g. scores, testing failures, trends)
- Patient results review
- Specimen rejection logs
- Turnaround time reports
- Records of preventive measures, corrective actions, & follow-up
- Personnel Competency Records

When the laboratory discovers a testing process failure, the laboratory must conduct an investigation to identify the cause of the failure, its impact on patient care, appropriate

corrective action for affected patients and appropriate modifications to their QCP to prevent recurrence, as applicable. The investigation must include documentation of all corrections, corresponding corrective actions for all patients affected by the testing process failure, and evaluation of the effectiveness of the corrective action(s). The laboratory must implement the correction(s) and corresponding corrective action(s) necessary to resolve the failure and reduce the risk of recurrence of the failure in the future. If necessary, the laboratory must update the risk assessment with the new information and modify the QCP, as needed.

Probes §493.1256(d)

Has the laboratory established written policies and procedures for the ongoing monitoring of the QCP (use D5391, D5791 or D5891 as appropriate) and evaluation of its effectiveness? (Use D5393, D5793 or D5893 as appropriate)

In the event of a testing process failure, has the laboratory evaluated all patient test results since the last acceptable quality control? Use D5783.

D5447

(Rev.)

§493.1256 Standard: Control procedures.

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

Interpretive Guidelines 493.1256(d)(3)(i)

For monitoring the abnormal range, the laboratory must select controls that correlate with the patient values either in terms of specimen matrix or range to be evaluated. A laboratory must not use control materials outside the patient reportable range. Control samples not containing the analytes or substances to be controlled are not acceptable as control material.

Routine Chemistry:

For monitoring the abnormal range, the laboratory should select control materials that correlate with the patient values both in terms of specimen matrix and range to be evaluated. For example, an elevated serum-based bilirubin control should be employed when measuring neonatal bilirubins; a low-level protein control or cerebrospinal fluid control should be used for monitoring cerebrospinal fluid protein.

Hematology:

For instruments which perform hemoglobin, hematocrit, red and white blood cell counts, platelets and/or differentials, acceptable controls are 2 levels of assayed materials, OR 1

level of assayed material and 1 patient specimen that was verified in the same batch of specimens with the assayed control material. The laboratory must establish criteria for an acceptable range of performance as required at D5481.

EXCEPTION:

Unless otherwise required by the test system's manufacturer or the laboratory's performance specifications, for instruments that perform white blood cell differentials directly from blood films (smears), a commercial control or patient specimen (differential) that has been verified through repetitive testing is an acceptable control and satisfies the requirements of §493.1256(d), as appropriate.

D5449
(Rev.)

§493.1256 Standard: Control procedures.

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

Interpretive Guidelines §493.1256(d)(3)(ii)

Urinalysis

Photomicrographs or charts of all possible urine sediment components will meet the control requirement for manual microscopic urinalysis examinations.

D5451
(Rev.)

§493.1256 Standard: Control procedures.

(d)(3)(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively;

Interpretive Guidelines §493.1256(d)(3)(iii)

For tests in which patient results are reported in terms of graded reactivity (1+, 2+, 3+, etc.) control(s) of graded reactivity must be used. For tests in which patient results are reported as a titer, controls of known titer must be used.

EXCEPTIONS:

A negative control is not required for anti-streptolysin O titer, anti-hyaluronidase titer tests. A positive control is not required for the cold agglutination test. For radial

immuno-diffusion, one control or calibration material is required on each plate.

D5453
(Rev.)

§493.1256 Standard: Control procedures.

(d)(3)(iv) Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; and

Interpretive Guidelines §493.1256(d)(3)(iv)

Bacteriology:

For direct antigen systems, laboratories may use bacterial cell suspensions to meet the requirement for control organisms since the cell suspensions are subjected to both the extraction and reaction phases of the test. However, a matrix similar to patient specimens is preferred. For example, for direct antigen tests for group A streptococcal antigen, commercially prepared, dried (solid-shafted) swabs, one containing group A streptococcus (S. pyogenes) as a positive control and another with non-group A streptococcus and/or Staphylococcus aureus as a negative control may be used.

Additionally, if the manufacturer's instructions do not specify what the positive control contains, the laboratory should contact the manufacturer to ensure that the positive control contains a cell suspension of the organism. Otherwise, the laboratory must have an alternative mechanism for meeting this requirement (e.g., laboratory suspension stock American Type Culture Collection (ATCC) organism, commercially prepared organism controls).

Toxicology:

For comprehensive broad spectrum qualitative drug screening, procedures using gas chromatography, a control material containing one or more drugs representative of each drug class reported (e.g., tricyclic antidepressants, barbiturates), must go through each test phase, including the extraction process.

NOTE: For gas chromatography and mass spectrometry used for drug confirmations, an analyte-specific control is required for both qualitative and quantitative tests.

D5455
(Rev.)

§493.1256 Standard: Control procedures.

(d)(3)(v) Each molecular amplification procedure, include two control materials

and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition.

Interpretive Guidelines §493.1256(d)(3)(*v*)

The laboratory is also responsible for following *any provided* manufacturer's instructions concerning procedure limitations for detecting nucleic acid target amplification sequences.

If the laboratory suspects the presence of interfering substances (inhibitors), the laboratory is responsible for using a control material (in addition to positive and negative control materials) capable of detecting interfering substances. Patient specimens may contain substances (inhibitors) that interfere with the enzymatic reaction of a molecular amplification procedure. These interfering substances could affect the assay's sensitivity causing a false negative result. Interfering substances may include, but are not limited to components within the patient specimen or exogenous substances introduced during the preanalytic and/or analytic phase of testing.

D5457
(Rev.)

§493.1256 Standard: Control procedures.

(d)(4) For thin layer chromatography--

(d)(4)(i) Spot each plate or card, as applicable, with a calibrator containing all known substances or drug groups, as appropriate, which are identified by thin layer chromatography and reported by the laboratory; and

(d)(4)(ii) Include at least one control material on each plate or card, as applicable, which must be processed through each step of patient testing, including extraction processes.

Interpretive Guidelines §493.1256(d)(4)

For qualitative urine drug screens performed by thin layer chromatography, a negative control is not required. However, a control containing one or more drugs representative of each drug group reported (e.g., tricyclic antidepressants, barbiturates) that goes through each test phase (including the extraction process) is required.

D5459
(Rev.)

§493.1256 Standard: Control procedures.

(d)(5) For each electrophoretic procedure include, concurrent with patient

specimens, at least one control material containing the substances being identified or measured.

D5461
(Rev.)

§493.1256 Standard: Control procedures.

(d)(6) Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced.

D5463
(Rev.)

§493.1256 Standard: Control procedures.

(d)(7) Over time, rotate control material testing among all operators who perform the test.

Interpretive Guidelines §493.1256(d)(7)

The laboratory may use this requirement to assist in competency assessment determinations specified in subpart M.

D5465
(Rev.)

§493.1256 Standard: Control procedures.

(d)(8) Test control materials in the same manner as patient specimens.

Interpretive Guidelines §493.1256(d)(8)

Control materials of a similar matrix to that of patient specimens should be utilized, if available, and the control materials must be treated in the same manner as patient specimens and go through all analytic test phases.

Flow Cytometry

In cell surface phenotyping by flow cytometry or fluorescent microscopy, control samples must be analyzed within the same time period after staining as test specimens.

Probes §493.1256(d)(8)

Flow Cytometry

How did the laboratory establish the time period in which stained cells must be analyzed to avoid significant loss of any cell subpopulations or total cell numbers?

If analysis will be based on a population of cells selected by flow cytometry "gating" on size or density parameters, or selected by depletion or enrichment techniques, are controls tested with each patient to detect the presence of contaminating cells in the selected population? (e.g., Monocyte contamination of "lymphocytes" gated by forward angle or forward angle versus 90° light scatter must be detected with a monocyte-specific antibody.) Use D5465 or D5425 as appropriate.

D5467

(Rev.)

§493.1256 Standard: Control procedures.

(d)(9) When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system.

D5469

(Rev.)

§493.1256 Standard: Control procedures.

(d)(10) Establish or verify the criteria for acceptability of all control materials.

(d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.

(d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory.

(d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

Interpretive Guidelines §493.1256(d)(10)

Acceptable ranges must be verified (assayed) or established (unassayed) by the laboratory for control materials and any calibrators that are used in lieu of control materials.

For procedures in which a spiked sample is used as a control, an acceptable range must be established for the amount of recovery of the spiked sample, either in percentage or actual concentration.

If laboratories rely on commercial companies to establish statistical limits for controls, the laboratory must have documentation to verify that its control results correlate with the established limits.

When patient specimens are used to meet the control requirements, data must be evaluated in accordance with §493.1256(d)(10)(iii).

There are no specific guidelines for the number of times a material must be tested to establish statistical limits. In general, twenty replicate tests should be considered the minimum for determining a standard deviation.

Probes §493.1256(d)(10)

What statistics does the laboratory have to demonstrate the number of assays and the period of time in which the laboratory repetitively tested control materials to verify or establish control limits?

How does the laboratory evaluate control results to detect any outliers, shifts or trends in control values due to instrument malfunctions or changes in the analytical system?

If more than one test system is in use for a test procedure, did the laboratory evaluate the data for each test method in the establishment of control limits?

D5471
(Rev.)

§493.1256 Standard: Control procedures.

(e) For reagent, media, and supply checks, the laboratory must do the following:

(e)(1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in §493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

Interpretive Guidelines §493.1256(e)(1)

Review the laboratory's quality control records and note when lot numbers change.

NOTE: Media checks are defined under §493.1256(e)(4) guidelines.

The laboratory must demonstrate that each reagent performs within the specifications established by the laboratory for the test procedure. Documentation of concurrent testing of reagents or acceptable quality control results will satisfy this requirement.

Reagents, disks, and test procedures used for identification purposes may include, but are not limited to, catalase, coagulase plasma, oxidase, bacitracin, optochin, Cefinase™, ONPG, X, and V factor strips and disks, germ tube, yeast morphology media, and commercial identification systems.

A negative reactivity control is not required for the mycology germ tube test.

Test each batch, lot, and shipment for positive and negative reactivity for reagents such as:

- Bacitracin;
- Catalase;
- Cefinase;
- Coagulase plasma;
- ONPG;
- Optochin;
- Oxidase;
- Spot indole; and
- X and V factor strips and disks.

For bacteriology, XV discs or strips need only be checked with an organism that produces a positive reaction.

Probes §493.1256(e)(1)

What records does the laboratory have to demonstrate that controls are tested when shipments of reagents, discs, stains, antisera or identification systems are opened or when the laboratory prepares these materials? Use D5471 for not recording performance and for nonperformance of quality control checks and stain checks.

D5473
(Rev.)

§493.1256 Standard: Control procedures.

(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

Interpretive Guidelines §493.1256(e)(2)

The laboratory must check routine stain Hematoxylin and Eosin each day for intended response, and predicted characteristics of the stain.

Interpretive Guidelines §493.1256(e)(2)-(e)(3)

Acid-fast stains must be checked each day of use for positive and negative reactivity.

D5475
(Rev.)

§493.1256 Standard: Control procedures.

(e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.

Interpretive Guidelines §493.1256(e)(3)

All fluorescent stains, including fluorochrome acid-fast stains, must be tested for positive and negative reactivity each time of use.

Flow Cytometry

Staining controls for cell surface immunophenotyping by flow cytometry should consist of either normal, cultured or abnormal cells known to be positive for selected standard antigens and must verify the proper performance of reagents. Frozen or other preserved cells may be used. A negative reagent control must be run for each test cell preparation, and is to consist of monoclonal antibody(ies) of the same species and isotype. Negative reagent controls will consist of:

- For indirect stains, an irrelevant primary antibody, if available, and in all cases, the same secondary antibody(ies) conjugated with the same fluorochrome(s) used in all relevant test combinations; and

- For direct stains, an irrelevant antibody conjugated to the same fluorochrome and at the same fluorochromes: protein ratio used in all relevant test combinations.

Probes §493.1256(e)(3)

For flow cell cytometric surface immunophenotyping, is a negative reagent control used to define a threshold for positive staining cells? If not, how does the laboratory define the threshold for positive staining cells?

D5477
(Rev.)

§493.1256 Standard: Control procedures.

(e)(4) Before, or concurrent with the initial use--

(e)(4)(i) Check each batch of media for sterility if sterility is required for testing;

(e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and

(e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.

Interpretive Guidelines §493.1256(e)(4)

A batch of media (solid, semi-solid, or liquid) consists of all tubes, plates, or containers of the same medium prepared at the same time and in the same laboratory; or, if received from an outside source or commercial supplier, consists of all of the plates, tubes or containers of the same medium that have the same lot numbers and are received in a single shipment.

A sample from each batch of media is sufficient as a check for:

- Sterility, if it is autoclaved or filtered during preparation;
- Ability to support growth, using at least one organism to demonstrate the ability of the media to support growth;
- Selectivity and/or inhibition, using at least one organism to confirm its selective characteristic, and at least one organism to confirm its inhibitory characteristic; and
- Biochemical response, using at least one organism which will produce the expected reaction (positive control) and with at least one organism which will not produce the expected reaction (negative control).

American Type Culture Collection (ATCC) control organisms are not necessarily

required. However, if the laboratory uses "in-house" isolates for control organisms, it must have established reactivity for each organism. Use D5469 as appropriate.

Central laboratories that prepare media for satellite locations must either perform the same quality control checks required of commercial manufacturers and furnish documentation of media quality control checks to each satellite location, or each laboratory must continue to perform media checks as required under §493.1256(e)(4).

If a laboratory screens cultures for growth or no growth, reports "No growth" and refers all growth to a reference laboratory, the screening laboratory must perform applicable quality control of the media.

D5479

(Rev.)

§493.1256 Standard: Control procedures.

(e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results.

Interpretive Guidelines §493.1256(e)(5)

The laboratory must meet any and all regulatory requirements and comply with the manufacturer's requirements to the extent that the manufacturer's requirements do not conflict with any regulatory requirements. We encourage laboratories to also comply with the manufacturer's recommendations for testing to the extent that the manufacturer's recommendations do not conflict with any regulatory requirements.

D5481

(Rev.)

§493.1256 Standard: Control procedures.

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results.

§493.1256(g) The laboratory must document all control procedures performed.

Interpretive Guidelines §493.1256(g)

The actual measurement(s) taken, reactions and/or observations must be recorded.

D5485

(Rev.)

§493.1256 Standard: Control procedures.

(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.

Interpretive Guidelines §493.1256(h)

Laboratories may choose to split samples for testing by another method or in another laboratory to evaluate the results obtained. Previously tested patient specimens (include specimens across the reportable range) must be tested in duplicate. Precision is determined through replicate testing of a previously tested patient specimen. The duplicate tests may be performed by the same individual or by different people and the results compared to previously defined acceptable limits for differences between duplicates.

Public Health Laboratories Performing Newly Developed Assays/Test Systems for Agents for Emergent Public Health Significance

Screening and confirmation methods for agents of emergent public health significance require the rapid development and transfer of technology and expertise from federal agencies to public health laboratories (or other designee laboratories). CMS may*, as needed,* issue guidance regarding emergent public health issues (*refer to CLIA website or contact CMS for any applicable guidance*). Because of unique situations of emergent diseases or other public health threats, control and calibration materials for the assay or test system may not be immediately available. Under these circumstances, the laboratory must follow the assay or test system's protocol(s) **without modification** and **document** the alternative *control procedures* employed to ensure accurate test results. Laboratories are encouraged to use multiple *alternative control procedures* (as described below) for ensuring accuracy.

When control and calibration materials are not available, examples of alternative control procedures that may be available include, but are not limited to, the following:

- Split specimens for testing by another method or in another laboratory;
- Include previously tested patient specimens (both positive and negative) tested in duplicate as surrogate controls;
- Test each patient specimen in duplicate;
- Test multiple specimen types from the same patient (e.g., saliva, urine, serum);
- Perform serial dilutions of positive specimens to confirm positive reactions;
- Provide additional supervisory review of results prior to release.

In the unique case of PPM procedures, examples of alternative control procedures might include but are not limited to:

- *Two testing personnel, qualified in accordance with 42 CFR § 493.1363, who are reviewing the same slide, or*

- *Ensuring that reference slides or pictograms are available, that testing personnel have demonstrated competency at using materials, and that testing personnel use established procedures for equipment maintenance and function checks.*

As soon as control and calibration materials become available, the applicable requirements in §493.1256 must be met.

For specific information regarding testing for agents of emergent public health significance and alternative methods/procedures for ensuring accuracy of this testing, refer to http://www.aphl.org/.

Probes §493.1256(h)

If control materials are not provided by the manufacturer, how does the laboratory ensure the validity of test results?

§493.1261 Standard: Bacteriology.

(Rev.)

(a) The laboratory must check the following for positive and negative reactivity using control organisms:

Interpretive Guidelines §493.1261(a)

When condition-level deficiencies in Bacteriology are in any or all phases of testing, use D5002.

For direct antigen systems, laboratories may use bacterial cell suspensions to meet the requirement for control organisms since the cell suspensions are subjected to both the extraction and reaction phases of the test. However, a matrix similar to patient specimens is preferred. For example, for direct antigen tests for group A streptococcal antigen, already prepared, dried (solid-shafted) swabs, one containing group A streptococcus (S. pyogenes) as a positive control and another with non-group A streptococcus and/or Staphylococcus aureus as a negative control may be used. Use D5449 to cite a laboratory that fails both a negative and positive control. Use D5453 for deficiencies related to the extraction process.

Additionally, if the manufacturer's instructions do not specify what the positive control

contains, the laboratory should contact the manufacturer to ensure that the positive control contains a cell suspension of the organism. Otherwise, the laboratory must have an alternative *control procedure* for meeting this requirement (e.g., laboratory suspension stock ATCC organism, commercially prepared organism controls).

For microbial identification systems utilizing two or more substrates, the laboratory must check each media using control organisms to verify positive and negative reactivity of each substrate. Use D5471 for deficiencies in this area.

If a laboratory utilizes primary isolation media (e.g., MacConkey, CLED, EMB*, DTM)*, for presumptive identification of organisms, then the media should meet the quality control requirements at D5471 and D5477.

For bacitracin, catalase, coagulase plasma, desoxycholate, oxidase, optochin, PYR disks, spot indole, staphylococcal latex reagents, streptococcal latex grouping reagents, and X and V factor strips and disks, use D5471.

For bacteriology, XV discs or strips need only be checked with an organism that produces a positive reaction. Use D5471.

For guidelines for molecular amplification testing, use D5455.

D5501
(Rev.)

§493.1261 Standard: Bacteriology.

(a)(1) Each day of use for beta-lactamase methods other than Cefinase™.

Interpretive Guidelines §493.1261(a)(1)

Beta-lactamase testing performed by acidometric, iodometric or chromogenic methodologies other than Cefinase™ must have positive and negative reactivity checked each day of use.

For Cefinase™, use D5471.

D5503
(Rev.)

§493.1261 Standard: Bacteriology.

(a)(2) Each week of use for Gram stains.

D5505

(Rev.)

§493.1261 Standard: Bacteriology.

(a)(3) When each batch (prepared in-house), lot number (commercially prepared), and shipment of antisera is prepared or opened, and once every 6 months thereafter.

Interpretive Guidelines §493.1261(a)(3)

In addition to Salmonella and Shigella antisera, antisera used for serotyping of homologous isolates, (i.e., streptococcal serotyping systems) must be checked for positive and negative reactivity. Polyvalent antisera should be tested with at least one organism from each polyvalent group.

Requirements for antisera QC apply to testing that has a direct impact on patient care.

D5507

(Rev.)

§493.1261 Standard: Bacteriology.

(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms.

(b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results.

Interpretive Guidelines §493.1261(b)(1-2)

"Approved control organism(s)" means either an appropriate control strain or an equivalent strain as defined below.

The laboratory must ensure proper standardization of the inoculum (e.g., use a 0.5 McFarland standard or its optical equivalent, or follow manufacturer's instructions for a commercially available system).

Antimicrobial Disk Diffusion Susceptibility
(Bauer, Kirby, Sherris and Turk Method)

Each new batch of medium and each new lot/shipment of antimicrobial disks must be checked as follows:

ANTIMICROBIAL DISK SUSCEPTIBILITY TEST

Appropriate Control Strain	Each New Batch of Media and Disks	Each Day If Isolates Are:
S. aureus ATCC 25923 or equivalent**	X	Staphylococcus spp.
E. coli ATCC 25922 or equivalent**	X	Enterobacteriaceae
P. aeruginosa ATCC 27853 and E. coli ATCC 25922 or equivalent**	X	Pseudomonas aeruginosa Acinetobacter spp.

The above table provides guidance to surveyors of the checks required for each new batch of medium and each new lot/shipment of antimicrobial disks. These must be checked as follows:

1. S. aureus ATCC 25923 or equivalent must be used to test each new batch of media or disks and it must be used each day if the isolate is Staphylococcus ssp.

2. E. coli ATCC 25922 or equivalent must be used to test each new batch of media or disks and it must be used each day if the isolate is Enterobacteriaceae ssp.

3. P. aeruginosa ATCC 27853 and E. coli ATCC 25922 or equivalent must be used to test each new batch of media or disks and it must be used each day if the isolate is Pseudomonas aeruginosa and/or Acinetobacter spp.

Zone sizes must be recorded for each antimicrobial control and limits must be established.

**An equivalent strain is one which demonstrates reactivity similar to an ATCC strain and for which limits have been established. Organisms which manufacturers recommend or require for use in their systems are acceptable strains of control organisms.

Direct susceptibility testing is a modification of the standardized disk diffusion susceptibility testing method. Therefore, the laboratory must establish the interpretive zone diameters for patient specimens, as well as establish the zone diameters for quality control organisms.

MINIMUM INHIBITORY CONCENTRATION (MIC)

Each new batch of macrodilution tubes, microdilution trays, or agar dilution plates must be checked as follows:

MINIMUM INHIBITORY CONCENTRATION (MIC)

Appropriate Control Strain	Each New Batch of Media	Each Day If Isolates are:
S. aureus ATCC 29213 or equivalent**	X	Staphylococcus spp.
E. coli ATCC 25922 or equivalent**	X	Enterobacteriaceae
P. aeruginosa ATCC 27853 and E. coli ATCC 25922 or equivalent **	X	*n*on-Enterobacteriaceae to include Acinetobacter spp., Stenotrophomonas maltophilia, Pseudomonas spp. and other nonfastidious, glucose nonfermenting, gram-negative bacilli
E. faecalis ATCC 29212 or equivalent**	X	Enterococcus spp.

The above table provides guidance to surveyors of the checks required for each new batch of macrodilution tubes, microdilution trays, or agar dilution plates. These must be checked as follows:

1. S. aureus ATCC 29213 or equivalent must be used to test each new batch of media and it must be used each day if the isolate is Staphylococcus ssp.

2. E. coli ATCC 25922 or equivalent must be used to test each new batch of media and it must be used each day if the isolate is Enterobacteriaceace ssp.

3. P. aeruginosa ATCC 27853 and E. coli ATCC 25922 or equivalent must be used to test each new batch of media and it must be used each day if the isolate is *n*on-Enterobacteriaceace to include Acinetobacter ssp., Stenotrophomonas maltophila, Pseudomonas spp. and/or other nonfastidious, glucose nonfermenting, gram-negative bacilli.

4. E. faecalis ATCC 29212 or equivalent must be used to test each new batch of media and it must be used each day if the isolate is Enterococcus ssp.

**An equivalent strain is one which demonstrates reactivity similar to an ATCC strain and for which limits have been established. Organisms which manufacturers recommend or require for use in their systems are acceptable strains of control organisms.

Each day the test is performed, the appropriate control strain(s) must be included to check the test system.

§493.1261 Standard: Bacteriology.

(c) The laboratory must document all control procedures performed, as specified in this section.

Interpretive Guidelines §493.1261(c)

QC records should include lot numbers, date prepared/opened, expiration dates, the actual measurements, reactions, and/or observations and demonstrate that controls were tested *and acceptable* when shipments of reagents, disks, stains, or antisera for identification systems were opened or when the laboratory prepared these materials.

D5511
(Rev.)

§493.1262 Standard: Mycobacteriology.

(a) Each day of use, the laboratory must check all reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction.

Interpretive Guidelines §493.1262(a)

When condition-level deficiencies in Mycobacteriology are identified in any or all phases of testing, use D5004.

For acid-fast stains (i.e., Ziehl-Neelsen, Kinyoun), use positive and negative stain controls each day of testing patient samples. Use D5473 for deficiencies in these practices. For fluorochrome acid-fast stains, use positive and negative stain controls each time of use. Use D5475 for deficiencies in these practices.

Controls for acid-fast and fluorochrome stains for clinical specimens may include previously processed specimens that contain confirmed acid-fast organisms such as Mycobacterium fortuitum or other non-tuberculous mycobacteria for the positive control, and a negative sputum seeded with Escherichia coli for a negative control. Control smears should be heat-fixed and stored in a protective box.

For controls when staining mycobacteriology cultures, use a previously confirmed acid-fast organism such as Mycobacterium fortuitum for the positive control, and a non-mycobacterial species such as Escherichia coli for the negative control.

For the BACTEC NAP test, positive and negative control organisms must be tested each week of use. Controls should include M. tuberculosis ATCC 27294 and M. kansasii

ATCC 35775. M. tuberculosis should be inhibited by NAP, while M. kansasii should have increasing growth index values in the presence of NAP.

For molecular amplification testing guidelines, use D5455.

Probes §493.1262(a)

How often are mycobacteriology cultures checked for growth prior to the issuance of final patient reports? How long are negative cultures held before a final patient report is issued (e.g., minimum of six weeks)? Use D5411 and D5413 as appropriate.

D5513
(Rev.)

§493.1262 Standard: Mycobacteriology.

(b) For antimycobacterial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use, using an appropriate control organism(s).

Interpretive Guidelines §493.1262(b)

A susceptible control strain of Mycobacterium tuberculosis, such as H37Rv or other appropriate control strain, must be used to check the susceptibility procedure.

For automated mycobacterial susceptibility testing, organisms which manufacturers recommend or require for use in their systems are acceptable strains of control organisms.

Probes §493.1262(b)

Are quality control samples tested at the same time specimens are tested? For example, a growth control without antimycobacterial agent should be inoculated at the time of patient testing.

(b)(1) The laboratory must establish limits for acceptable control results.

Probes §493.1262(b)(1)

Which control strains are used and how did the laboratory establish acceptable control limits for susceptibility tests?

(b)(2) Each week tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(b)(3) The results for the control organism(s) must be within established limits before reporting patient results.

Interpretive Guidelines 493.1262(b)(3)

The laboratory must ensure that it performs and documents all corrective action(s) taken whenever the test results do not meet the laboratory control limits for susceptibility. Use D5783.

§493.1262 Standard: Mycobacteriology.

(c) The laboratory must document all control procedures performed, as specified in this section.

Interpretive Guidelines §493.1262(c)

QC records should include lot numbers, date prepared/opened, expiration dates, the actual measurements, reactions, and/or observations and demonstrate that controls were tested *and acceptable* when shipments of reagents, disks, stains, or antisera for identification systems were opened or when the laboratory prepared these materials.

D5517
(Rev.)

§493.1263 Standard: Mycology.

(a) The laboratory must check each batch (prepared in-house), lot number (commercially prepared), and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control organism(s).

Interpretive Guidelines §493.1263(a)

When condition-level deficiencies in Mycology are identified in any or all phases of testing, use D5006.

For non-culture identification systems (e.g., direct antigen) use D5449 and/or D5453 as appropriate.

For mycology identification systems utilizing two or more substrates, the laboratory must check each media using control organisms to verify positive and negative reactivity of substrate. Use D5471.

A filamentous fungus such as Aspergillus species should be used to check staining of lactophenol cotton blue.

D5519
(Rev.)

§493.1263 Standard: Mycology.

(b) For antifungal susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antifungal agent(s) before, or concurrent with, initial use, using an appropriate control organism(s).

(b)(1) The laboratory must establish limits for acceptable control results.

Probes §493.1263(b)(1)

Which control strains are used and how did the laboratory establish acceptable control limits for susceptibility tests?

(b)(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

Probes §493.1263(b)(2)

Are quality control samples tested at the same time specimens are tested?

(b)(3) The results for the control organism(s) must be within established limits before reporting patient results.

§493.1263(c) The laboratory must document all control procedures performed, as specified in this section.

Interpretive Guidelines §493.1263(c)

QC records should include lot numbers, date prepared/opened, expiration dates, the actual measurements, reactions, and/or observations and demonstrate that controls were tested *and acceptable* when shipments of reagents, discs, stains, or antisera for identification systems were opened or when the laboratory prepared these materials.

D5523
(Rev.)

§493.1264 Standard: Parasitology.

(a) The laboratory must have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens.

Interpretive Guidelines §493.1264(a)

When condition-level deficiencies in Parasitology are identified in any or all phases of

testing, use D5008.

The laboratory must have adequate reference material, but does not have to maintain several different reference systems. Textbooks with photographs, previously stained slide preparations, preserved specimens, or slides from proficiency testing programs are some acceptable systems.

If the laboratory uses zinc sulfate for concentration of fecal specimens for ova and parasite examinations, the acceptable specific gravity of the zinc sulfate solution is 1.18 for fresh fecal samples and 1.20 for formalinized fecal samples. Use D5411 as applicable.

For non-culture identification systems (e.g., direct antigen) use D5449 and/or D5453 as appropriate.

D5525
(Rev.)

§493.1264 Standard: Parasitology.

(b) The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.

Interpretive Guidelines §493.1264(b)

Check for the following:

- Presence of an ocular micrometer for the microscope(s) used;
- Availability of a stage micrometer;
- Instructions for calibration. Use D5403;
- Records of the measurements and calculations used to show that each objective (high, oil, low) has been calibrated; and
- Criteria for the use of the micrometer for determining the size of ova and parasites. Use D5403.

Probes §493.1264(b)

How has the laboratory determined the accuracy of the ocular calibration and that the staff has the knowledge for proper use?

D5527
(Rev.)

§493.1264 Standard: Parasitology.

(c) Each month of use, the laboratory must check permanent stains using a fecal sample control material that will demonstrate staining characteristics.

Interpretive Guidelines §493.1264(c)

The fecal sample control may contain either parasites or added leukocytes sufficient to demonstrate staining characteristics. A commercially prepared quality control slide for intestinal parasites is also an acceptable control for checking permanent stains.

While a wet mount preparation may not be sufficiently sensitive to detect small numbers of ova or parasites in fecal specimens, or to render a final species identification, the regulations do not require use of concentrated and permanent stain techniques to identify fecal parasites. It is the laboratory's responsibility to ensure that it can accurately and reliably identify the organisms it claims to be able to identify. Use D3007 and/or D5411 as applicable. Upon request, the laboratory must specify the method employed by the laboratory for screening fecal specimens and provide information to clients on the test report that may affect the interpretation of test results. Use D5807 and/or D5809 as applicable.

The working iodine solution is stable for approximately two weeks. If the laboratory does not prepare fresh working iodine solution at least every two weeks, it must ensure that the iodine solution has not deteriorated by observing positive clinical specimens or formalin-fixed specimens. Use D5417. Protozoan cysts stained with iodine contain golden yellow cytoplasm, brown glycogen material and have refractile nuclei.

§493.1264 Standard: Parasitology.

(d) The laboratory must document all control procedures performed, as specified in this section.

Interpretive Guidelines §493.1264(d)

QC records should include lot numbers, date prepared/opened, expiration dates, the actual measurements, reactions, and/or observations and demonstrate that controls were tested *and acceptable* when shipments of reagents, disks, stains, or antisera for identification systems were opened or when the laboratory prepared these materials. QC records should also include documentation of the measurements and calculations for calibration of each objective (low, high, oil immersion) of the ocular micrometer, and demonstrate that permanent stain controls were tested with a fecal sample control material each month of use.

§493.1265 Standard: Virology.

(a) When using cell culture to isolate or identify viruses, the laboratory must simultaneously incubate a cell substrate control or uninoculated cells as a negative control material.

Interpretive Guidelines §493.1265(a)

When condition-level deficiencies in Virology are identified in any or all phases of testing, use D5010.

Any laboratory testing patient specimens for the Human Papillomavirus (HPV) must enroll and successfully participate in a CMS-approved proficiency testing program for HPV beginning in 2008. Laboratories should refer to Subpart H for further information. The laboratory's CLIA certificate must include the subspecialty of Virology. The laboratory must also be in compliance with all of the CLIA regulations governing the preanalytic, analytic, and post analytic phases of testing including proficiency testing and personnel requirement.

Cell Culture

For commercially purchased cell culture media, the requirement for media quality control checks is satisfied by visually examining the media for sterility and ensuring the ability of the media to sustain cell life. If the media is prepared or produced in the laboratory, use D5477:

- Each component of cell culture media should be checked for sterility using bacterial culture techniques. In addition, fetal bovine serum must be checked for toxicity using cell culture systems;

- The combined product (e.g., Hanks, Eagles and Earles) should be checked for sterility using bacterial culture techniques and the ability to propagate growth with cell cultures; and

- Cell culture systems should be checked for mycoplasma contamination at regular intervals established by the laboratory.

Non-Culture Methods

1. For other non-culture identification (e.g., antigen identification) systems that are used for viral identification, the laboratory is not required to maintain live viral cultures for quality control purposes. However, positive and negative controls are required to evaluate the detection phase, if such controls are available commercially or in the laboratory. Use D5449 and/or D5453 as appropriate.

2. If organism controls are not available, a previously extracted viral antigen as the positive control plus a previously confirmed negative control of the same matrix as the patient sample may be used. Use D5485. A positive organism control must be subjected to the extraction process if such a control is available in the laboratory. Use D5453.

3. For fluorescent stains, the control requirements are met by using virus-infected cells for a positive control among uninfected cells for a negative control. Use D5475.

The intent of the regulations is for the laboratory to have methodologies available to isolate and identify the viruses that are etiologically related to the clinical disease for which services are offered. For example, if a laboratory offers services only for Herpes testing, it must have available host systems for the isolation and/or test methods for the identification of the Herpes virus. If the laboratory is not using the appropriate host system, use D3007.

"Host system" is defined as the animal, egg or cell culture model, which supports the propagation of viruses.

Clinical information important for the determination and selection of the proper host system should include (Use D5305):

- Clinical symptoms of the patient;
- Age of the patient;
- Source of the specimen;
- Date of onset of clinical symptoms;
- Recent travel information of patient;
- Test request; and
- Date of specimen collection.

Cell culture is the host system used most frequently. The specific cell line (type) is usually selected based upon its known sensitivity and susceptibility to different viruses. For example, the cell lines to be used as host systems for the following clinical specimens could be:

- Upper respiratory infection specimens: Primary Monkey Kidney (PMK), Human Fetal Diploid Lung (HFDL), or equivalent;
- Enteric specimens: PMK, Human Fetal Diploid Kidney (HFDK), or equivalent;

- Urine specimens: HFDL, PMK, or equivalent;

- Genital specimens: Human Foreskin (HFD), Vero (Continuous Monkey Kidney), or equivalent;

- Vesicular lesions: HFDL, PMK, BSC-1 (Monkey Cell Line), or equivalent; and

- Tissues or Spinal fluids: PMK, Vero, BSC-1, HFDK or HFDL, or equivalent.

Prior to the inoculation of the cell cultures, the laboratory should check the cell culture systems for the following:

- The age of the cell culture monolayer (no more than 7-10 days post "seeding") (Use D5417);

- Maintenance media that is free from inhibitory substances (Use D5477); and

- Sterility (visual observation for turbidity) (Use D5477).

Uninoculated cell substrate controls are used to determine whether the specificity of a test system has been ensured. Generally, an uninoculated cell control for each cell line that is inoculated is used per inoculation day to determine whether the consequent cytopathic effect (CPE) in the cells inoculated with patient specimen was caused by specific etiologic agent(s), or caused by the nonspecific deterioration of the cells themselves. Often, as monolayer host cells age, the cells deteriorate, exhibiting "rounding" and "pulling-apart." This cell change may be confused with CPE if uninoculated cells are not available to compare with the inoculated cells.

Probes §493.1265(a)

How does the laboratory determine the specific cell line to be used as the host system? Use D3007 or D5411 as applicable.

When reviewing the laboratory's identification procedures for the clinical diseases for which services are offered, how does the laboratory rule out the presence of Clostridium difficile toxin in those cell cultures in which the patient specimen exhibits non-specific effects unrelated to viral cytopathic effect (CPE)? Use D3007 or D5411 as applicable.

If presumptive reports are issued based on CPE, how does the laboratory confirm the identification reported? Use D3007 or D5411 as applicable.

For tests such as hemagglutination inhibition and viral neutralization in which antisera must be standardized, how has the laboratory determined the optimum dilution of the antisera to ensure maximum sensitivity and specificity? Use D5437.

Neutralization Tests

How does the laboratory standardize its dilution of the viral isolate and control virus to the appropriate Tissue Culture Dose 50 or equivalent, each time the test is performed? Use D5437.

How many varieties of uninoculated cell cultures does the laboratory use to check each new lot of anti-serum or serum pool for toxicity? Use D5477 or D5479 as applicable.

Hemagglutination Inhibition Tests

After having determined the hemagglutination titer, how does the laboratory determine the working dilution of the viral isolate (i.e., usually 4 Hemagglutination units)? How does the laboratory ensure that this working dilution is correct for isolates and controls? Use D5421 or D5423 as applicable.

How often and for which hemagglutination inhibition tests does the laboratory include a serum/cell/buffer control and a cell/buffer control? Use D5425.

Does the laboratory include one known virus or viral antigen specific to each antisera used in the test procedure? Use D5449.

Direct Immunofluorescence Tests

How does the laboratory determine which immune serum conjugate(s) to use when identifying viruses using antisera that react with viruses that are etiologically similar (e.g., an antigen test for specimens from patients with flu-like symptoms that identifies Respiratory Syncytial Virus, Influenza, and Parainfluenza)? How does the laboratory ensure the specificity of this conjugate for the specific virus being identified? Use D5421 or D5423 as applicable.

How does the laboratory rule out non-specific reactivity for each conjugate used? Use D5421 or D5423 as applicable.

Indirect Immunofluorescence Tests

Has the laboratory determined the optimum dilution of its anti-species, e.g., antibody to host system or cell culture (such as anti-PMK, conjugated immune serum)? Use D5421 or D5423 as applicable.

Has the laboratory determined the optimum dilution of the virus specific immune serum? Use D5421 or D5423 as applicable.

Determine whether the laboratory is checking positive and negative reactivity using (Use D5475):

- Uninoculated cells plus immune serum plus anti-species conjugate (negative

control); and

- Viral antigen or known virus infected cells plus immune serum plus anti-species conjugate (positive control).

Determine whether the laboratory checks each new batch or shipment of conjugate using known virus infected cells plus PBS plus anti-species conjugate. Use D5471.

§493.1265 Standard: Virology.

(b) The laboratory must document all control procedures performed, as specified in this section.

Interpretive Guidelines §493.1265(b)

QC records must identify the host cell cultures employed, the number of tubes or plates inoculated or uninoculated, maintenance medium used, the number of times the patient specimen was sub-cultured, the specific sub-culture or passage in which the virus was identified, the CPE observed, and post inoculation date of observations. If the deficiency is due to absence of dates of testing and observations, use D5787.

§493.1267 Standard: Routine chemistry.

(Rev.)

For blood gas analyses, the laboratory must perform the following:

Interpretive Guidelines §493.1267(a)-(d)

When condition-level deficiencies in Routine Chemistry are identified in one or more phases of testing, use D5016.

Control materials generally are not available to verify the reportable range at the very high range of patient results. When necessary, the laboratory may verify the results by splitting patient samples and assaying them on two different blood gas analyzers.

Quality control records should include lot numbers, date prepared/opened, expiration dates, the actual measurements, reaction and/or observations and demonstrate that controls were tested *and acceptable* as required.

Probes §493.1267(a)-(d)

For blood gas testing, do the records include barometric pressure and room temperature, as necessary?

Do the records of a laboratory that moves from testing site to testing site demonstrate the performance of control samples following transport of equipment when such activity

affects test performance specifications and/or instrument calibration?

D5535
(Rev.)

§493.1267 Standard: Routine chemistry.

(a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer.

Interpretive Guidelines §493.1267(a)

For blood gas analysis, the laboratory must perform calibration and calibration verification in accordance with the manufacturer's instructions. If the laboratory meets the manufacturer's instructions and the requirements at this section, the laboratory does not have to adhere to calibration and calibration verification requirements at §493.1255.

D5537
(Rev.)

§493.1267 Standard: Routine chemistry.

(b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing.

Interpretive Guideline§493.1267(b)

"Each 8 Hours of testing" is defined as each shift of 8 consecutive hours the laboratory is in operation, including "on-call" shifts. When documenting standards/controls results, the laboratory must identify the shifts in which controls are tested with patients.

For a laboratory that is only open 8 hours/day and the instrument autocalibrat*es*, the laboratory must test both a low and high value in the eight hours to meet the requirement.

In addition to testing one control each eight hours, the combination of controls and calibrators used each day of testing must include a high and low value. Controls should be rotated to check normal, alkalosis and acidosis levels.

D5539
(Rev.)

§493.1267 Standard: Routine chemistry.

(c) Test one sample of control material each time specimens are tested unless automated instrumentation internally verifies calibration at least every 30 minutes.

Interpretive Guidelines §493.1267(c)

If blood gas analysis is performed with an instrument that does not internally verify the calibration at least every thirty minutes, then a calibrator or control must be tested each time patient specimens are tested. It is not the intent of this requirement to require the laboratory to maintain records of each auto-calibration.

§493.1267 Standard: Routine chemistry.

(d) Document all control procedures performed, as specified in this section.

D5543
(Rev.)

§493.1269 Standard: Hematology.

(a) For manual cell counts performed using a hemocytometer--

(a)(1) One control material must be tested each 8 hours of operation; and

(a)(2) Patient specimens and control materials must be tested in duplicate.

Interpretive Guidelines §493.1269(a)

When condition-level deficiencies in Hematology are identified in any or all phases of testing, use D5024.

For all manual cell counts performed using a hemocytometer (e.g., synovial fluids, CSF, semen) the laboratory may meet the requirement for duplicate testing by counting two chambers from one dilution.

"Hours of operation" is defined as each shift of 8 consecutive hours the laboratory is in operation, including "on-call" shifts. When documenting standards/controls results, the laboratory must identify the shifts in which controls are tested with patients.

If the manufacturer of an instrument that performs automated differentials does not give criteria for when to perform a manual differential, the laboratory must establish criteria indicating when to perform a manual differential including instructions for reporting the results. Use D5423.

Control requirements for automated instruments that perform hemoglobin, hematocrit, red and white cell counts and differentials are found at §493.1256(d)(3)(i). Use D5447. The calibration verification exception for automated cell counters is found at D5439.

D5545

(Rev.)

§493.1269 Standard: Hematology.

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed.

Interpretive Guidelines §493.1269(b)-(c)

The laboratory performing *automated* coagulation tests subject to §493.1269 must either establish criteria or verify manufacturer's criteria for an acceptable range of performance as required in §493.1253(b). Use D5421 or D5423 as appropriate.

An automated (nonmanual) coagulation test system samples the plasma, combines the plasma with the reagents, detects the end point or clot formation and displays the test results without operator intervention.

The International Sensitivity Index (ISI) is the correction factor for variable sensitivities of thromboplastins. The International Normalized Ratio (INR) is a calculation primarily used for monitoring a patient's oral anticoagulant therapy. The INR corrects for the variability in Prothrombin Time (PT) results attributable to the ISI. Therefore, this allows all PT's to be corrected to the international standard.

INR Calculation

The INR is equal to the ratio of the patient's PT (in seconds) to the laboratory's established normal mean PT (in seconds), then raised to the power of the ISI.

$$INR = (\text{Patient PT} \div \text{Mean Normal Range PT})^{ISI}$$

NOTE: A scientific calculator is needed to calculate the INR.

Example:
Patient PT (in seconds) =18.5
Normal mean PT (in seconds) =12.9
ISI value (obtain from the package insert of the laboratory's current lot of thromboplastin reagent) =2.002

1. $18.5 \div 12.9 = 1.434$ (Patient Ratio)
2. $1.434^{2.002} = 2.056$ (INR Result)
3. Report the INR as: INR = 2.1

For International Normalized Ratio (INR) calculations, ensure that the laboratory:

- Establishes a normal patient Prothrombin time mean with each new

thromboplastin lot number;

- Verifies that the normal patient Prothrombin time mean study has been performed according to the manufacturer's instructions;

- Incorporates the current and pertinent normal patient Prothrombin time mean and ISI value for each lot of thromboplastin (manual, instrument, or LIS);

- Documents the manual check of the INR calculation for each new lot number;

- Documents each thromboplastin lot number, with the normal patient Prothrombin time mean and the ISI value provided by the manufacturer (manual or instrument);

- Periodically verifies, for each thromboplastin lot number in use, the correct normal patient Prothrombin time mean and the International Sensitivity Index (ISI) value are being used for calculating the INR value; and

- Periodically verifies the accuracy of the INR calculation (manual, instrument or LIS).

To verify prothrombin time testing with INR calculations:

- Check the accuracy of normal patient Prothrombin time mean calculation (manual, instrument or LIS).

- Verify that the ISI used in the calculation correlates with the ISI specified in the reagent package insert. Select an abnormal low or abnormal high prothrombin time result and verify the calculation.

Probes §493.1269(b)-(c)

Is the laboratory using the ISI value from the current manufacturer's package insert in calculating the INR values?

How does the laboratory ensure that the ISI values are changed with each change of thromboplastin lot number?

Has the laboratory established its own normal patient mean with each lot of thromboplastin?

For coagulation testing, do the records include timer checks and temperature checks as necessary?

D5547
(Rev.)

§493.1269 Standard: Hematology.

(c) For manual coagulation tests--

(c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and

(c)(2) Patient specimens and control materials must be tested in duplicate.

§493.1269 Standard: Hematology.

(d) The laboratory must document all control procedures performed, as specified in this section.

Interpretive Guidelines §493.1269(d)

Quality control records should include lot numbers, date prepared/opened, expiration dates, the actual measurement(s) taken, reactions and/or observations and demonstrate that controls were tested *and acceptable* when shipments of reagents or stains were opened or when the laboratory prepared these materials. However, do not dictate the acceptable format for documentation.

D5551
(Rev.)

§493.1271 Standard: Immunohematology.

(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e).

Interpretive Guidelines §493.1271(a)(1)

21 CFR §606.151 requires the following standard operating procedures for compatibility testing:

a. A method of collecting and identifying the blood samples of recipients to ensure positive identification.

b. The use of fresh recipient serum or plasma samples less than 3 days old for all pretransfusion testing if the recipient has been pregnant or transfused within the

previous 3 months.

NOTE: If information on the patient's history of transfusion or pregnancy is not available, then a fresh specimen is to be used.

c. Procedures to demonstrate incompatibility between the donor's cell type and the recipient's serum or plasma type.

NOTE: These procedures may consist of a serologic crossmatch, or a computer crossmatch. The computer crossmatch is a process of ensuring that a unit of blood is compatible with a specified recipient by means of electronically matching patient pretransfusion test results (ABO/Rh, etc.) with information about the blood donor that is stored in the LIS. The computer crossmatch is not strictly a "test" under CLIA; however, laboratories using this procedure must ensure that the LIS functions as intended. Refer to FDA Guidance for Industry: "Computer Crossmatch" (Computerized Analysis of the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type). *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-crossmatch-computerized-analysis-compatibility-between-donors-cell-type-and-recipients*.

NOTE: Laboratories using an immediate spin or computer crossmatch should have policies on the use of an antiglobulin crossmatch when warranted.

d. A provision that, if the unit of donor's blood has not been screened by a method that will demonstrate agglutinating, coating and hemolytic antibodies, the recipient's cells shall be tested with the donor's serum (minor crossmatch) by a method that will so demonstrate**.**

e. Procedures to expedite transfusion in life-threatening emergencies. Records of all such incidents shall be maintained, including complete documentation justifying the emergency action, which shall be signed by a physician.

The laboratory must maintain complete documentation, signed by a physician, which justifies the emergency action.

When condition-level deficiencies in Immunohematology are identified in any or all phases of testing, use D5026.

Transfusion-related immunohematology testing performed on blood donors and recipients to determine compatibility is considered high complexity testing. When performed on blood donors or recipients, the following analytes are always high complexity: ABO group/ D (Rho) typing/antigen typing, direct antiglobulin tests, tests for unexpected antibody detection and identification, and crossmatch procedures. If personnel do not meet the qualifications or fulfill the responsibilities for high complexity testing, cite under subpart M—Personnel for Nonwaived Testing.

There generally are no daily quality control requirements for reagent red cell panels used in antibody identification. However, we encourage laboratories to follow the manufacturer's recommendations for QC.

For laboratories using multiple racks of reagent typing sera and cells, laboratories should perform quality control on a representative sample of each lot of reagent in use on each day of testing. In addition, quality control needs to be performed on each new lot of reagent when first used.

When in-date reagents are unavailable, it may become necessary to frame written policies for their temporary use beyond their expiration dates until non-expired supplies become available. Under no circumstances, however, should a laboratory adopt policies that would allow for the regular use of expired reagents.

Determine if the laboratory has policies regarding:

- Compatibility testing for patients with a history of a prior antibody;
- Compatibility testing for patients with **no** history of a prior antibody; and
- Course of action to be taken for positive antibody screening and/or incompatible crossmatch.

Probes §493.1271(a)(1)

If the patient has been previously tested, how are results of current testing compared with interpretations of previous testing? When the results of current testing are discrepant with results of previous testing, how has the laboratory resolved the difference? Use D5777.

§493.1271 Standard: Immunohematology.

(a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells.

Interpretive Guidelines §493.1271(a)(2)

Determine if the laboratory has a policy to detect and resolve ABO discrepancies. If the laboratory does not have such procedures, use D5401. If the laboratory does not use patient records to confirm ABO group (i.e., current testing compared with historical records when available), use D5777.

(a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent.

Interpretive Guidelines §493.1271(a)(3)

Determine if the laboratory has established a policy specifying when testing for weak D must be performed.

Probes §493.1271(a)(3)

Is the laboratory following this policy?

D5553
(Rev.)

§493.1271 Standard: Immunohematology.

(b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b).

Interpretive Guidelines §493.1271(b)

Refer to the current version of 21 CFR Parts 600 through 799 for the specified sections:

- §606.100(b)(12) - Criteria for determining whether returned blood is suitable for reissue;
- §606.160(b)(3)(ii) – Visual inspection of whole blood and red blood cells during storage and immediately before distribution;
- §606.160(b)(3)(v) – Emergency release of blood, including signature of requesting physician obtained before or after release;
- §610.40 Testing for communicable diseases;
- §640.5(b) Determination of Blood group;
- §640.5(c) Determination of Rh factor;
- §640.5(e) Inspection of whole blood during storage and immediately prior to issue; and
- §640.11(b) Inspection of RBC during storage and at the time of issue.

Probes §493.1271

If equipment and reagents are used in mobile or temporary testing sites, how are they protected from extreme temperature fluctuations when not in use (e.g., evenings, weekends, and holidays)?

D5555
(Rev.)

§493.1271 Standard: Immunohematology.

(c) Blood and blood products storage. Blood and blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected.

Interpretive Guidelines §493.1271(c)

Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. *E*xpired blood should *not* be in the routine inventory. Unacceptable units should be segregated from routine inventory.

(c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period.

(c)(2) Inspections of the alarm system must be documented.

Interpretive Guidelines §493.1271(c)

Acceptable temperature ranges must be established and actual readings of temperature-controlled storage areas must be recorded during the time that blood or blood products for transfusion are stored. Whole Blood, Red Blood Cells, and Liquid Plasma should be stored between 1 and 6º C; room temperature Platelets and Platelet Rich Plasma between 20 and 24º C or 1 and 6º C as indicated on the product label. Fresh Frozen Plasma, Plasma, and Cryoprecipitated AHF should be stored at -18º C or colder. Temperatures continuously monitored by a recording thermograph or central monitoring system are acceptable. The charts or central monitoring system must be retained to document that temperatures are maintained within acceptable limits as stated on the blood component label.

Verify that the laboratory regularly inspects the alarm system(s) according to its established policy. When the facility performs alarm checks, the temperature at which the alarm sounds should be compared to the temperature on the recording chart. Verify that the alarm activates at the appropriate temperature(s).

Reissue requirements are as follows: The container should have a tamper-proof seal which remains unbroken; records should indicate that the blood was maintained at 1 - 10º C while outside the control of the establishment; and the unit must be inspected prior to reissue. The laboratory must have a process for ensuring that blood components are

maintained within acceptable limits while out of control of the laboratory.

Probes §493.1271(c)

Does the laboratory ensure that the freezer(s) used to store blood products is maintained at the recommended temperature(s) on a continuous basis?

Does the laboratory document and explain unacceptable storage temperatures? Use D5793.

What are the laboratory's criteria for determining blood or blood product suitability for reissue? Are they following their policy?

How are untested autologous units, potentially infectious units, and reagents stored and segregated to prevent contamination?

If the laboratory does not have an emergency power source for the blood storage equipment and temperature alarm system, how does the laboratory ensure that blood is maintained at the appropriate temperature when a power failure occurs?

If the laboratory is not staffed 24 hours a day, seven days a week, how does it ensure prompt response to an activated alarm (evenings, weekends, and holidays)?

D5557
(Rev.)

§493.1271 Standard: Immunohematology.

(d) Retention of Samples of Transfused Blood. According to the laboratory's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of transfusion reactions. The laboratory must promptly dispose of blood not retained for further testing that has passed its expiration date.

Interpretive Guidelines §493.1271(d)

There is no specific timeframe for retaining donor and recipient blood samples. However, it is common practice to keep these samples for a minimum of seven days after each transfusion in case there is a need for retesting.

D5559
(Rev.)

§493.1271 Standard: Immunohematology.

(e) Investigation of transfusion reactions.

(e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures.

(e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused.

Interpretive Guidelines §493.1271(e)(2):

Transfusion Related Fatalities must be reported to Federal and State authorities as specified in 21 CFR §606.170(b) and 42 CFR §493.1103(d).

Examine records of transfusion reaction investigations for completeness, accuracy, and promptness. Verify that investigations of transfusion reactions are conducted in accordance with the facility's established protocols. Records must include each step of the investigation, including conclusions and any follow-up.

Probes §493.1271(e)(2):

Did the laboratory report Transfusion Related Fatalities to the applicable authorities? Cite at D3025.

If problems or technical errors are identified during a transfusion reaction investigation, are corrective actions taken and, as applicable, procedures instituted to prevent a recurrence?

Did the laboratory assess the adequacy of the procedures implemented? Use D5793.

§493.1271 Standard: Immunohematology.

(f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

Interpretive Guidelines §493.1271(f)

All non-transfusion related immunohematology QC records must be retained for at least 2 years. Use D3035.

Transfusion-related immunohematology QC records, including but not limited to, donor processing, compatibility testing, and transfusion reaction investigations, must be retained for the timeframe stated at 21 CFR §606.160(d).

D5601
(Rev.)

§493.1273 Standard: Histopathology.

(a) As specified in §493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions(s) of the control slide with each special stain must be documented.

Interpretive Guidelines §493.1273(a)

When condition-level deficiencies in Histopathology are identified in any or all phases of testing, use D5028.

The technical component, preparation of slides (TC) can be prepared in one laboratory and the finished product sent to another laboratory for professional interpretation (PC). Both laboratories should show documentation of adequate slide preparation which is processing, and processing includes the QC of the stain at both locations.

The laboratory must demonstrate that each reagent performs within the specifications established by the laboratory for the test procedure. Documentation of concurrent testing of reagents or acceptable quality control results will satisfy this requirement.

When the laboratory uses a manufacturer's kit, the reagents of the kit must not be combined, mixed, or replaced with components of another kit from a different lot number, unless otherwise permitted and specified by the manufacturer in the package insert. Use D5419.

Laboratories which use automated staining methodologies must follow the manufacturer's instructions. Use D5411.

Flow Cytometry

Staining controls for cell surface immunophenotyping by flow cytometry should consist of either normal, cultured, or abnormal cells known to be positive for selected standard antigens and must verify the proper performance of reagents. Frozen or other preserved cells may be used. A negative reagent control must be run for each test cell preparation, and is to consist of monoclonal antibody(ies) of the same species and isotype or equivalent. Negative reagent controls will consist of:

(a) For indirect stains, an irrelevant primary antibody and the same secondary antibody(ies) conjugated with the same fluorochrome(s) used in all relevant test combinations; and

(b) For direct stains, an irrelevant antibody conjugated to the same fluorochrome and at the same fluorochromes: protein ratio used in all relevant test combinations.

Probes §493.1273(a)

For flow cell cytometric surface immunophenotyping, is a negative reagent control used to define a threshold for positive staining cells? If not, how does the laboratory define the threshold for positive staining cells?

Is a quality control slide with the appropriate differential or special stain tested at the same time patient specimens are tested?

D5603
(Rev.)

§493.1273 Standard: Histopathology.

(b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in §493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under §§493.1449(b), (*f*), or (*g*).

D5605
(Rev.)

§493.1273 Standard: Histopathology.

(c) An individual who has successfully completed a training program in neuromuscular pathology approved by HHS may examine and provide reports for neuromuscular pathology.

Interpretive Guidelines §493.1273(c)

HHS approves the American Academy of Neurology Committee for Neuromuscular Pathology Training Program *and the United Council for Neurologic Subspecialties (UCNS).*

D5607
(Rev.)

§493.1273 Standard: Histopathology.

(d) Tissue pathology reports must be signed by an individual qualified as specified

in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis.

Interpretive Guidelines §493.1273(d)

The laboratory must ensure that only those individuals qualified to evaluate histopathology specimens can release his or her electronic signature for reporting purposes.

The tests in histopathology include both gross examination (macroscopic) and microscopic examination of the slide(s) with evaluation and diagnostic interpretation, and diagnostic findings reported.

In the event of a computer-generated signature, the laboratory must ensure that the system is protected from use by unauthorized individuals.

If the technical supervisor who performed the examination and diagnosis is not available to sign the report, an individual, also qualified as a technical supervisor in Histopathology, must reexamine and diagnose in order to sign out the report.

D5609
(Rev.)

§493.1273 Standard: Histopathology.

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results.

Interpretive Guidelines §493.1273(e)

"SNOMED®" - Systemized Nomenclature of Medicine is an example of a recognized system of disease nomenclature.

§493.1273(f) The laboratory must document all control procedures performed, as specified in this section.

Interpretive Guidelines §493.1273(f)

QC records should include lot numbers, date prepared/opened, expiration dates, the actual measurements, reactions, and/or observations and demonstrate that controls were tested *and acceptable* when shipments of reagents, stains, or kits were opened or when the laboratory prepared these materials.

D5613
(Rev.)

§493.1274 Standard: Cytology.

(a) Cytology slide examination site. All cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

§493.1274 Standard: Cytology.

(b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable:

D5615
(Rev.)

§493.1274 Standard: Cytology.

(b)(1) All gynecologic slide preparations must be stained using a Papanicolaou or modified Papanicolaou staining method.

Interpretive Guidelines §493.1274(b)(1)

The Papanicolaou staining procedure is a polychrome method that enhances differences in cellular morphology. The procedure utilizes a nuclear stain, hematoxylin and two cytoplasmic counterstains, OG-6 and EA. The Papanicolaou method is used for staining cytologic preparations because it provides well-defined nuclear detail, stains cytoplasm of various cell types different colors, and renders transparent cytoplasm. There are a variety of formulas for making hematoxylin, OG-6, and EA stains. The actual staining technique may vary among laboratories depending on the type of stains used and the laboratories' modification of the staining method. Modifications of the staining procedure must include the four main steps of the standard Papanicolaou staining method: fixation, nuclear staining, cytoplasmic staining, and clearing.

Cytology laboratories may receive reagents, solutions, and stains from a manufacturer in large volume stock containers. For ease in handling, portions of these reagents are usually decanted into smaller working containers, which must be labeled in accordance with §493.1252(c). Some manufacturers do not label stain or reagent containers with the expiration date; however, lot numbers and package inserts refer to this information.

If the laboratory uses a manufacturer's kit, the reagents of the kit must not be combined, mixed, or replaced with components of another kit from a different lot number, unless otherwise permitted and specified by the manufacturer in the package insert (use D5419). Laboratories which use automated staining methodologies must follow the manufacturer's instructions (use D5411).

The cytology laboratory must document the expiration date of stock reagents, working stains, and solutions made in the laboratory. Use D5415.

Laboratories may use staining procedures, other than the Papanicolaou method, for staining nongynecologic specimens.

Review the written staining procedure for staining gynecologic specimens. Confirm that the written procedures reflect:

- Stains used (i.e., Harris, Gill or other type of hematoxylin, OG-6, modified OG-6, EA36, EA50, EA65, modified EA) or the identity of a combination counterstain;
- Solutions used (water, alcohol, clearing reagent, acid and bluing agent);
- Concentration of each solution used (i.e., percentage (%) of alcohol, acid, ammonium hydroxide or lithium carbonate solution);
- Length of time or number of dips slides are placed in each stain or solution;
- The staining dishes must be labeled to reflect content (not just lids); and
- Procedure for coverslipping slides.

Current time frames must be specified in the procedure manual for each step in the staining of cytology specimens using the Papanicolaou staining method. Adjustments to time frame changes must be documented.

Step-by-step written procedures must be available and followed to prepare nongynecologic specimens.

Use D5403 if any of the above findings is not met.

The laboratory must ensure that the gynecologic and non-gynecologic stains have been tested to ensure predictable staining characteristics on a daily basis. Use D5473.

NOTE: Any fixatives, reagents, or preservatives intended to be used on one liquid-based manufacturer's instrument must not be used on another manufacturer's instrument.

D5617
(Rev.)

§493.1274 Standard: Cytology.

(b)(2) Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used.

Interpretive Guidelines §493.1274(b)(2)

The laboratory must develop its own policies and procedures for the prevention of cross-contamination between gynecologic and nongynecologic specimens. The majority of gynecologic specimens are fixed prior to transport to the laboratory. Staining times may differ between gynecologic and nongynecologic specimens. Commonly used methods include separate staining dishes for various specimens (i.e., gynecologic specimens, CSF, sputa, other body fluids), or separate staining times (i.e., gynecologic specimens in the morning and nongynecologic specimens in the afternoon), with the staining dishes washed and stains filtered between staining times.

Probes §493.1274(b)(2)

What does the laboratory do to ensure that cross-contamination between gynecologic and nongynecologic specimens does not occur?

D5619
(Rev.)

§493.1274 Standard: Cytology.

(b)(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining.

Interpretive Guidelines §493.1274(b)(3)

A monochromatic stain such as toluidine blue may be used to determine the cellularity of nongynecologic specimens. Once a specimen has been concentrated, usually by centrifugation, a small drop of specimen is placed on a slide. A drop of stain is placed next to the specimen, allowed to mix, and coverslipped. Cellularity is evaluated microscopically. Highly cellular specimens have a high potential for cross-contamination. One option would be for the laboratory to stain these specimens after routine staining has been completed.

Laboratories which use automated staining methodologies must follow the manufacturer's instructions. Use D5411.

Probes §493.1274(b)(3)

How is the cellularity of nongynecologic specimens checked prior to cytopreparation (staining)?

What procedure does the laboratory use to determine which specimens must be stained separately?

§493.1274 Standard: Cytology.

(c) Control Procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following:

D5621
(Rev.)

§493.1274 Standard: Cytology.

(c)(1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under §§493.1469 or 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of this section).

Interpretive Guidelines §493.1274(c)(1)

The 10 percent rescreen of negative cases is not required for a one-person laboratory consisting of a technical supervisor or a laboratory which only employs pathologists qualified as technical supervisors. However, these laboratories must establish and follow a program to detect errors. This program must include, but is not limited to, cytologic/histologic correlations, retrospective review of negative cases, documentation of initial and rescreening results, and statistics [(c)(2)-(5) of this section].

The laboratory must review all slides from each case selected for rescreen.

(c)(1)(i) The review must be performed by an individual who meets one of the following qualifications:

(c)(1)(i)(A) A technical supervisor qualified under §§493.1449(b) or (*e*).

(c)(1)(i)(B) A cytology general supervisor qualified under §493.1469.

(c)(1)(i)(C) A cytotechnologist qualified under §493.1483 who has the experience specified in §493.1469(b)(2).

Interpretive Guidelines §493.1274(c)(1)(i)

The laboratory must document which individual(s) are qualified to conduct the 10 percent rescreen. Slides reviewed as part of the 10 percent rescreen must be included in the workload limit of the cytology general supervisor or the cytotechnologist performing the review. Use D5639.

(c)(1)(ii) Cases must be randomly selected from the total caseload and include

negatives and those from patients or groups of patients that are identified as having a higher than average probability of developing cervical cancer based on available patient information.

Interpretive Guidelines §493.1274(c)(1)(ii)

The laboratory must have a procedure to determine which slides are rescreened. This procedure should ensure that individuals screening the slides do not know which slides will be chosen for rescreen.

The laboratory must establish criteria to ensure that random negative gynecological cases selected for rescreening include, when possible, cases from patients that are identified as having a higher than average probability for developing cervical cancer.

(c)(1)(iii) The review of those cases selected must be completed before reporting patient results.

D5623
(Rev.)

§493.1274 Standard: Cytology.

(c)(2) Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies.

Interpretive Guidelines §493.1274(c)(2)

The laboratory must compare clinical information with cytology final reports. For example, an atrophic smear (usually characteristic of a post menopausal woman) from a 21-year-old female with an LMP (last menstrual period) of 2-weeks-ago constitutes inconsistent findings and must be resolved.

The laboratory must define criteria to determine a discrepancy between a final cytological diagnosis of High Grade Squamous Intraepithelial Lesion (HSIL) or squamous carcinoma, adenocarcinoma or other malignant neoplasias and the correlating histology report.

Cases considered HSIL include: moderate and severe dysplasia, carcinoma in-situ (CIS)/Cervical Intraepithelial Neoplasia (CIN) 2 and CIN 3 or with features suspicious for invasion.

Probes §493.1274(c)(2)

How does the laboratory identify and resolve discrepancies for:

- Clinical information vs. cytology report; and
- Gynecologic cytology report vs. histopathology report?

D5625
(Rev.)

§493.1274 Standard: Cytology.

(c)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report.

Probes §493.1274(c)(3)

How does the laboratory track previous cases on an individual patient?

What criteria does the laboratory use to determine discrepancies when reviewing normal or negative slides from the past five years? How does the laboratory document the review?

How does the laboratory use the retrospective review to assess the analytic system and communicate findings to the appropriate staff? Use D5793

D5627
(Rev.)

§493.1274 Standard: Cytology.

(c)(4) Records of initial examinations and all rescreening results must be documented.

D5629
(Rev.)

§493.1274 Standard: Cytology.

(c)(5) An annual statistical laboratory evaluation of the number of--

(c)(5)(i) Cytology cases examined;

(c)(5)(ii) Specimens processed by specimen type;

(c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation);

(c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison;

(c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and

(c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

Interpretive Guidelines §493.1274(c)(5)

For laboratories performing Non-Gynecologic Cytology Only: §493.1274(c)(5)(i), (c)(5)(ii), and (c)(5)(iii).

For laboratories performing Gynecologic Cytology or laboratories performing both Gynecologic and Non-Gynecologic Cytology: §493.1274(c)(5)(i), (c)(5)(ii), (c)(5)(iii), (c)(5)(iv), (c)(5)(v), and (c)(5)(vi).

D5631
(Rev.)

§493.1274 Standard: Cytology.

(c)(6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken.

Probes §493.1274(c)(6)

How does the laboratory evaluate each individual's case reviews against the overall laboratory statistics?

What corrective actions are taken to resolve discrepancies?

§493.1274 Standard: Cytology.

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following:

D5633

(Rev.)

§493.1274 Standard: Cytology.

(d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

Interpretive Guidelines §493.1274(d)(1)

The maximum workload limit established by the technical supervisor must be based on each individual's capabilities. A generic workload limit for the laboratory as a whole does not meet this requirement.

Probes §493.1274(d)(1)

What criteria does the technical supervisor use to determine the slide limit for each person who examines slides?

D5635

(Rev.)

§493.1274 Standard: Cytology.

(d)(1)(i) The workload limit is based on the individual's performance using evaluations of the following:

Interpretive Guidelines §493.1274(d)(1)(i)

The technical supervisor maintains documentation of the slide performance and provides feedback.

Probes §493.1274(d)(1)(i)

What records are maintained to document the technical supervisor's evaluation of the slide performance of each individual?

(d)(1)(i)(A) Review of 10 percent of the cases interpreted as negative for the conditions defined in paragraph (e)(1) of this section.

(d)(1)(i)(B) Comparison of the individual's interpretation with the technical supervisor's confirmation of patient smears specified in paragraphs (e)(1) and (e)(3) of this section.

Probes §493.1274(d)(1)(i)(B)

How does the technical supervisor ensure that feedback is provided on slide examination

performance to each person evaluating slides?

What mechanism is used to allow individuals an opportunity to discuss instances of misdiagnosis?

D5637
(Rev.)

§493.1274 Standard: Cytology.

(d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

Probes §493.1274(d)(1)(ii)

What criteria does the technical supervisor use to determine when a workload adjustment is needed?

How are records maintained to document that workload records are reassessed at least every six months and adjusted when necessary?

D5639
(Rev.)

§493.1274 Standard: Cytology.

(d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition---

Interpretive Guidelines §493.1274(d)(2)

The maximum total number of slides an individual may screen is 100 per 24 hours regardless of site or laboratory. Although the regulation establishes this maximum number, not every individual will be able to accurately examine 100 slides in 24 hours. The laboratory must establish how many slides can be screened per day for each individual. Refer to §493.1274(d)(1) to ensure that the technical supervisor has established a maximum number of slides that each individual is capable of evaluating. The laboratory must ensure that persons employed at other sites or locations do not exceed the maximum of 100 slides in 24 hours.

This 100-slide limit is also applicable to those technical supervisors who examine previously unevaluated cytology specimens.

Probes §493.1274(d)(2)

How does the laboratory ensure that each individual examining slides (cytotechnologists, cytology general supervisors and technical supervisors in cytology, as applicable) examines no more than 100 slides in a 24-hour period regardless of site or location?

(d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;

Probes §493.1274(d)(2)(i)

What records are used to verify that the maximum number of 100 slides is examined in no less than 8 hours, especially in the situation in which individuals screen slides at different sites or locations?

D5641
(Rev.)

§493.1274 Standard: Cytology.

(d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined.

The formula--

$$\frac{\text{Number of hours examining slides X 100}}{8}$$

is used to determine maximum slide volume to be examined;

D5643
(Rev.)

§493.1274 Standard: Cytology.

(d)(2)(iii) Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and

Interpretive Guidelines §493.1274(d)(2)(iii)

Nongynecologic slide preparations made using automated, semi-automated or other liquid-based slide preparatory techniques include specimens prepared by centrifugation, cytocentrifugation, filtering techniques or monolayering techniques. Any instrument

used to assist in the adherence of cells to the slide is considered to meet this requirement. This requirement refers to slide preparatory techniques, not liquid based coverslips. Slides prepared by traditional methods (usually smears prepared by hand) are not included.

Maximum Workload Limits for Nongynecologic Specimens

Traditional Smear Technique	100 Slides
Automated, Semi-Automated, Liquid-Based	200 Slides
Combination of Techniques (Based on Prorated Time)	100 - 200 Slides

§493.1274(d)(2)(iv) Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100 slide workload limit.

D5645
(Rev.)

§493.1274 Standard: Cytology.

(d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

Interpretive Guidelines §493.1274(d)(3)

Verify that the laboratory monitors the number of slides examined by each individual and the number of hours spent examining slides.

D5647
(Rev.)

§493.1274 Standard: Cytology.

(d)(4) Records are available to document the workload limit for each individual.

Probes §493.1274(d)(4)
What records are maintained of each individual's workload limit when various types of slides are evaluated?

§493.1274 Standard: Cytology.

(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following:

D5649
(Rev.)

§493.1274 Standard: Cytology.

(e)(1) A technical supervisor confirms each gynecologic slide preparation interpreted to exhibit reactive or reparative changes or any of the following epithelial cell abnormalities:

(e)(1)(i) Squamous Cell

Interpretive Guidelines §493.1274(e)(1)(i)

NOTE: This requirement is in addition to the review and confirmation by a technical supervisor of all nongynecologic preparations as described under §493.1274(e)(3).

Probes §493.1274(e)(1)(i)

How does the laboratory ensure that the technical supervisor confirms every slide containing cells exhibiting reactive, reparative, atypical squamous/glandular cells, LSIL, HSIL, and all carcinomas?

(e)(1)(i)(A) Atypical squamous cells of undetermined significance (ASC-US) or cannot exclude HSIL (ASC-H).

(e)(1)(i)(B) LSIL-Human papillomavirus (HPV)/mild dysplasia/cervical intraepithelial neoplasia 1 (CIN 1).

(e)(1)(i)(C) HSIL-moderate and severe dysplasia, carcinoma in situ (CIS)/CIN 2 and CIN 3 or with features suspicious for invasion.

(e)(1)(i)(D) Squamous cell carcinoma.

(e)(1)(ii) Glandular Cell

(e)(1)(ii)(A) Atypical cells not otherwise specified (NOS) or specified in comments (endocervical, endometrial, or glandular).

(e)(1)(ii)(B) Atypical cells favor neoplastic (endocervical or glandular).

(e)(1)(ii)(C) Endocervical adenocarcinoma in situ.

(e)(1)(ii)(D) Adenocarcinoma endocervical, adenocarcinoma endometrial, adenocarcinoma extrauterine, and adenocarcinoma NOS.

(e)(1)(iii) Other malignant neoplasms.

D5651
(Rev.)

§493.1274 Standard: Cytology.

(e)(2) The report of gynecologic slide preparations with conditions specified in paragraph (e)(1) of this section must be signed to reflect the technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review.

Interpretive Guidelines §493.1274(e)(2)

The laboratory must ensure that the technical supervisor is the only individual to release his or her electronic signature for reports requiring technical supervisory review.

If an electronic signature is used, the laboratory must ensure that the system is protected from use by unauthorized individuals.

If the technical supervisor who performed the examination and diagnosis is not available to sign the report, an individual, also qualified as a technical supervisor in Cytology, must reexamine and confirm the findings prior to signing the report.

D5653
(Rev.)

§493.1274 Standard: Cytology.

(e)(3) All nongynecologic preparations are reviewed by a technical supervisor. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review.

Interpretive Guidelines §493.1274(e)(3)

The laboratory must ensure that the technical supervisor:

- Is the only individual to release his or her electronic signature for reports requiring technical supervisory review; and
- Reviews all nongynecologic cytological preparations.

If an electronic signature is used, the laboratory must ensure that the system is protected from use by unauthorized individuals.

If the technical supervisor who performed the examination and diagnosis is not available to sign the report, an individual, also qualified as a technical supervisor in Cytology, must reexamine and confirm the findings prior to signing the report.

D5655
(Rev.)

§493.1274 Standard: Cytology.

(e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

Interpretive Guidelines §493.1274(e)(4)

The report should clearly specify when the slide is unsatisfactory for evaluation. Unsatisfactory slide preparations should not be reported as negative or normal. Use D5805.

Probes §493.1274(e)(4)

What criteria have been developed for categorizing a slide preparation as unsatisfactory (e.g., scant cellularity, obscuring blood, obscuring inflammation, or lack of endocervical component)?

D5657
(Rev.)

§493.1274 Standard: Cytology.

(e)(5) The report contains narrative descriptive nomenclature for all results.

Interpretive Guidelines §493.1274(e)(5)

In cytology, great variation exists among the systems and terms a laboratory may use to report patient results on cytology reports. The laboratory must specify the descriptive nomenclature used for reporting patient results. This nomenclature must define the criteria used to classify patient results in a particular category in a clear and concise manner to ensure that all employees report patient results in a uniform, consistent manner. Use of the Papanicolaou numerical system without narrative description is not acceptable.

The Bethesda System is an example of a recognized system of narrative descriptive nomenclature for gynecologic cytology.

Probes §493.1274(e)(5)

When cytology evaluations are recorded on worksheets in "code" how does the laboratory ensure that the correct interpretation is used in reporting the results? Use D5801.

D5659
(Rev.)

§493.1274 Standard: Cytology.

(e)(6) Corrected reports issued by the laboratory indicate the basis for correction.

Interpretive Guidelines §493.1274(e)(6)

Corrected reports, either hard copy or electronic, must clearly indicate both the corrected results(s), and the fact that the report is a corrected report. The corrected reports should be promptly sent to the authorized person and to all known recipients of the original incorrect report.

Probes §493.1274(e)(6)

How does the laboratory indicate that the report is a corrected report (to avoid confusion with the initial report)? Use D5821.

How does the laboratory include the cause or reason for the correction in the report?

D5660
(Rev.)

§493.1274 Standard: Cytology.

(f) Record and slide retention.

(f)(1) The laboratory must retain all records and slide preparations as specified in §493.1105.

D5661
(Rev.)

§493.1274 Standard: Cytology.

(f)(2) Slides may be loaned to proficiency testing programs in lieu of maintaining them for the required time period, provided the laboratory receives written acknowledgment of the receipt of slides by the proficiency testing program and maintains the acknowledgment to document the loan of these slides.

(f)(3) Documentation of slides loaned or referred for purposes other than proficiency testing must be maintained.

D5663
(Rev.)

§493.1274 Standard: Cytology.

(f)(4) All slides must be retrievable upon request.

Probes §493.1274(f)(4)

If the laboratory loans slides, what protocol has been established to ensure prompt return of slides, when necessary?

D5665
(Rev.)

§493.1274 Standard: Cytology.

(g) Automated and semi-automated screening devices. When performing evaluations using automated and semi-automated screening devices, the laboratory must follow manufacturer's instructions for preanalytic, analytic, and postanalytic phases of testing, as applicable, and meet the applicable requirements of this subpart K.

Interpretive Guidelines §493.1274(g)

Some automated devices, such as instruments where only a portion of the slide is reviewed, may have a higher workload limit than 100 slides. This must be stated in the manufacturer's product insert to be applicable. However, the maximum workload limit for those slides which require 100% manual review (as a result of automated or semi-automated analysis OR in the routine workload) remains 100 slides.

Probes §493.1274(g)

When technology (automated/semi-automated devices) is introduced into the laboratory, how does the laboratory ensure its operation is within the specifications of previous methods used by the laboratory?

Some automated devices remove a percentage of the slides from the workload. How does the laboratory ensure that the correct slides are archived?

D5667
(Rev.)

§493.1274 Standard: Cytology.

(h) Documentation. The laboratory must document all control procedures performed, as specified in this section.

Interpretive Guidelines §493.1274(h)

QC records should include lot numbers, date prepared/opened, expiration dates, *and* observations *which* demonstrate that controls were tested when shipments of reagents, stains, or kits were opened or when the laboratory prepared these materials.

The actual measurements(s) taken, reactions and/or observations must be recorded. However, do not dictate the acceptable format for documentation.

The laboratory must maintain documentation to demonstrate that ten percent of the negative cases were rescreened.

All QC records must be maintained for *at least* two years, *including but not limited to* five year retrospective review, 10 percent rescreens, cytology/histology correlations, cytotechnologist's performance evaluations, *all* individual's *statistics,* and laboratory's statistics (use D3031). Use D3043 for retention of glass slides and D3041 for retention of patient test reports.

The laboratory must document the evaluation of quality control data and ensure that corrective actions are effective. Use D5793.

NOTE: Please refer to D2064 and D6116 for *Proficiency Testing issues related to* laboratories performing Human Papillomavirus (HPV) testing.

Probes §493.1274(h)

What information is documented on the quality control records?

What records does the laboratory maintain to document that stains are filtered or changed when necessary?

D5681
(Rev.)

§493.1276 Standard: Clinical *c*ytogenetics.

(a) The laboratory must have policies and procedures for ensuring accurate and reliable patient specimen identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, photographic printing, and reporting and storage of results, karyotypes, and photographs.

Interpretive Guidelines §493.1276(a)

When *there are* condition-level deficiencies *identified* in Clinical Cytogenetics in any or all phases of testing, use D5034.

Determine which of the following services may be provided:

- Tissue Cultures (e.g., skin, lung, product of conception);
- Bone Marrow Cultures;
- Solid Tumors;
- Lymph Nodes;
- Chorionic Villus Samples (CVS);
- Peripheral Lymphocyte Cultures;
- Amniotic Fluid Cultures;
- High resolution chromosome analysis;
    - Special techniques (e.g., Fragile "X" Studies, Chromosome Breakage analysis);
- Karyotype analysis (photographic and/or computer methods);
- Transplant studies;
- Chromosome staining (banding techniques) such as:
    - Quinacrine fluorescence (Q Banding);
    - Giemsa/trypsin (G Banding);
    - Sodium phosphate/acridine or giemsa/heat (R Banding);
    - Barium hydroxide/heat (C Banding);
    - Nuclear Organizing Region - Silver Stain (NOR);
    - Distamycin A/4-6-diamidino-2-phenylindole (DA/DAPI); or
    - Giemsa 11 (pH 11.0 for heterochromatin) (G 11).

NOTE: The above listing is not intended to be all-inclusive.

Review a sample of patient case files to determine if it is possible to go from the accession number to the patient's file with karyotypes, report and observation records, the microscope slide, photographs, or requisition forms.

Probes §493.1276(a)

When photographs are taken, are the coordinates of the microscope noted for each cell selected? If not, how does the laboratory identify the cell for future reference?

What system does the laboratory use to ensure that records reflect accurate patient identification when:

- Photographing chromosome spreads;
- Using computer systems to assist in karyotyping; or
- Storing photographic images of chromosomes and chromosomes spreads?

D5683
(Rev.)

§493.1276 Standard: Clinical cytogenetics.

(b) The laboratory must have records that document the following:

(b)(1) The media used, reactions observed, number of cells counted, number of cells karyotyped, number of chromosomes counted for each metaphase spread, and the quality of the banding.

(b)(2) The resolution is appropriate for the type of tissue or specimen and the type of study required based on the clinical information provided to the laboratory.

(b)(3) An adequate number of karyotypes are prepared for each patient.

Interpretive Guidelines §493.1276(b)(1)-(b)(3) Culture Type	***Minimum Number of Spreads Counted per Patient***	***Minimum Number of Cells Analyzed per Patient***
Amniotic Fluid		
Flasks	*15 cells from at least 2 independent primary cultures*	*5 cells from at least 2 independent primary cultures*
in situ	*15 cells from at least 10 colonies from 2 independent primary cultures*	*5 cells from different colonies and split between different primary cultures*
Many laboratories use a combination of the flask and in situ culture methods or use the flask method as a backup for the in situ method.		
Chorionic Villus		
Direct	*15 cells*	*5 cells*
Culture	*as in amniotic fluid, flask technique*	
Peripheral Blood		
Constitutional	*20 cells*	*5 cells*
Possible sex chromosome abnormality	*30 cells (total count)*	*5 cells*
Blood (cancer)	*20 cells*	*20 cells*
Bone Marrow (cancer)	*20 cells*	*20 cells*
Tissue Fibroblasts	*15 cells from 2 independent cultures*	*5 cells split between 2 independent cell cultures*
For confirmation of chromosomally abnormal amniotic fluid results, or familial chromosome abnormality, examination of fewer cells is permitted.		

A number of factors may influence the quality of the metaphase spreading (e.g., humidity, air flow, cell concentration, and cell storage conditions).
An analysis of at least 50 cells is recommended when:

- Single trisomic cells are found during a study;
- Mosaicism is suspected on the basis of a phenotype not correlating with the karyotype during the study; or
- Sex chromosome abnormalities are suspected.

Additionally, when mosaicism is suspected, ensure that an adequate number of cells or nuclei are scored.

- Follow manufacturer's instructions for the probe in accordance with the FDA requirements for "Analyte Specific Reagents (ASR)."

- Establish or verify test system performance using each new probe and each new lot of probe in accordance with D5421 or D5423; thereafter the laboratory must ensure test methodology performance in accordance with D5411.

- Establish criteria for scoring the number of probe signals and the number of cells to be examined. Use D5425.

For fragile X analysis:

- Males - at least 50-100 cells should be scored for negative analysis.

- Females - at least 100-150 cells should be scored for negative analysis.

The presence of the Xq27.3 fragile site should be confirmed with chromosome banding.

Fragile X studies require low folate medium and media which includes treatment with an antimetabolite such as fluorodeoxyuridine (FUdR), methotrexate, excess thymidine, fluordeoxycytidine (FdC) or other proven induction systems.

General guidance

Examine the karyotypes and a slide from among the laboratory cases and determine if the quality of banding and resolution was sufficient to render the reported interpretation. Examination of the long arm on the 18th chromosome should demonstrate at least two distinct dark staining G-bands at the 400 band level.

Verify that the laboratory's policy establishes a specific band level of resolution that would be dependent upon the study requested.

High resolution chromosome analysis should refer to studies done above the 550 band stage. (Above 650 band stage for an unfocused study. A focused study should be done at a level of resolution at which the band in question is clearly separated from surrounding bands in one member of the homologous pair in question.) Use D5683.

Probes §493.1276(b)(1)-(b)(3)

For fragile X analysis, if a folate deficient medium is not used as described above, how does the laboratory ensure the validity of the test system and the accuracy of results? Use D5411 or D5413, as applicable.

How many photographic and/or computerized karyotypes are prepared from each cell line? (A minimum of 2 is recommended.)

What band level of resolution is used by the laboratory to rule out structural defects (i.e., routine or 400-500 band stage, or high resolution or 650-850 band stage)?

D5685

§493.1276(c) Determination of sex must be performed by full chromosome analysis.

D5687

§493.1276(d) The laboratory report must include a summary and interpretation of the observations, number of cells counted and analyzed, and use the International System for Human Cytogenetic Nomenclature.

Probes §493.1276(d)

Does the laboratory report include:

- Type of banding method used, if applicable;
- Stage of cell mitosis when banded;
- Number of cells counted and analyzed microscopically;
- Number of cells from which photographic or computerized karyotypes were prepared; and
- Estimate of the banding resolution achieved?

Does the laboratory, where appropriate, ensure that FISH clinical interpretations are made in conjunction with standard cytogenetic analyses and evaluated against patient medical history and other diagnostic test results?

Preliminary reports of karyotypes based on less than full analysis are acceptable if the diagnosis is clear.

For what types of cultures are preliminary reports issued? These may include, but are not limited to, the following:

- Bone marrow analysis (within 14 days);
- Unstimulated blood cultures (within 14 days); and
- Lymphocytes from newborns (within 7 days).

What is the **average** length of time for reporting? (*U*se D5801 or D5815, as appropriate):

- Amniotic fluid cell cultures (90% of prenatal diagnosis cases should be signed out in 21 days);
- Routine lymphocyte cultures (approximately 4-5 weeks); and
- Fibroblast cultures (approximately 2-3 months)?

Do records document:

- Observations made concurrently with the performance of each step in the examination of specimens/cultures*?* (*U*se D5683); and
- The number of cases reviewed, signed out and/or the frequency of failed or sub-optimal cultures?

§493.1276 Standard: Clinical cytogenetics.

§493.1276 (e) The laboratory must document all control procedures performed, as specified in this section.

Probes §493.1276(e)

Each day of use, does the laboratory test the positive and negative reactivity of staining materials to ensure predictable staining characteristics? Use D5473.

Does the laboratory, concurrent with the initial use, check each batch of media for pH (amniotic cell cultures should be kept between pH 6.8 and 7.8), sterility, and ability to support growth? Use D5477.

Does the laboratory employ an alternative procedure for the immediate assessment and monitoring of all testing over time? For example: Control materials are not routinely available to demonstrate chromosome abnormalities for linkage, breakage, or translocation, but the laboratory must demonstrate an alternative mechanism for detecting chromosome abnormalities to be analyzed. Use D5485.

An alternative procedure might include *split* sample with another laboratory, repeat patient specimen, special stains, FISH assays, and/or molecular assays.

D5729
(Rev.)

§493.1278 Standard: Histocompatibility.

HLA (Human Leukocyte Antigens) typing is the identification of histocompatibility antigens and/or alleles. When condition-level deficiencies in Histocompatibility are identified in any or all phases of testing, cite D5042.

(a) General. The laboratory must meet the following requirements:

(a)(1) ***Use a continuous monitoring system and alert system*** **to monitor the storage temperature of specimens (donor and recipient) and reagents** ***and notify laboratory personnel when temperature limits are exceeded.***

Interpretive Guidelines §493.1278(a)(1)

Verify that the laboratory has a continuous monitoring and alert system for freezers and refrigerators where patient specimens and reagents are stored. Storage conditions should ensure the integrity of recipient and donor specimens and reagents is preserved. The laboratory should establish the temperature at which the system will activate. Liquid Nitrogen (LN2) reservoirs should be monitored to always ensure adequate supply of LN2.

Examples of "continuous monitoring" include electronic notification systems, which may not be physically located at the primary site, or a manual process that will detect when temperature limits are exceeded.

Under this requirement, laboratories should have a backup method for continuous monitoring and alert systems, such as an alternate monitoring system. An emergency power source for the continuous monitoring alarm system in the event of an electrical failure is one means of ensuring continuous monitoring of temperatures. If emergency power is not available, the laboratory should have policies/procedures on how to ensure continuous monitoring using an alternate method to ensure a prompt response to out-of-range temperatures, 24 hours a day, 7 days a week, including holidays. An acceptable practice for laboratories that are not staffed 24 hours would include the use of a notification system.

Verify that the laboratory has an emergency plan for alternate storage appropriate for its operational needs. Continuous monitoring of temperatures by a recording thermograph is acceptable, provided the data and time of use are annotated.

Probes §493.1278(a)(1)

Is there evidence of a process to ensure notification of alerts when the limits are exceeded?

How does the laboratory monitor the level of LN2? How does the laboratory respond to alerts when limits are exceeded?

Does the laboratory have a policy that outlines alternate storage of specimens and reagents when storage temperatures are exceeded?

Does the laboratory have an emergency plan to address widespread failures, such as electrical outages, that may affect storage conditions and continuous monitoring systems and specimen and reagent integrity?

D5731
(Rev.)

§493.1278 Standard: Histocompatibility.

(a)(2) ***Establish and follow written policies and procedures for the storage and retention of specimens based on the specific type of specimen. All specimens must be easily retrievable. The laboratory must have an emergency plan for alternate storage.***

Interpretive Guidelines §493.1278*(a)*(2)

In addition to current specimens, HLA laboratories may store historic specimens from recipients necessary for pre-transplant crossmatching. These specimens may be used for monitoring the recipient's antibody status or for the investigation of organ rejection.

In addition to having a continuous monitoring system for specimens (and reagents), the laboratory must have a plan in place to store all specimens in an alternate location when storage temperatures are exceeded. An emergency plan for alternate storage of both current and historic patient serum specimens for pre-transplant crossmatching and investigation of organ rejection is critical.

Probe §493.1278(a)(2)

What is the laboratory's plan for storage and retention that ensures easy retrieval of specimen(s) for each specimen type?

Does the laboratory have a policy for alternate storage of specimens?

Does the laboratory have an emergency plan to address widespread failures that may affect specimen integrity, such as power outages, that may affect storage conditions and continuous monitoring systems?

D5735
(Rev.)

§493.1278 Standard: Histocompatibility.

(a)(3) If the laboratory uses immunologic reagents to facilitate or enhance the isolation or identification of lymphocytes or lymphocyte subsets, the efficacy of the methods must be monitored with appropriate quality control procedures.

Interpretive Guidelines 493.1278(a)*(3)*

Lymphocytes can be isolated from peripheral blood, lymph nodes, and spleen. These cells can be further separated into subsets, such as T cells and B cells. *The laboratory should have policies and/or procedures for assessment of these specimens to determine their acceptability, and efficacy of the methods, to include criteria for acceptability. Quality control procedures must be sufficient to determine the acceptability of specimens that have been treated for the enhancement or isolation of cellular lines or subsets. For deficiencies related to the procedure, to assess specimen acceptability use D5403 through D5409, depending on the issue identified; for control material acceptability, use D5469.*

D5737
(Rev.)

§493.1278 Standard: Histocompatibility.

(a)*(4)* Participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

Interpretive Guidelines §493.1278(a)*(4)*

Programs that meet the requirement for validating interlaboratory variability must assess the primary areas of testing in histocompatibility laboratories by test techniques. For example, antibody screening and identification, HLA typing for Class I (HLA-A, B, C) and Class II (HLA-DR, DQ), and lymphocyte crossmatching. If a national or regional program is not available, laboratories participating in a local exchange system should document information concerning the frequency of exchange and the grading system. A laboratory's performance in a regional or national exchange program should be evaluated against a peer group performing the same technique. Cite the deficiency D2000 if the laboratory is not enrolled in a program or has not developed an exchange program or is enrolled in a program/has developed an exchange program but fails to participate.

D5739
(Rev.)

§493.1278 Standard: Histocompatibility.

(b) *Human leukocyte antigen (*HLA*)* typing. The laboratory must do the following:

(b)(1) Use HLA antigen terminology from the World Health Organization (WHO) Nomenclature Committee for Factors of the HLA System.

Probe §493.1278(b)(1)

Does the laboratory use the current WHO nomenclature for their HLA typing? (For example, review test reports or other documentation.)

D5749
(Rev.)

§493.1278 Standard: Histocompatibility.

(b)(2) Have available and follow written criteria for determining when antigen and allele typing are required.

D5757
(Rev.)

§493.1278 Standard: Histocompatibility.

(c) Antibody screening and identification. The laboratory must make a reasonable effort to have available monthly serum specimens for all potential transplant recipients for periodic antibody screening, identification, and crossmatch.

D5763
(Rev.)

§493.1278 Standard: Histocompatibility.

(d) Crossmatching. For each type of crossmatch that a laboratory performs, the laboratory must do the following, as applicable:

Interpretive Guidelines §493.1278(d)

Crossmatch methods in histocompatibility may include, but are not limited to, serologic and non-serologic methods, such as flow cytometry, molecular methods, and any other activity used to assess immunologic compatibility, such as a virtual or computer-based crossmatch.

(d)(1) Establish and follow written policies and procedures for performing a crossmatch.

Interpretive Guidelines §493.1278*(d)(1)*

The laboratory must have written policies and procedures that outline the decision criteria for performing a crossmatch and the method to be used.

Confirm that the laboratory has verified the reagents appropriate for the specific

crossmatch method(s) in use. For deficiencies related to the verification of crossmatch methods, use D5421; for the establishment of crossmatch methods, use D5423.

Probe §493.1278(d)(1)

What crossmatch method does that laboratory utilize? Does the laboratory have a policy and procedure in place to ensure the validity of results?

D5765
(Rev.)

§493.1278 Standard: Histocompatibility.

(*d*)(2) Have available and follow written criteria for the following:

(d)(2)(i) Defining donor and recipient HLA antigens, alleles, and antibodies to be tested;

(d)(2)(ii) Defining the criteria necessary to assess a recipient's alloantibody status;

Probe §493.1278(d)(2)(ii)

What criteria does the laboratory use to determine the recipient's sensitization history and current alloantibody status? Examples include, but are not limited to, prior transplants or transfusions, and pregnancy status.

(d)(2)(iii) Assessing recipient antibody presence or absence on an ongoing basis;

Probe §493.1278(d)(2)(iii)

When additional information is critical for the interpretation of test results, how does the laboratory convey this information to the individual ordering or using test results? For example, if the laboratory reports the mean fluorescence intensity (MFI), have they included an interpretation that allows the transplant service clinician to determine if a transplant is contraindicated?

If pertinent information is missing, cite at D5805.

(d)(2)(iv) Typing the donor, to include those HLA antigens to which antibodies have been identified in the potential recipient, as applicable;

Interpretive Guidelines §493.1278(d)(2)(iv)

Laboratories that use different methods to type donors and/or recipients should assess compatibility between donors and recipients, as needed based on the typing method used. For example, compatibility of a donor typed at the serological level should be determined

for a recipient with antibodies that have been identified at the allele level.

(d)(2)(v) Describing the circumstances in which pre- and post-transplant confirmation testing of donor and recipient specimens is required;

(d)(2)(vi) Making available all applicable donor and recipient test results to the transplant team;

Probe §493.1278(d)(2)(vi)

When additional information is critical for the interpretation of test results, how does the laboratory convey this information to the individual ordering or using test results? If pertinent information is missing, cite at D5805. Example: If the laboratory reports MFI (Mean Fluorescence Intensity) value, have they included an interpretation?

(d)(2)(vii) Ensuring immunologic assessments are based on test results obtained from a test report from a CLIA-certified laboratory; and

Probe §493.1278(d)(2)(vii)

How does the laboratory ensure that testing is performed by a CLIA-certified laboratory?

(d)(2)(viii) Defining time limits between recipient testing and the performance of a crossmatch.

Probe §493.1278(d)(2)(viii)

What are the criteria for defining time limits between recipient testing and the performance of a crossmatch?

D5767
(Rev.)

§493.1278 Standard: Histocompatibility.

(d)*(3) *The test report must specify the type of crossmatch performed.

D5769
(Rev.)

§493.1278 Standard: Histocompatibility.

(e) Transplantation. Laboratories performing histocompatibility testing for infusion and transplantation purposes must establish and follow written policies and procedures specifying the histocompatibility testing (that is, HLA typing, antibody screening and

identification, and crossmatching) to be performed for each type of cell, tissue, or organ to be infused or transplanted. The laboratory's policies and procedures must include, as applicable—

(e)(1) Testing protocols that address:

Interpretive Guidelines §493.1278(e)(1)

The protocol agreement between the laboratory and the transplant service should include the recommendation for the collection of a monthly serum specimen on all active wait-listed patients.

If the laboratory provides support to a transfusion service, there should be a policy and procedure in place that outlines how requests and testing are handled. The laboratory should be an active participant in the transplant center's clinical program. It should provide the technical assistance and pertinent data necessary to help establish transplant protocols for solid organ, tissue, and cellular transplants and infusions. Each protocol should define which HLA Class I (A, B, C) and Class II (DR, DQ, DP) loci and resolution are required and circumstances under which retyping is required. These policies and procedures should be developed in conjunction with the transplantation center.

Probes §493.1278(e)(1)

Is there a transplant agreement for the specific transplant protocol?

Does the procedure in use reflect the protocol agreement?

What is the laboratory's frequency for screening potential transplant recipient sera for preformed HLA-specific antibodies?

(e)(1)(i) Transplant type (organ, tissue, cell);

Probe §493.1278(e)(1)(i)

What type of transplant services does the laboratory support?

(e)(1)(ii) Donor (living, deceased, or paired): and

Interpretive Guidelines §493.1278(e)(1)(ii)

Laboratories must have processes and protocols in place for each donor type. There may be different protocols for deceased versus living donors (for example: differences in turn-around times or levels of testing). Paired donor programs may also have specific requirements, which must also be outlined in the protocol.

(e)(1)(iii) Recipient (high risk vs. unsensitized);

Interpretive Guidelines §493.1278(e)(1)(iii)

Laboratories must have processes and protocols in place that outline the testing based on the risk status of the recipient.

(e)(2) Type and frequency of testing required to support clinical transplant protocols; and

Interpretive Guidelines §493.1278(e)(2)

Policies must address the type of testing, frequency of testing and address when testing and final crossmatches are required for patients who have demonstrated pre-transplant sensitization.

The laboratory or clinical team should have policies and procedures in place to define when there is a need for additional recipient specimens for immunological assessment and the circumstances when the collection of additional recipient specimens is not needed, such as in pediatric cases.

Probes §493.1278(e)(2)

What are the criteria for determining the type of testing, frequency of testing, and when testing and final crossmatches are required?

If the laboratory performs a virtual crossmatch, what are the criteria for determining when a virtual crossmatch can be performed or additional testing is needed?

(e)(3) Process to obtain a recipient specimen, if possible, for crossmatch that is collected on the day of the transplant. If the laboratory is unable to obtain a recipient specimen on the day of the transplant, the laboratory must have a process to document its efforts to obtain the specimen.

Interpretive Guidelines §493.1278(e)(3)

The laboratory must have a policy to obtain a recipient specimen, if possible, for crossmatch that is collected on the day of transplant. If the laboratory is not able to obtain the recipient specimen on the day of the transplant, there must be documentation showing it attempted to obtain the specimen. The laboratory's attempt to obtain the specimen does not have to be documented on the day of the transplant and can be completed after the day of the transplant.

D5773
(Rev.)

§493.1278 Standard: Histocompatibility.

(f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

Interpretive Guidelines §493.1278(f)

Documentation may be in electronic or hard copy format and should be retrievable.

D5775
(Rev.)

§493.1281 Standard: Comparison of test results.

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

Interpretive Guidelines §493.1281(a)-(c)

The laboratory must have a system to monitor and evaluate all testing it performs. Examples of materials that may be used to evaluate the same test performed by different methodologies, at multiple locations, and/or on multiple instruments in the same laboratory are proficiency testing samples, split samples or "blind" testing of materials with known values.

A laboratory that performs the same test at multiple locations or on more than one instrument must have written criteria for acceptable differences in test values (e.g., between different or identical models of an instrument from the same manufacturer, between instruments from different manufacturers).

If the laboratory performs calibration verification as specified in §493.1255(b), it may use the calibration verification to meet the requirements at §493.1281(a), provided the 3 levels of materials used for calibration verification meet the laboratory's criteria for acceptable differences in test values.

D5777
(Rev.)

§493.1281 Standard: Comparison of test results.

(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available:

(b)(1) Patient age.

(b)(2) Sex.

(b)(3) Diagnosis or pertinent clinical data.

(b)(4) Distribution of patient test results.

(b)(5) Relationship with other test parameters.

Interpretive Guidelines §493.1281(b)

The laboratory must have a system in place to monitor and evaluate test results for inconsistencies with patient information, and for correlation between test results. For example, a laboratory could multiply the hemoglobin result by a factor of 3, to see if the result is equal to the hematocrit.

If the laboratory has auto-validation in its Laboratory Information System (LIS), *they must take* steps to reduce the likelihood of sample-switching errors. For example, when the creatinine result is significantly different from the patient's previous creatinine test results, or if the MCV is significantly different from the patient's previous test results and the patient did not receive a blood transfusion.

For automated laboratories, inconsistent patient results may be evaluated through the use of verified LIS supported logic, patient distribution test results, verified automated test comparison logic programs and individual test repeat criteria.

Probes §493.1281(b)

How does the laboratory obtain sufficient information to enable an evaluation of test results with clinically relevant patient information?

Does the laboratory have procedures to assess and evaluate patient test results for inconsistencies?

For example:

- Hemoglobin and Hematocrit (MCHC value exceeds reference range);
- BUN and Creatinine comparison;
- Albumin and Total Protein;
- Correlation of urine culture with urine microscopic; and
- Alkaline phosphatase with orthopedic surgical patients and/or pediatric patients; and

- Correlation of microscopic sediment findings with macroscopic results, such as, the presence of protein with casts, positive occults blood with red cells, and positive leukocyte esterase with white cells.

§493.1281 Standard: Comparison of test results.

(c) The laboratory must document all test result comparison activities.

Interpretive Guidelines §493.1281(c)

The actual measurement(s) of test results and comparison activities must be recorded. Acceptable formats for documentation may vary. Cite documentation deficiencies at §493.1281(a) or §493.1281(b). Use D5775 or D5777, as appropriate.

D5779
(Rev.)

§493.1282 Standard: Corrective Actions.

(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

Interpretive Guidelines §493.1282(a)

Corrective action must be taken when unacceptable differences in test values occur with testing performed using different methodologies or instruments or with the same test performed at multiple testing sites.

Probes §493.1282(a)

When test results do not correlate with patient information (e.g., age, sex, submitted diagnosis) what actions are taken by the laboratory to confirm test results or patient information?

D5781
(Rev.)

§493.1282 Standard: Corrective actions.

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur:

(b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in §493.1253(b), which include but are not limited to--

(b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications;

(b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and

(b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

Interpretive Guidelines §493.1282(b)(1)

The laboratory's corrective action records should contain sufficient information to resolve the problem and prevent reoccurrence.

Probes §493.1282(b)(1)

When equipment malfunctions or a test method problem exists, how does the laboratory identify and solve the problem?

What corrective actions are taken if patient test results fall outside of the laboratory's reportable range of patient test results?

If a dilution procedure is used when patient results exceed the test system's reportable range, how does the laboratory ensure the appropriate diluent is used for each type of specimen? Use D5401.

How does the laboratory verify and document the accuracy of the results for diluted specimens? Use D5421 or D5423 as appropriate.

D5783
(Rev.)

§493.1282 Standard: Corrective actions.

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

Interpretive Guidelines §493.1282(b)(2)

When an internal control fails to fall within the defined limits of acceptability, the laboratory must identify the reason for the failure and correct the problem before

resuming testing of patients. The laboratory must evaluate all patient test results since the last acceptable external control.

Probes §493.1282(b)(2)

When suboptimal staining or improper coverslipping are identified through quality control procedures, what corrective actions does the laboratory take?

What actions does the laboratory take when controls reflect an unusual trend or are outside of the acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem?

D5785
(Rev.)

§493.1282 Standard: Corrective actions.

(b)(3) The criteria for proper storage of reagents and specimens, as specified under §493.1252(b), are not met.

Probes §493.1282(b)(3)

What action does the laboratory take if the storage temperature *and/or humidity* for a test system's *temperature and/or humidity sensitive materials (reagents, controls, calibrators, specimens, media, etc.), spaces, or equipment* falls outside the acceptable limits?

D5787
(Rev.)

§493.1283 Standard: Test records.

(a) The laboratory must maintain an information or record system that includes the following:

(a)(1) The positive identification of the specimen.

(a)(2) The date and time of specimen receipt into the laboratory.

(a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability.

(a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

Interpretive Guidelines §493.1283(a)

The regulations provide laboratories the flexibility to establish a system that ensures positive patient identification through specimen accessioning and storage, testing and reporting of test results. This may include a system that involves labeling the specimen container and request slip or the patient's medical record or chart with a unique patient identification number, but does not preclude the use of other mechanisms to assist in patient identification and tracking of specimens throughout the testing and reporting processes. The patient's name may be used as part of the identification system.

Ensure that work records reflect all the tests and dates of performance of in-house patient testing. For example, in bacteriology, each step from media inoculation to organism isolation and identification must be documented on worksheet records either manually or in a computer system.

Corrections of laboratory results *should* include the corrected result, incorrect result (noted as such), the date of the correction, and the initials of the person making the correction.

Laboratory records should not be documented in pencil and the use of whiteout is not acceptable for making corrections.

Probes §493.1283(a)

Do the records reflect all patient testing and the dates of their performance?

If handwritten values were reported, can the laboratory demonstrate the analytic source of those results?

If the laboratory has not retained the appropriate test records, cite D3031, D3033, or D3035.

D5789
(Rev.)

§493.1283 Standard: Test records.

(b) Records of patient testing including, if applicable, instrument printouts, must be retained.

Interpretive Guidelines §493.1283(b)

The regulations do not require that instrument printouts be posted directly in the patient's medical record or chart. However, these printouts must be maintained as part of the laboratory's record retention requirements specified throughout the regulations.

Probes §493.1283(b)

Are the original analytic work records complete (e.g., in a randomly chosen sample, is there an instrument printout for every day of the month on which testing was performed)?

Are the original, as opposed to transcribed and/or edited work records, being retained? If the laboratory fails to retain the records for the appropriate amount of time, use D3031.

D5791
(Rev.)

§493.1289 Standard: Analytic systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in §§493.1251 through 493.1283.

Interpretive Guidelines §493.1289(a)-(c)

Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions at all location/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, other laboratories ordering tests, and non-laboratory areas *of* the facility of which it is a part.

When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves *investigation,* identification, and resolution of the problem, *followed by* development of policies that will prevent recurrence.

The laboratory should:

- *Establish and/or revise written policies and procedures to prevent recurrence of the problems identified;*
- *Communicate the established and/or revised policies to the laboratory personnel and other staff, clients, etc., as appropriate; and*
- *Document that the established and/or revised policies and procedures to prevent recurrence have been followed.*

Over time, the laboratory must *document* monitor*ing of* the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem.

All pertinent laboratory staff must be involved in the assessment process through discussions or active participation.

QA of the Analytic System includes assessing:

- Test procedures;
- *Test* systems, equipment, instruments, reagents, materials, and supplies *for accuracy and reliability*;
- Specimen and reagent storage condition;
- Equipment/instrument/test/system maintenance and function checks;
- Establishment and verification of method performance specifications;
- Calibration and calibration verification;
- Control procedures;
- Comparison of test results;
- Corrective actions; and
- Test records.

For Clinical Cytogenetics cases, the laboratory should identify increases in or excessive culture failure rates, determine the contributing factors, document efforts to reduce or eliminate these factors, and assess the effectiveness of actions taken (i.e., a decrease in the culture failure rate).

Review assessment policies, procedures, and reports to verify that the laboratory has a system in place to ensure continuous improvement. Corrective action reports are one indication that the laboratory is monitoring and evaluating laboratory performance and the quality of services.

Select a sample of abnormal cytology patient reports and determine that, when available, the histopathology *comparison was performed, the* cytology comparison was performed, and the cytology 5-year retrospective review was performed. Ensure the laboratory documents any discrepancies and performs corrective action.

Review quality control records to determine if the laboratory's monitoring efforts are detecting control failures, shifts, and trends. If the surveyor identifies previously undetected quality control failures or omission, then the laboratory's system for monitoring and evaluating quality control may not be adequate.

For International Normalized Ratio (INR) calculation, ensure the laboratory:

- Periodically verifies, for each thromboplastin lot number in use, the correct

normal prothrombin time mean and (the International Sensitivity Index (ISI) value are being used for calculating the INR value.

- Periodically verifies the accuracy of the INR calculation (manual, instrument or LIS).

To verify Prothrombin time testing with INR calculations:

- Check the accuracy of normal Prothrombin time mean calculation (manual, instrument or LIS).

- Verify the ISI used in the calculation correlates with the ISI specified in the reagent package insert. Select an abnormal low or abnormal high prothrombin time result and verify the calculation.

Probes §493.1289(a)

For clinical cytogenetics cases, does the laboratory monitor the frequency of culture failures and sub-optimal analyses?

Does the laboratory add additional maintenance procedures and/or function checks, when needed, to ensure accurate and reliable test results?

What is the laboratory's system for monitoring and evaluating test results for inconsistencies with patient information?

D5793
(Rev.)

§493.1289 Standard: Analytic systems quality assessment.

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff.

Interpretive Guidelines §493.1289(b)

Verify that the laboratory has a system in place to monitor and evaluate test results for inconsistencies with patient information, and for correlation between test results. For example, a laboratory could multiply the hemoglobin result by a factor of 3, to see if the result is equal to the hematocrit. If the laboratory has auto-validation in its Laboratory Information System (LIS), verify that the laboratory is taking steps to reduce the likelihood of sample-switching errors, for example, when the creatinine result is significantly different from the patient's previous creatinine test results, or if the MCV is significantly different from the patient's previous test results and the patient did not

receive a blood transfusion.

Probes §493.1289(b)

How does the laboratory address multiple failed or sub-optimal cultures that have been submitted from one client?

How does the laboratory use the review of all normal or negative gynecologic specimens received within the previous 5 years to assess the analytic system and communicate findings to the staff?

(c) The laboratory must document all analytic systems assessment activities.

Interpretive Guidelines §493.1289(c)

The steps taken by the laboratory to identify and correct problems and prevent their recurrence must be documented. All laboratory policies amended due to its QA activities must also be noted.

POSTANALYTIC SYSTEMS

D5800
(Rev.)

§493.1290 Condition: Postanalytic Systems.

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in §493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in §493.1299 for each specialty and subspecialty of testing performed.

Interpretive Guidelines §493.1290

Significant deficiencies cited under this condition may indicate deficiencies under personnel responsibilities. Use D5800 when deficiencies are identified that are: significant and have the potential to, or adversely affect, patient testing, are systemic and pervasive throughout the laboratory, and are not limited to any one specialty or subspecialty.

D5801
(Rev.)

§493.1291 Standard: Test report.

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:

Interpretive Guidelines §493.1291(a)

The regulations apply to manual as well as automated record systems (e.g., a laboratory information system or LIS). Regardless of the means used to transmit laboratory results, routine checks should be conducted to verify that transmissions are being accurately and reliably conveyed to the final report destination.

For CLIA purposes, the final report destination for test results is considered to be the authorized person and/or their designated personal representative (a personal representative is generally a person authorized under applicable law to make health care decisions for the individual). See 45 CFR §164.502(g). Additional individuals or entity(s) who are responsible for using the test results may also receive test results from the laboratory if they are designated by the authorized person on the test requisition. As

of April 7, 2014, a new CLIA regulation was added at § 493.1291(l) in order to provide patients with more access to laboratory test report(s). In accordance with amendments to the HIPAA Privacy Rule, the new regulation states: "Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient". The HIPAA Privacy Rule preempts contrary state laws on patient access to laboratory test report(s), but where a HIPAA-covered laboratory can continue to comply with both the HIPAA Privacy Rule and state law, it must frame its policies and procedures in a way that complies with both laws. Further, the HIPAA Privacy Rule does not preempt more stringent state laws, even if contrary to the Privacy Rule. CLIA laboratories that are not subject to HIPAA will have discretion to provide patients with direct access to their laboratory test reports, subject to any applicable state laws that may constrain access.

To ensure the accurate, timely, confidential, and easily understood reporting of patient test results to the authorized person, their personal representative (if applicable) and others who are identified as responsible for using the test results on the requisition, a laboratory may contract with another entity to assist in the delivery of patient reports in a manner that complies with all applicable laws, including the CLIA regulatory and statutory requirements. Please note that if the laboratory is subject to HIPAA and the entity with which it contracts meets the HIPAA definition of a business associate, see 45 CFR §160.103 (definition of "business associate"), the laboratory's contract or other written arrangement with its business associate must contain the elements specified at 45 CFR §164.504(e).

Probes §493.1291(a)

How does the laboratory ensure that transmitted reports are legible and the information received at the final destination was the same data sent by the laboratory?

If the laboratory uses a LIS or facsimile, what security measures have been instituted to ensure that transmitted reports go directly from the device sending reports to the authorized person, their personal representative (if applicable), and others who are identified as responsible for using the test results on the requisition?

How does the laboratory ensure data safety for internal and external electronic communications?

§493.1291 Standard: Test report.

(a)(1) Results reported from calculated data.

(a)(2) Results and patient-specific data electronically reported to network or interfaced systems.

(a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

Interpretive Guidelines §493.1291(a)(3)

Manually transcribed or electronically transmitted results from an outside referral laboratory or from within the laboratory system (e.g., satellite or point-of-care testing locations) must be periodically verified for accuracy and timely reporting.

D5803
(Rev.)

§493.1291 Standard: Test report.

(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

Interpretive Guidelines §493.1291(b)

The test report information should be legible, understandable, and complete.

D5805
(Rev.)

§493.1291 Standard: Test report.

(c) The test report must indicate the following:

(c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.

Interpretive Guidelines §493.1291(c)(1) - (c)(6)

Use D5203 for deficiencies related to specimen identification problems.

When used on the test report, the patient's name must be accompanied by an identification or accession number. When for confidentiality purposes a patient's name is not used or when the identity of the person is not known, a unique patient identifier and identification or accession number must be used on the report.

(c)(2) The name and address of the laboratory location where the test was performed.

Interpretive Guidelines §493.1291(c)(2)

Laboratories having a single certificate for multiple sites/locations must have a system in place to identify which tests were performed at each site. When testing is performed in more than one location in a hospital, the specific location in the hospital must be stated on the laboratory report (for example, ER, NICU, etc.)

A code to identify the name and address of the laboratory performing testing is acceptable as long as the code is clearly annotated on the patient test report. This may be accomplished by using abbreviated indicators (e.g., asterisks) as long as they are identified and apparent to the individual receiving the report. This or a similar system may be seen on cumulative reports. The name and address of the reference laboratory may also be defined on a subsequent page or on the back of the report. Laboratories have latitude to develop other formats to meet this requirement.

§493.1291 Standard: Test report.

(c)(3) The test report date.

Interpretive Guidelines §493.1291(c)(3)

The date of the test report is the date results were generated as a final report and must not change on copies *or electronic reports* generated at a later date.

If a preliminary result is generated, it should be clearly labeled and include the date of the preliminary report, to differentiate it from the final test result in the final report or in the electronic reporting system.

If a laboratory test order contains multiple tests and these tests are completed on different days, the report should show when each test was completed.

Example:

An order for CBC, CMP and HIV is received in the lab and completed on 8/14/23, each test must show 8/14/23 as test report date.

On the other hand, if the CBC and CMP were completed on 8/14/23, but the HIV was completed on 8/15/23, the report date must be as follows:
CBC: 8/14/23
CMP: 8/14/23
HIV: 8/15/23

(c)(4) The test performed.

Interpretive Guidelines §493.1291(c)(4)

The laboratory must establish performance specifications in accordance with §493.1253(b)(2), and must make them available to clients in accordance with

§493.1291(e).

(c)(5) Specimen source, when appropriate.

Interpretive Guidelines §493.1291(c)(5)

Some examples of source of the specimen needed by the laboratory to accurately perform testing and report results would be: type of body fluid; whether a submitted separated specimen is plasma, serum, urine, etc.

§493.1291 Standard: Test report.

(c)(6) The test result and, if applicable, the units of measurement or interpretation, or both.

Interpretive Guidelines §493.1291(c)(6)

If the laboratory prints normal ranges on the patient test report, verify that *appropriate* normal ranges *(e.g., age specific)* are printed by the LIS on the patient test report.

"Less than" is used for reporting test results (qualitative or quantitative) that are below the laboratory's detection limits for an analyte. (Detection limits must be established through method verification as described in §493.1253.)

"Equivalent designation" is used to report test results for those methods that yield results below a clinically significant level (e.g., for a quantitative immunology test, patient results may be clinically negative at a 1:8 titer and test results may be reported as "1:8 negative". The normal range is 1:8 or less.)

"Greater than" is used for reporting test results (qualitative or quantitative) that are above the laboratory's detection limits for an analyte. If patient test results exceed the laboratory's reportable range, the laboratory must report the result as greater than the highest detection limit, reassay a diluted patient specimen and report the calculated result, or send the specimen to a reference laboratory.

For flow cytometry, to interpret results, staff should have access to the complementary clinical picture of the patient. This may include such results as white cell count, cell differential, cell morphology, and cytogenetics.

Flow cytometry patient data files should include any gating analysis regions used to obtain reported test results.

For genetic tests, the laboratory should include the test method(s) employed, *any variants that were detected, and any additional information that may affect the interpretation of the test results, such as software or program names and versions that assist in the analysis and interpretation of the genetic data, if applicable,* on the test report.

Probes §493.1291(c)(6)

When additional information is critical for the interpretation of test results (e.g., screening vs. confirmatory procedures*, interpretation software*), how does the laboratory convey this information to the individual ordering or using test results?

If the laboratory does not print normal ranges on the test report, how does the laboratory notify the client that reported results are abnormal for the patient due to their particular sex and/or age?

How does the laboratory convey updates to the analysis and interpretation software to the individual ordering or using the test results?

§493.1291 Standard: Test report.

(c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

Interpretive Guidelines §493.1291(c)(7)

If the laboratory functions as a reference laboratory, how does it notify the referring laboratory or client of unacceptable specimens in a timely manner? Use D5801 to cite timeliness deficiencies. Use D5805 to cite the referring laboratory's failure to notify the appropriate individual concerning the unacceptable specimen.

D5807
(Rev.)

§493.1291 Standard: Test report.

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

Interpretive Guidelines §493.1291(d)

The laboratory must ensure the "reference intervals" or "normal" values it provides to its clients are accurate, include appropriate units of measurement, and reflect the method performed and the patient population (if applicable).

Probes 493.1291(d)

Does the laboratory use the race-free equation for the estimated glomerular filtration rate (eGFR)?

D5809
(Rev.)

§493.1291 Standard: Test report.

(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in §493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

Interpretive Guidelines §493.1291(e)

When the laboratory changes methods, establishes a new procedure, or refers tests to another laboratory, the laboratory must make the updated information concerning parameters such as patient preparation, preservation of specimens, specimen collection, new "normal" ranges, or units of measure available to its clients.

Probes §493.1291(e)

How does the laboratory keep its clients informed about tests offered, methods used, and specimen requirements?

What means does the laboratory use to provide interpretation of results to its clients?

D5811
(Rev.)

§493.1291 Standard: Test report.

(f) Except as provided in §493.1291(l), test results must be released only to authorized persons and, if applicable, the persons responsible for using the test results and the laboratory that initially requested the test.

Interpretive Guidelines §493.1291(f)

Test results must be released to the authorized person and, if the authorized person is a patient, the patient's personal representatives and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable. If the authorized person is not a patient, test results must be released to the authorized person, and, if applicable, the persons responsible for using the test results and the laboratory that initially requested the test. Test results must also be released to any additional individuals/entities designated on the test requisition. These entities are understood to be "responsible for using" the test results.

When the authorized person, and, if applicable, the individual responsible for using the test results receives the results, the laboratory's CLIA responsibility ends. When a reference laboratory receives a specimen from another referring laboratory, the referring laboratory is responsible for getting the results back to the authorized person and, if applicable, any individuals responsible for using the results.

See D5301 for the definition of an "authorized person".

Probes §493.1291(f)

What security measures have been instituted to ensure that reports go directly from the device sending reports (e.g., LIS, facsimile) to the authorized person and: (i) if the authorized person is a patient, the patient's personal representatives and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable; and (ii) if the authorized person is not a patient, the persons who are identified as responsible for using the test results and the laboratory that initially requested the test, as applicable?

How does the laboratory ensure that only the authorized person(s) can access a patient's results?

D5813
(Rev.)

§493.1291 Standard: Test report.

(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

Interpretive Guidelines §493.1291(g)

The laboratory records should document the date, time, test results, and person to whom the test results were reported.

See D5301 for the definition of an "authorized person".

Probes §493.1291(g)

What means does the laboratory use to ensure the authorized person is alerted in a timely manner to critical, alert, or panic test results?

D5815
(Rev.)

§493.1291 Standard: Test report.

(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

Interpretive Guidelines §493.1291(h)

If the turnaround time for reporting patient test results will be delayed, which may negatively impact patient care, the laboratory should have an alternative method for reporting patient results.

Cite deficiencies only when the laboratory has failed to notify its client(s) when delays in testing patient specimens have the potential for or are adversely affecting patient care.

Probes §493.1291(h)

What criteria has the laboratory established for notifying the appropriate individual of the delay in testing? Use D5403.

How will the laboratory report patient test results if the LIS, *network (phone, fax, printers, electronic health records, etc.),* or test system is down? *What are the laboratory procedures if the LIS, network, or test system is down for an extended time?*

D5817
(Rev.)

§493.1291 Standard: Test report.

(i) If a laboratory refers patient specimens for testing--

(i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory;

Interpretive Guidelines §493.1291(i)(1)

If the laboratory transcribes results from the reference laboratory report, the test results, interpretation and information directly related to the interpretation must be copied exactly as reported by the reference laboratory. The report must adhere to the requirements in §§493.1291(c)(1)–(c)(7) and 493.1291(d).

(i)(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and

Interpretive Guidelines §493.1291(i)(2)

An "exact duplicate" is an exact copy of the information sent to the individual requesting the test or using the test result(s), and includes the name and address of the laboratory performing the test. The exact copy need not be paper, it may be retrieved from a computer system, microfilm or microfiche record, as long as it contains the exact information as sent to the individual ordering the test or utilizing the test results. The duplicate laboratory report must contain information positioned such that it is clear and includes all original interpretive information. For tests requiring an authorized signature or containing personnel identifiers (e.g., Pathology), the exact duplicate must include the signatures or identifiers. "Pathology" includes all of its subspecialties (i.e., Histopathology, Oral pathology, Cytology).

A "preliminary report" means a test result that has been reported to the authorized person or laboratory that initially requested the test before the final test result is completed. Frequently, a preliminary report will contain significant, but not definitive information (e.g., a urine culture preliminary report of >100,000 Gram-negative bacilli after 24 hours incubation or a beta subunit preliminary report of > 200 miu/ml). It should be noted on the report when the result is a preliminary result and that a final report will follow.

A "partial report" means multiple tests are ordered on the same specimen or patient. If partial reports are issued for only those tests that have been completed, then the report date will be the date when all tests have been completed. However, the laboratory should be able to identify the date that each new test is appended to the report.

The laboratory must have a system for retaining copies of all reports including original, preliminary, corrected, and final reports. This includes computer-generated reports.

(i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

Interpretive Guidelines §493.1291(i)(3)

Test report forms may include codes to identify the name and address of the laboratory that performed the test, provided *that* the interpretations of the codes are available to the authorized person using the test results.

D5819
(Rev.)

§493.1291 Standard: Test report.

(j) All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

Interpretive Guidelines §493.1291(j)

The regulations do not specify the mechanism or frequency for which a laboratory should evaluate its record storage and retrieval system.

D5821
(Rev.)

§493.1291 Standard: Test report.

(k) When errors in the reported patient test results are detected, the laboratory must do the following:

Interpretive Guidelines §493.1291(k)

Errors in test results may include incorrect patient identification, test results, reference or normal ranges, interpretive information, or other significant information. See D5625 for specific guidance regarding certain amended cytology reports.

(k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.

Interpretive Guidelines §493.1291(k)(1)

When determining whether the laboratory gave prompt notification of test and/or reporting errors to the authorized person(s), their agent (if applicable), and others who are identified as responsible for using the test results on the requisition, consider whether contact information was provided to the laboratory, when the error was identified, when the authorized person was notified, and the extent of the error (e.g., clinically significant results reported on the wrong patient).

Probes §493.1291(k)(1)

What mechanism(s) does the laboratory use for notifying the authorized person(s) of the corrected values?

(k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.

Interpretive Guidelines §493.1291(k)(2)

Corrected reports, either hard copy or electronic, must clearly indicate both the corrected results(s) and the fact that the report is a corrected report. The corrected reports should be promptly sent*, as defined by laboratory policy,* to the authorized person, their agent (if applicable)*,* and*/or* others who are identified as responsible for using the test results on

the requisition.

For corrected reports in Cytology, use D5659.

Probes §493.1291(k)(2)

How does the laboratory ensure that incorrect original results are not reissued verbally, in writing or electronically?

§493.1291 Standard: Test report

(k)(3) Maintain duplicates of the original report, as well as the corrected report.

Interpretive Guidelines §493.1291(k)(3)

The laboratory must have a system for maintaining copies of the original and corrected reports. Computer-generated reports or electronically stored copies are acceptable.

Copies of all reports, including corrected reports, provided by the referral laboratory must be maintained by both the referral and referring laboratories for the required time periods.

Probes §493.1291(k)(3)

For laboratories that maintain the patient's medical record as the test report, what is the mechanism for differentiating between the incorrect original report and the corrected report?

D5823
(Rev.)

§493.1291 Standard: Test report.

(l) Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient.

Interpretive *Guidelines* §493.1291(l)

The laboratory must have and follow a written policy that is available to the laboratory staff and details how it handles patient requests for access to their completed laboratory reports. Test reports are considered to be complete when all results associated with the ordered tests are finalized and ready for release.

D5891

(Rev.)

§493.1299 Standard: Postanalytic systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in §493.1291.

Interpretive Guidelines §493.1299(a)-(c)

Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, other laboratories ordering tests, and non-laboratory areas of the facility of which it is a part.

When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves investigation, identification, and resolution of the problem, *followed by* development of policies that will prevent recurrence.

The laboratory should:

- *Establish and/or revise written policies and procedures to prevent recurrence of the problems identified;*
- *Communicate the established and/or revised policies to the laboratory personnel and other staff, clients, etc., as appropriate; and*
- *Document that the established and/or revised policies and procedures to prevent recurrence have been followed.*

Over time, the laboratory must *document* monitor*ing of* the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem.

All pertinent laboratory staff must be involved in the assessment process through discussions or active participation.

QA of the **Postanalytic System** includes assessing practices/issues related to test reports. Examples include monitoring and evaluating the accuracy*, timeliness,* and completeness of the laboratory's test reports (i.e., patient information, test results, normal ranges, and the disposition of unacceptable specimens), and the laboratory's turn-around times and procedures for notification of test results e.g., routine tests, STATS, abnormal or panic values*, and downtime procedures*.

Review a cross-section of patient test reports for accuracy of patient information, test

results and normal ranges to verify that the laboratory is effectively monitoring and evaluating the quality and accuracy of the information supplied to its clients.

Verify that the laboratory has a system in place to monitor and evaluate its established reporting time frames and procedures for notification of test results, routine tests, STATS, abnormal or panic values.

If the laboratory uses an LIS, the laboratory must have a mechanism to periodically verify the accuracy of:

- Its calculated data;
- Its results sent to interfaced systems; and
- Patient specific data.

Laboratories should assess data security protocols as part of the laboratory's quality assessment.

In the event that the laboratory becomes aware of information that reasonably suggests that an in vitro diagnostic device may have caused or contributed to a patient death or serious injury, verify that the laboratory has reported such instances to the FDA.

Reports must be submitted on FDA Form 3500A (https://www.fda.gov/medwatch/getforms.htm) or an electronic equivalent as soon as practical, but no later than 10 days from the time personnel become aware of the event. For more information on reporting requirements, contact the FDA: Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health, Food and Drug Administration, HFZ-440, 2098 Gaither Road, Rockville, MD 20850, Phone: 240-276-0450, Fax: 240-276-0652.

D5893
(Rev.)

§493.1299 Standard: Postanalytic system quality assessment.

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff.

Interpretive Guidelines §493.1299(b)

Review assessment policies, procedures and reports to verify that the laboratory has a system in place to ensure continuous improvement. Corrective action reports are one indication that the laboratory is monitoring and evaluating laboratory performance and

the quality of services.

§493.1299(c) The laboratory must document all postanalytic systems quality assessment activities.

Interpretive Guidelines §493.1299(c)

The steps taken by the laboratory to identify and correct problems, and prevent their recurrence must be documented. All laboratory policies amended due to its QA activities must be noted.

Probes §493.1299(a)-(c)

What mechanism does the laboratory use to update and correlate the information to clients (e.g., client reference manuals), procedure manuals, reporting systems (e.g., LIS) when the laboratory introduces a new test system with different normal/reference range?

Subpart M--Personnel for Nonwaived Testing

§493.1351 General

(Rev.)

This subpart consists of the personnel requirements that must be met by laboratories performing moderate complexity testing, PPM procedures, high complexity testing, or any combination of these tests.

Interpretive Guidelines §493.1351

We will continue to require individuals to submit detailed information, such as degrees, transcripts, or Primary Source Verification (PSV) documents for verification of educational credentials.

LABORATORIES PERFORMING PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES

§493.1353 Scope.

(Rev.)

In accordance with §493.19(b), the moderate complexity procedures specified as PPM procedures are considered such only when personally performed by a health care provider during a patient visit in the context of a physical examination. PPM procedures are subject to the personnel requirements in §§493.1355 through 493.1365.

Interpretive Guidelines §493.1353

PPM procedures are exempt from routine inspections only when performed under a Certificate *for p*rovider-*p*erformed *m*icroscopy *p*rocedures.

D5980

(Rev.)

§493.1355 Condition: Laboratories performing PPM procedures; laboratory director.

The laboratory must have a director who meets the qualification requirements of §493.1357 and provides overall management and direction in accordance with §493.1359.

D5981

(Rev.)

§493.1357 Standard: laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of PPM procedures as specified in §493.19(c) and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if the licensing is required.

(b) The laboratory director must meet one of the following requirements:

(b)(1) Be a physician, as defined in §493.2.

(b)(2) Be a midlevel practitioner, as defined in §493.2, authorized by a State to practice independently in the State in which the laboratory is located.

Interpretive Guidelines §493.1357(b)(2)

Midlevel practitioner means a nurse midwife, nurse practitioner, *nurse anesthetist, clinical nurse specialist,* or physician's assistant licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.

(b)(3) Be a dentist, as defined in §493.2.

D5983
(Rev.)

§493.1359 Standard: PPM laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. The laboratory director must--

D5985
(Rev.)

§493.1359 Standard: PPM laboratory director responsibilities.

(a) Direct no more than five laboratories; and

D5987
(Rev.)

§493.1359 Standard: PPM laboratory director responsibilities.

(b) Ensure that any procedure listed under §493.19(c)--

(b)(1) Is personally performed by an individual who meets the qualification requirements in §493.1363; and

(b)(2) Is performed in accordance with applicable requirements in subparts H, J, *and* K of this part.

D5988
(New)

§493.1359 Standard: PPM laboratory director responsibilities.

(c) Evaluate the competency of all testing personnel and ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—

(c)(1) Direct observations of routine patient test performance, including, if applicable, specimen handling, processing, and testing;

(c)(2) Monitoring the recording and reporting of test results;

(c)(3) Review of test results or worksheets;

(c)(4) Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and

(c)(5) Assessment of problem-solving skills; and

D5989
(New)

§493.1359 Standard: PPM laboratory director responsibilities.

(d) Evaluate and document the performance of individuals responsible for PPM testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations and documentation must be performed at least annually.

Interpretive Guidelines §493.1359(d)

Provider-performed microscopy (PPM) procedure is a non-waived moderate complexity test per §493.19(b)(2). The competency assessment intervals are the same as those for moderate and high complexity.

If a CLIA Certificate of Compliance (CoC) or Certificate of Accreditation (CoA) laboratory performs PPM procedures, then that laboratory is subject to all CLIA regulations related to moderate complexity testing. In those laboratories with a CoC or CoA, a technical consultant can perform competency assessment for moderate complexity testing, including PPM procedures under §493.1413(b)(8). However, in a CLIA certificate for PPM, the laboratory director is responsible for performing the competency assessment.

D5990
(Rev.)

§493.1361 Condition: Laboratories performing PPM procedures; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1363 to perform the functions specified in §493.1365 for the volume and complexity of testing performed.

D5991
(Rev.)

§493.1363 Standard: PPM testing personnel qualifications.

Each individual performing PPM procedures must--

(a) Possess a current license issued by the State in which the laboratory is located if the licensing is required; and

(b) Meet one of the following requirements:

(b)(1) Be a physician, as defined in §493.2.

(b)(2) Be a midlevel practitioner, as defined in §493.2, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located.

(b)(3) Be a dentist as defined in §493.2 of this part.

D5993
(Rev.)

§493.1365 Standard: PPM testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results. Any PPM procedure must be--

(a) Personally performed by one of the following practitioners:

(a)(1) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.

(a)(2) A midlevel practitioner, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located, during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider, in which the midlevel practitioner is a member or an employee.

(a)(3) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee; and

D5995
(Rev.)

§493.1365 Standard: PPM testing personnel responsibilities.

(b) Performed using a microscope limited to a brightfield or a phase/contrast microscope.

LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING

D6000
(Rev.)

§493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of §493.1405 of this subpart and provides overall management and direction in accordance with §493.1407 of this subpart.

Interpretive Guidelines §493.1403:

The *c*ondition *of* laboratory director is not met when the laboratory director:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the laboratory director's responsibilities.

An individual qualified as laboratory director may not qualify as a technical consultant in a particular specialty or subspecialty unless he or she has the required testing experience.

D6003
(Rev.)

§493.1405 Standard: Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.

Interpretive Guidelines §493.1405

Ensure that the laboratory director is not prohibited from owning, operating, or directing a laboratory.

NOTE: *R*efer to section 353(i)(3) of the PHS Act as amended by the TEST Act, which now states, "No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section (see §493.1840), except that if the revocation occurs pursuant to paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph."

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and

Interpretive Guidelines §493.1405(a)

The term "State" as used in this provision, includes the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of Northern Mariana Islands, the *U.S.* Virgin Islands, Guam and American Samoa.

(b) The laboratory director must--

(b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and

Interpretive Guidelines §493.1405(b)(2)(i)

Individuals who have earned a Doctor of Optometry are qualified to serve as a laboratory director of certain moderate complexity tests under CLIA, but only for test procedures performed in their specialty area. Optometrists may perform tests that are FDA-approved or cleared, of waived or moderate test complexity with the specimen source *of tears* such as lactoferrin, adenovirus, IgE, and osmolality.

(b)(2)(ii) Have had laboratory training or experience consisting of:

Interpretive Guidelines §493.1405(b)(2)(ii)

***NOTE**: See §493.2 for the definition of laboratory training or experience.*

(b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; *and*

(b)(2)(ii)(B) *Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407; or*

Interpretive Guidelines §493.1405(b)(2)(ii)(B)

The 20 *CE credit hours* must be obtained prior to qualifying as a laboratory director. The *CE* courses must encompass preanalytic, analytic, and postanalytic phases of testing, and be of such quality as to provide the physician with education equivalent to the experience described in §493.1405(b)(2)(ii)(A). Courses related to laboratory payment and *Current Procedural Terminology (*CPT) coding would not fulfill this requirement.

For a list of some *CE* providers, please see the CLIA web page at www.cms.hhs.gov/clia. The list of courses on the CLIA web page is not all inclusive. Other courses may meet the criteria, but all courses must be accredited.
In evaluating the 20 *CEs*, verify they include the laboratory director responsibilities detailed in §493.1407.

(b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, or clinical or medical laboratory science or medical technology from an accredited institution; or

Interpretive Guidelines §493.1405(b)(3)(i)(A)

NOTE: *See §493.2 for the definition of an accredited institution, continuing education (CE) credit hours, doctoral degree, experience directing or supervising, and laboratory training or experience.*

(b)(3)(i)(B) Hold an earned doctoral degree; and

(b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or

(b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(b)(3)(ii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407; and

(b)(3)(ii)(A) Be certified and continue to be certified by a board approved by HHS; and

(b)(3)(ii)(B) Have had at least 1 year of experience directing or supervising nonwaived laboratory testing; or

(b)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(b)(4)(i)(B)(1) Meet bachelor's degree equivalency; and

(b)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science; or

(b)(4)(i)(C)(1) Meet bachelor's degree equivalency; and

(b)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(b)(4)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; and

(b)(4)(iii) Have at least 1 year of supervisory laboratory experience in nonwaived testing; and

(b)(4)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1407; or

(b)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological science, or clinical or medical laboratory science, or medical technology from an accredited institution; or

(b)(5)(i)(B) At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—

(b)(5)(i)(B)(1) Forty-eight (48) semester hours of medical laboratory science or medical laboratory technology courses; or

(b)(5)(i)(B)(2) Forty-eight (48) semester hours of science courses that include—

(b)(5)(i)(B)(2)(i) Twelve (12) semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry;

(b)(5)(i)(B)(2)(ii) Twelve (12) semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and

(b)(5)(i)(B)(2)(iii) Twenty-four (24) semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination; and

(b)(5)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; and

(b)(5)(iii) Have at least 2 years of supervisory laboratory experience in nonwaived testing; and

(b)(5)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1407.

(b)(6) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of moderate complexity testing under this section if they were qualified and serving as a laboratory director of moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

Interpretive Guidelines §493.1405(b)(6)

The grandfathering provision will allow individuals already qualified and employed as a laboratory director of moderate complexity testing as of the effective date of the final rule December 28, 2024, to continue to be qualified under the new provisions provided the individuals remain continuously employed in their position after the effective date of

December 28, 2024. To be considered to be "continuously employed" in their position, the individual may have no more than 6 months of break in employment in their position in a two-year period.

The responsibility is on the individual to provide documentation showing their eligibility to meet this provision.

D6004
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.

Interpretive Guidelines §493.1407

If the laboratory has more than one person qualifying as director, the laboratory is required to designate one individual who has ultimate responsibility for overall operation and administration of the laboratory. *These responsibilities should be delegated in writing.*

The requirement that a laboratory must be under the direction of a qualified person is not automatically met simply because the director meets the education and experience requirements. It must be demonstrated that the individual is, in fact, providing effective direction over the operation of the laboratory.

In determining whether the director responsibilities are met, consider deficiencies found in other conditions, e.g., facility administration, general laboratory systems, preanalytic systems, analytic systems, postanalytic systems, and proficiency testing.

(a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of §§493.1409, 493.1415, and 493.1421, respectively.

Interpretive Guidelines §493.1407(a)

If the laboratory director is not qualified as a technical consultant or clinical consultant, he or she must employ individuals meeting the appropriate qualifications.

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

Interpretive Guidelines §493.1407(b)

The laboratory director may delegate to a technical consultant, in writing, the responsibilities in §§ 493.1407(e)(3), (4), (5), (6), (7), (11), (12), and (13).

The laboratory director may delegate to a clinical consultant, in writing, the responsibilities in §§ 493.1407(e)(8) and (9).

D6005
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(c) The laboratory director must:

(c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and

(c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

Interpretive Guidelines §493.1407(c)(2)

The on-site visits are meant to supplement regular interactions between off-site directors and the lab (for example, by telephone or other telepresence). Documentation of laboratory director's on-site visits should demonstrate the laboratory is in continuous compliance with current laws and regulations, including but not limited to the assessment of the physical environment for safe laboratory testing. The laboratory director's on-site visits cannot be delegated.

The laboratory director determines the type or process of documentation needed as evidence of performing on-site visits. Documentation may include, but is not limited to, sign in/sign out logs, meeting minutes/summary, notes of observations, and travel vouchers.

D6006
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(d) Each individual may direct no more than five laboratories.

Interpretive Guidelines §493.1407(d)

An individual may serve as a director of 5 nonwaived certified laboratories. An individual may serve as a technical consultant or clinical consultant for any number of laboratories.

D6007
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e) The laboratory director must--

(e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

D6010
(Rev.)

§493.*1407* Standard: Laboratory director responsibilities.

(e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and

Interpretive Guidelines §493.1407(e)(2)

OSHA/EPA issues cannot be cited using these requirements. If immediate jeopardy exists, the director should be informed immediately.

If you observe or obtain information regarding potential safety violations not applicable under CLIA, notify the appropriate State or local authority. Consult with the Regional Office (RO) for notification to other Federal agencies such as the Occupational Safety and Health Administration (OSHA) http://www.osha.gov/, Environmental Protection Agency (EPA) http://www.epa.gov/, or Nuclear Regulatory Commission (NRC). The appropriate Federal, State or local authority, if warranted, will investigate and, if necessary, conduct an on-site visit.

D6011
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

D6012
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(3) Ensure that—

***(e)*(3)(i) The test methodologies selected have the capability of providing the quality of results required for patient care;**

D6013
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

***(e)*(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and**

D6014
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

***(e)*(3)(i*ii*) Laboratory personnel are performing the test methods as required for accurate and reliable results;**

D6015
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that--

D6016
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;

D6017
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(4)(ii) The results are returned within the timeframes established by the proficiency testing program;

D6018
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

D6019
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;

D6020
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(5) ***Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;***

D6023
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

D6024
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, *and that patient test results are reported only when the system is functioning properly;*

D6026
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(8) Ensure that reports of test results include pertinent information required for interpretation;

D6027
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

D6028
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

D6029
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

D6030
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

Interpretive Guidelines §493.1407(e)(12)

Personnel performing only preanalytic *(e.g., entering requisitions into a computer system)* and postanalytic activities *(e.g., sending final reports)* are not required to be listed on Form *CMS*-209. Surveyors do not normally check for documented competency evaluation on these individuals. However, if you discover problems in the laboratory and you find that a factor in these problems is poor performance of incompetent staff, cite D6030 or D6103 (laboratory director).

D6031
(Rev.)

§493.*1407* Standard: Laboratory director responsibilities.

(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

Interpretive Guidelines §493.14*0*7(e)(13)

The laboratory director can delegate to the technical consultant the responsibility of making the procedure manual available, but cannot delegate the responsibility for signing*, dating, and approving* new and revised procedures.

D6032
(Rev.)

§493.1407 Standard: Laboratory director responsibilities.

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

Interpretive Guidelines §493.1407(e)(14)

The director must assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process. The list of assigned duties must be current.

D6033
(Rev.)

§493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.

The laboratory must have a technical consultant who meets the qualification requirements of §493.1411 of this subpart and provides technical oversight in accordance with §493.1413 of this subpart.

Interpretive Guidelines §493.1409

The Condition of technical consultant is not met when the technical consultant:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the technical consultant's responsibilities.

D6034
(Rev.)

§493.1411 Standard: Technical consultant qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

Interpretive Guidelines §493.1411

The type of experience required under this regulation is **clinical** in nature. This means, examination and test performance on human specimens for purposes of obtaining information for the diagnosis, treatment, and monitoring of patients, or for providing information to others who will do the diagnosing and treating of the patient's condition. Patient or medically-oriented experience, which is defined as the ordering of tests and interpreting and applying the results of these tests in diagnosing and treating a patient's illness is **unacceptable** to meet the requirement for laboratory training or experience.

The term “laboratory training or experience” means that the individual qualifying has the training and experience in the specialties and subspecialties in which the individual is providing technical consultation.

Technical consultants should have documentation of hands-on testing experience. This documentation may consist of, but is not limited to, the individual’s initials on worksheets or work cards, attestation of the laboratory director to the experience the individual has, or formal laboratory rotation through a medical residency program or laboratory internship program.

Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is considered acceptable experience. Research experience is also acceptable experience if it is obtained while performing tests on human specimens.

D6035

(Rev.)

§493.1411 Standard: Technical consultant qualifications.

(a)The technical consultant must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

(b) The technical consultant must--

(b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or

(b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(b)(3)(i)(B) Meet either requirements in § 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C);

and

(b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(b)(4)(i)(B) Meet § 493.1405(b)(5)(i)(B); and

(b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and

(b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

(b)(6) For blood gas analysis, the individual must—

(b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or

(b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or

Interpretive Guidelines §493.1411(b)(2)-(b)(6)

NOTE: *See §493.2 for the definition of laboratory training or experience.*

Some examples of how one-year of training or experience can be met are:

- *Medical technology internship;*
- *1-year experience performing nonwaived tests in a particular specialty(ies) or subspecialty(ies); or*
- *Performance of nonwaived testing in a particular specialty(ies) or subspecialty(ies) on a part-time basis, equivalent to 2080 hours.*

(b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

Interpretive Guidelines §493.1411(b)(7)

The grandfathering provision will allow individuals already qualified and employed as a technical consultant of moderate complexity testing as of the effective date of the final rule December 28, 2024, to continue to be qualified under the new provisions provided the individuals remain continuously employed in their position after the effective date of December 28, 2024. To be considered "continuously employed," in their position, the individual may have no more than 6 months of break in employment in their position in a two-year period.

The responsibility is on the individual to provide documentation showing their eligibility to meet this provision.

Note 1 to paragraph (b): The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

D6036
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

The technical consultant is responsible for the technical and scientific oversight of the laboratory. ***The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.***

Interpretive Guidelines §493.1413

In a specialty in which neither the director nor testing personnel can qualify to provide **technical** consultation, the laboratory may engage the services of a qualified person either on a part-time or full-time basis for this service. Under these circumstances, the qualified person is not required to be on the premises full-time or at all times tests are being performed in his/her specialty(ies). However, the technical consultant must be available to provide consultation and should spend time in the laboratory sufficient to

supervise the technical performance of the staff in his/her specialty(ies).

D6038
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(a) The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and
Interpretive Guidelines §493.1413(a)

Since the testing personnel usually will not have experience and training in all specialties, technical consultation is essential in identifying training needs and ensuring that each individual performing testing receives regular in-service training and education. There should be documentation, such as a log book or training/discussion reports, to indicate the services provided or activities performed by the technical consultant. These activities should correlate with the responsibilities delegated to the technical consultant by the laboratory director. The technical consultant is responsible for evaluating the capabilities of the technical personnel and advising the director on proper test performance in the specialty.

D6039
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.
(b) The technical consultant is responsible for--

(b)(1) Selection of test methodology appropriate for the clinical use of the test results;

D6040
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

D6041
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(3) Enrollment and participation in an HHS approved proficiency testing

program commensurate with the services offered;

D6042
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

D6043
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

D6044
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

D6045
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

Interpretive Guidelines §493.1413(b)(7)

In some instances, in-service training may be specifically related to an instrument or test, or may be very general in nature. The laboratory may establish its own format, content, and schedule or provide training on an as-needed basis. This is acceptable provided the laboratory does not have deficiencies related to test performance.

D6046
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

Interpretive Guidelines §493.1413(b)(8)

The technical consultant is responsible for assessing the competency of the testing personnel. The six (6) competency assessment procedures are found under the technical consultant responsibilities. All individuals performing patient testing must undergo documented competency assessment. This includes but is not limited to the laboratory director, consultants, or supervisors who also perform patient testing.

In order to be able to perform competency assessment, the individual must meet the regulatory qualifications of a TC, and performance of competency assessment should be delegated in writing to the individual.

Certificate for Provider-performed Microscopy Procedures: There is no technical consultant.

Depending on the situation, non-compliance can be cited at General Laboratory Systems (D5209/§493.1235), laboratory director (D6030/§493.1407), or technical consultant (D6046-D6055/§493.1413(b)(8)-§493.1413(b)(9)).

Probes §493.1413(b)(8)

What mechanism is used to ensure that testing personnel are following the laboratory's policies and procedures?

Evaluations of technical and clinical consultants' performance is located at §493.1235 - Personnel Competency Assessment Policies and §§493.1239(a)-(b) - General Laboratory Systems Assessment.

D6047
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

D6048
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(8)(ii) Monitoring the recording and reporting of test results;

D6049
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

D6050
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

D6051
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

D6052
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(8)(vi) Assessment of problem solving skills; and

D6053
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

D6054
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(9) Thereafter, evaluations must be performed at least annually

D6055
(Rev.)

§493.1413 Standard: Technical consultant responsibilities.

(b)(9) unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

D6056
(Rev.)

§493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant.

The laboratory must have a clinical consultant who meets the qualification requirements of §493.1417 of this part and provides clinical consultation in accordance with §493.1419 of this part.

Interpretive Guidelines §493.1415

The Condition of clinical consultant is not met when the clinical consultant:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the clinical consultant's responsibilities.

D6057
(Rev.)

§493.1417 Standard: Clinical consultant qualifications.

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must--

(a) Be qualified as a laboratory director under §493.1405(b)(1), (2), or *(3)*; or

(b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

D6058
(Rev.)

§493.1419 Standard: Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.

D6059
(Rev.)

§493.1419 Standard: Clinical consultant responsibilities.

The clinical consultant must--

(a) Be available to provide clinical consultation to the laboratory's clients;

D6060
(Rev.)

§493.1419 Standard: Clinical consultant responsibilities.

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

D6061
(Rev.)

§493.1419 Standard: Clinical consultant responsibilities.

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

Probes §493.1419(c)

Has the clinical consultant reviewed the reports to ensure that test results include patient information required for specific patient interpretations?

Has the clinical consultant reviewed the reports to ensure that the correct reference range is listed (i.e. the race-free equation is being used to calculate the estimated glomerular filtration rate (eGFR))?

D6062
(Rev.)

§493.1419 Standard: Clinical consultant responsibilities.

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

D6063
(Rev.)

§493.*1421* Condition: Laboratories performing moderate complexity testing; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1423, to perform the functions specified in §493.1425 for the volume and complexity of tests performed.

Interpretive Guidelines §493.1421

The Condition of testing personnel is not met when the testing personnel:

- Is not qualified; or
- Does not fulfill the testing personnel responsibilities.

The criteria used to determine the adequacy of the testing personnel involves evaluating testing personnel responsibilities, and ensuring that these responsibilities are specified in writing by the director, and that the responsibilities are appropriate to ensure compliance with the requirements concerning reporting and recordkeeping, quality control monitoring, quality assurance activities and proficiency testing participation. Cite this deficiency only when compliance problems are found in these areas that can be directly related to insufficient numbers of testing personnel. (Use D6028, which relates the finding of insufficient personnel to director responsibilities.)

D6064
(Rev.)

§493.*1423* Standard: Testing personnel qualifications.

Each individual performing moderate complexity testing must--

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

Interpretive Guidelines §493.1423

NOTE: *See §493.2 for the definition of laboratory training or experience.*

The laboratory director is responsible for ensuring the testing personnel have the appropriate education and experience and receive the appropriate training for the type and complexity of testing performed. The experience required is **clinical** in nature. This means examination of and test performance on human specimens for purposes of obtaining information for the diagnosis, treatment, and monitoring of patients, or for providing information to others who will do the diagnosing and treating of the patient's condition. (Use D6029).

Each individual must have documentation of training applicable to the types and complexity of testing performed. This training should be such that the individual can demonstrate that he/she has the skills required for proper performance of preanalytic, analytic, and postanalytic phases of testing. For example, if the individual performs a rapid Strep test, he/she should be able to demonstrate the skills for:

- Proper specimen handling prior to testing, e.g., ensuring the specimen is properly labeled and received and tested within appropriate timeframes, the swab is received at the proper temperature, and the ampule on the swab containing transport media is broken;

- Proper test performance according to the laboratory's policies and manufacturer's instructions, e.g., using reagents that are not outdated, are at the proper temperature, and of the same lot number, accurate timing of all steps in the procedure, proper performance of quality control procedures; and

- Proper reporting of patient test results in accordance with the laboratory's policies, e.g., notifying the person authorized to receive test results of a positive result, not reporting the test result if quality control fails.

D6065
(Rev.)

§493.*1423* Standard: Testing personnel qualifications.

(b) Meet one of the following requirements:

(b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or

(b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or

Interpretive Guidelines §493.1423(b)(2)

See §493.2 for the definition of an accredited institution.

(b)(3) Meet the requirements in § 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or

(b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or

(b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

Interpretive Guidelines §493.1423(b)(5)

Ensure that the military discharge paperwork (i.e., DD Form 214) reflects the occupational specialty and includes weeks of training. The occupational specialty must be related to the laboratory and must be at least 50 weeks long.

(b)(6)(i) Have earned a high school diploma or equivalent; and

D6066
(Rev.)

§493.1423 Standard: Testing personnel qualifications.

(b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has-

(b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens;

(b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures;

(b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use;

(b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

(b)(6)(ii)(E) A working knowledge of reagent stability and storage;

(b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory;

(b)(6)(ii)(G) An awareness of the factors that influence test results; and

(b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

Interpretive Guidelines §493.1423(b)(6)

Personnel qualifying under this requirement must have a high school diploma or GED. There is no standardized approach to home schooling across the country. Should a surveyor be presented with home high school diploma, in general, they would accept the home high school diploma at face value and focus on the employee's training and competency. At this time, CMS is not aware that Primary Source Verification (PSV) companies verify home school programs.

Probes §1493.1423(b)(6)

How does the laboratory ensure that personnel receiving orientation and training have the necessary skills for properly performing assigned responsibilities?

D6190
(New)

§493.1423 Standard: Testing personnel qualifications.

(b)(7) For blood gas analysis, the individual must—

(b)(7)(i) Be qualified under paragraph (b)(1), (2), (3), (4), (5), or (6) of this section; or

(b)(7)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(b)(7)(ii)(B) Have at least 1 year of laboratory training or experience, or both, in blood gas analysis; or

(b)(7)(iii)(A) Have earned an associate degree related to pulmonary function from an accredited institution; and

(b)(7)(iii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis.

D6191
(Rev.)

§493.1423 Standard: Testing personnel qualifications.

(b)(8) Notwithstanding any other provision of this section, an individual is considered qualified as a testing personnel under this section if they were qualified and serving as a testing personnel for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

Interpretive Guidelines §493.1423(b)(8)

The grandfathering provision will allow individuals already qualified and employed as a testing personnel of moderate complexity testing as of the effective date of the final rule December 28, 2024, to continue to be qualified under the new provisions provided the individuals remain continuously employed in their position after the effective date of December 28, 2024. To be considered to be "continuously employed," in their position, the individual may have no more than 6 months of break in employment in their position in a two-year period.

The responsibility is on the individual to provide documentation showing their eligibility to meet this provision.

D6068
(Rev.)

§493.1425 Standard: Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

D6069
(Rev.)

§493.1425 Standard: Testing personnel responsibilities.

(a) Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

D6070
(Rev.)

§493.1425 Standard: Testing personnel responsibilities.

(b) Each individual performing moderate complexity testing must--

(b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

D6071
(Rev.)

§493.1425 Standard: Testing personnel responsibilities.

(b)(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples;

D6072
(Rev.)

§493.1425 Standard: Testing personnel responsibilities.

(b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

D6073
(Rev.)

§493.1425 Standard: Testing personnel responsibilities.

***(b)*(4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;**

D6074
(Rev.)

§493.1425 Standard: Testing personnel responsibilities.

***(b)*(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and**

Interpretive Guidelines §493.1425(b)(5)

If, during the survey, testing personnel demonstrate an inability to identify a problem that adversely affects a patient test result, cite D6029 under director responsibilities.

Some examples of problems that may adversely affect patient test results may include, but are not limited to:

- A pleural fluid that is mislabeled and, therefore, is processed as a urine culture;
- Performing a potassium on a hemolyzed sample; or
- Tests are incubated at 37°C when the manufacturer's instructions require 25°C incubation.

D6075
(Rev.)

§493.1425 Standard: Testing personnel responsibilities.

***(b)*(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.**

LABORATORIES PERFORMING HIGH COMPLEXITY TESTING

D6076
(Rev.)

§493.1441 Condition: Laboratories performing high complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart.

Interpretive Guidelines §493.1441

The Condition of laboratory director is not met when the laboratory director:

- Position is not filled;
- Is not qualified; or

Does not fulfill the laboratory director responsibilities.

D6078
(Rev.)

§493.1443 Standard: Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R.

Interpretive Guidelines §493.1443

Ensure that the laboratory director is not prohibited from owning, operating, or directing a laboratory.

NOTE: *Refer to section 353(i)(3) of the PHS Act as amended by the TEST Act, which now states, "No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section (see §493.1840), except that if the revocation occurs pursuant to paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph.*

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and

Interpretive Guidelines §493.1443(a)

The term "State" as used in this provision, includes the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of Northern Mariana Islands, the *U.S.* Virgin Islands, Guam and American Samoa.

(b) The laboratory director must--

(b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(b)(1)(ii) ***Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or***

(b)(2)(i) Be a doctor of medicine, a doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; and

(b)(2)(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1445; or

Interpretive Guidelines §493.1443(b)(2)(ii) and (iii)

NOTE: *See §493.2 for the definition of continuing education (CE) credit hours and experience directing or supervising.*

(b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or

(b)(3)(i)(B) Hold an earned doctoral degree; and

(b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or

(b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(b)(3)(ii) Be certified and continue to be certified by a board approved by HHS; and

(b)(3)(iii) Have at least 2 years of:

(b)(3)(iii)(A) Laboratory training or experience, or both; and

(b)(3)(iii)(B) Laboratory experience directing or supervising high complexity testing; and

(b)(3)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in §493.1445; or

Interpretive Guidelines §493.1443(b)(3)

An individual with a doctoral degree that does not meet the definition at 493.2 may qualify under 493.1443(b)(3)(i)(B).

"Certified" means the individual has completed all the designated board's requirements, including the examination. Currently approved boards are:

ABB - American Board of Bioanalysis,

ABB - Public Health Microbiology certification,

ABCC - American Board of Clinical Chemistry,

ABFT - American Board of Forensic Toxicology (limited to individuals with a doctoral degree),*

ACHI - American College of Histocompatibility and Immunogenetics (formerly known as American Board of Histocompatibility and Immunogenetics (ABHI)),

ABMGG - American Board of Medical Genetics and Genomics (formerly ABMG - American Board of Medical Genetics),

ABMLI - American Board of Medical Laboratory Immunology,

ABMM - American Board of Medical Microbiology,

DMLI - Diplomate in Medical Laboratory Immunology,
American Society for Clinical Pathology (ASCP) Board of Certification (BOC)

NRCC - National Registry for Certified Chemists – Clinical Chemist or Toxicological Chemist certifications only (limited to individuals with a doctoral degree),*

****NOTE:** ABFT and NRCC also certify non-doctoral individuals; however, the director of high-complexity testing must have a doctoral degree.*

(b)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

Interpretive Guidelines §493.1443(b)(4)

The grandfathering provision will allow individuals already qualified and employed as a laboratory director of high complexity testing as of the effective date of the final rule December 28, 2024, to continue to be qualified under the new provisions provided the individuals remain continuously employed in their position after the effective date of

December 28, 2024. To be considered to be "continuously employed," in their position, the individual may have no more than 6 months of break in employment in their position in a two-year period.

The responsibility is on the individual to provide documentation showing their eligibility to meet this provision.

(b)(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology.

D6079
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

Interpretive Guidelines §493.1445

The requirement that a laboratory must be under the direction of a qualified person is not automatically met simply because the director meets the education and experience requirements. It must be demonstrated that the individual is, in fact, providing effective direction over the operation of the laboratory.

In determining whether the director responsibilities are met, consider deficiencies found in other conditions, e.g., facility administration, general laboratory systems, preanalytic systems, analytic systems, postanalytic systems, and proficiency testing.

If the laboratory has more than one person qualifying as a director, one individual must be designated as accepting ultimate responsibility for the overall operation and administration of the laboratory. *These responsibilities must be delegated in writing.*

(a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under §§493.1447, 493.1453, 493.1459, and 493.1487, respectively.

Interpretive Guidelines §493.1445(a)

An individual qualified as laboratory director under §493.1443 may not qualify as technical supervisor in a particular specialty or subspecialty unless he or she has the required training or experience. If the director of high complexity testing is not qualified

to perform the duties of the technical supervisor or clinical consultant, he or she must employ individual(s) meeting the respective qualifications.

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

Interpretive Guidelines §493.1445(b)

The laboratory director may reapportion to a technical supervisor, in writing, the responsibilities in: §§493.1445(e)(3), (4), (5), (6), (7), (12), (13), and (14).
The laboratory director may reapportion to a clinical consultant, in writing, the responsibilities in: §§493.1445(e)(8) and (9).

The only responsibilities that may be delegated to the general supervisor are listed at §§493.1463(b)(1)-(4).

D6080
(Rev.)

§493.*1445* Standard: Laboratory director responsibilities.

(c) The laboratory director must:

(c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and

(c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

Interpretive Guidelines §493.1445(c)(2)

The on-site visits are meant to supplement regular interactions between off-site directors and the lab (for example, by telephone or other telepresence). Documentation of laboratory director's on-site visits should demonstrate the laboratory is in continuous compliance with current laws and regulations, including but not limited to the assessment of the physical environment for safe laboratory testing. The laboratory director's on-site visits cannot be delegated.

The laboratory director determines the type or process of documentation needed as evidence of performing on-site visits. Documentation may include, but is not limited to, sign in/sign out logs, meeting minutes/summary, notes of observations, and travel vouchers.

D6081
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(d) Each individual may direct no more than five laboratories.

Interpretive Guidelines §493.1445(d)

An individual may serve as a director of 5 nonwaived certified laboratories. However, an individual may serve as technical consultant, clinical consultant or technical supervisor for any number of laboratories.

D6082
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e) The laboratory director must--

(e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

D6083
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and

D6084
(Rev.)

§493.*1445* Standard: Laboratory director responsibilities.

provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

Interpretive Guidelines §493.1445(e)(2)

OSHA/EPA issues cannot be cited using these requirements.

If you observe or obtain information regarding potential safety violations not applicable under CLIA, notify the appropriate State or local authority. Consult *CMS* for notification to other Federal agencies such as the Occupational Safety and Health Administration (OSHA) www.osha.gov, Environmental Protection Agency (EPA) www.epa.gov, or Nuclear Regulatory Commission (NRC). The appropriate Federal, State or local authority, if warranted, will investigate and, if necessary, conduct an on-site visit.

D6085
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(3) Ensure that--

(e)(3)(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

D6086
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

D6087
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

D6088
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that--

D6089
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;

D6090
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(4)(ii) The results are returned within the timeframes established by the proficiency testing program;

D6091
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

D6092
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

D6093
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(5) Ensure that the quality control and *quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;*

D6095
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical

performance for each test system;

D6096
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and

D6097
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(7) that patient test results are reported only when the system is functioning properly;

D6098
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(8) Ensure that reports of test results include pertinent information required for interpretation;

D6099
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

D6100
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under § 493.1489(b)*(5);*

D6101
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

D6102
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(12) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

D6103
(Rev.)

§493.*1445* Standard: Laboratory director responsibilities.

(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

Interpretive Guidelines §493.1445(e)(13)

Personnel performing only preanalytic *(e.g., entering requisitions into a computer system)* and postanalytic activities *(e.g., sending final reports)* are not required to be listed on Form 209. Surveyors do not normally check for documented competency evaluation on these individuals. However, if you discover problems *in the preanalytic and postanalytic activities related to testing personnel not listed on the Form CMS-209, cite D6030 or D6103* (laboratory director).

D6106
(Rev.)

§493.*1445* Standard: Laboratory director responsibilities.

(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

Interpretive Guideline §493.1445(e)(14)

The laboratory director can delegate to the technical supervisor the responsibility of making the procedure manual available, but cannot delegate the responsibility for signing*, dating, and approving* new and revised procedures.

D6107
(Rev.)

§493.1445 Standard: Laboratory director responsibilities.

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

Interpretive Guidelines §493.1445(e)(15)

The director must assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process. The list of assigned duties must be current.

D6108
(Rev.)

§493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.

The laboratory must have a technical supervisor who meets the qualification requirements of §493.1449 of this subpart and provides technical supervision in accordance with §493.1451 of this subpart.

Guidelines §493.1447

The Condition of technical supervisor is not met when the technical supervisor:

- Position is not filled;
- Is not qualified; or

- Does not fulfill the technical supervisor responsibilities

D6109
(Rev.)

§493.1449 Standard: Technical supervisor qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

Interpretive Guidelines §493.1449

***NOTE**: See §493.2 for the definition of laboratory training or experience.*

D6111
(Rev.)

§493.1449 Standard: Technical supervisor qualifications.

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor--

(b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(c) Bacteriology, Mycobacteriology, Mycology, Parasitology or Virology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, mycobacteriology, mycology, parasitology, or virology, the individual functioning as the technical supervisor must—

(c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(c)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty; or

(c)(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(c)(3)(i)(B) Meet the requirements in § 493.1443(b)(3)(i)(B); and

Interpretive Guidelines §493.1449(c)(3)(i)

NOTE: *See §493.2 for the definition of an accredited institution, doctoral degree, and laboratory training or experience.*

(c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or

(c)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(c)(4)(i)(B)(1) Meet bachelor's degree equivalency; and

(c)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in chemical, biological, clinical or medical laboratory science, or medical technology; or

(c)(4)(i)(C)(1) Meet bachelor's degree equivalency; and

(c)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, or clinical or medical laboratory science coursework and an approved or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the or the assessment of the health of, human beings; and

(c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or

(c)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(c)(5)(i)(B) Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—

(c)(5)(i)(B)(1) Forty-eight (48) semester hours of medical laboratory technology courses; or

(c)(5)(i)(B)(2) Forty-eight (48) semester hours of science courses that include

(c)(5)(i)(B)(2)(i) Twelve (12) semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry;
(c)(5)(i)(B)(2)(ii) Twelve (12) semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and

(c)(5)(i)(B)(2)(iii) Twenty-four (24) semester hours of chemistry, biology, or medical laboratory science or technology in any combination; and

(c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty.

(d) Diagnostic Immunology, Chemistry, Hematology, Radiobioassay, or Immunohematology - If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology, the individual functioning as the technical supervisor must—

(d)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or

(d)(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(d)(3)(i)(B) Meet the education requirement at § 493.1443(b)(3)(i)(B); and

(d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the applicable specialty; or

(d)(4)(i)(A) Have an earned master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(d)(4)(i)(B) Meet the education requirement at paragraphs (c)(4)(i)(B) or (C) of this section; and

(d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or

(d)(5)(i)(A) Have an earned bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or

(d)(5)(i)(B) Meet the education requirement at paragraph (c)(5)(i)(B) of this section; and

***(d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty*.**

(e) Cytology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must—

(e)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(e)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(e)(2) An individual qualified under paragraph (b) or (e)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraph (b) or (e)(1)(ii) of this section provided the technical supervisor qualified under paragraph (b) or (e)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.

Interpretative guidelines 493.1449(e)(2):

NOTE: Delegation of cytology technical supervisor responsibilities to an individual in the final year of full-time training leading to certification may not include interpretation of cytology specimens.

CMS considers those individuals who have completed their training and are waiting to obtain their board certification to qualify under this regulation.

(f) Histopathology - If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must—

(f)(1) Meet one of the following requirements:

(f)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(f)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or
Interpretive Guidelines 493.1449(f)(1)(i)(B):

An individual who has successfully completed a training program in neuromuscular pathology approved by HHS may examine and provide reports for neuromuscular pathology. In July 2003, HHS approved The American Academy of Neurology Committee for Neuromuscular Pathology Training Program.

(f)(1)(ii) An individual qualified under paragraph (b) of this section or this paragraph (f)(1) may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens.

Interpretive Guidelines 493.1449(f)(1)(ii):

CMS considers those individuals who have completed their residency and are waiting to obtain their board certification to qualify under this regulation.

(f)(2) For tests in dermatopathology, meet one of the following requirements:

(f)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(f)(2)(i)(B) Meet one of the following requirements:

(f)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(f)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology; or

(f)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology; or

Interpretive Guidelines 493.1449(f)(2)(i)(B)(3):Certification in dermatology by the American Osteopathic Board of Dermatology is equivalent to board certification by the American Board of Dermatology.

(f)(2)(ii) An individual qualified under paragraph (b) or (f)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens.

Interpretive Guidelines 493.1449(f)(2)(ii):

CMS considers those individuals who have completed their residency and are waiting to obtain their board certification to qualify under this regulation.

(f)(3) For tests in ophthalmic pathology, meet one of the following requirements:

(f)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(f)(3)(i)(B) Must meet one of the following requirements:

(f)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(f)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or

(f)(3)(ii) An individual qualified under paragraph (b) or (f)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or

Interpretive guidelines 493.1449(f)(3)(ii):

CMS considers those individuals who have completed their residency and are waiting to obtain their board certification to qualify under this regulation.

(g) Oral Pathology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements:

(g)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(g)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(g)(2) Be certified in oral pathology by the American Board of Oral Pathology; or

(g)(3) An individual qualified under paragraph (b) or (g)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (g)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens.

Interpretive Guidelines 493.1449(g)(3):

CMS considers those individuals who have completed their residency and are waiting to obtain their board certification to qualify under this regulation.

(h) Histocompatibility - If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either—

(h)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(h)(1)(ii) Have training or experience that meets one of the following requirements:

(h)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(h)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(h)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or

(h)(2)(i) Have an earned doctoral degree in a biological, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at § 493.1443(b)(3)(i)(B); and

(h)(2)(ii) Have training or experience that meets one of the following requirements:

(h)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(h)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(h)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility.

(i) Clinical cytogenetics- If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must—

(i)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(i)(1)(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or

(i)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at §493.1443(b)(3)(i)(B); and

(i)(2)(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.

(j) Notwithstanding any other provision of this section, an individual is considered qualified as a technical supervisor under this section if they were qualified and serving as a technical supervisor for high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

Interpretive Guidelines §493.1449(j)

The grandfathering provision will allow individuals already qualified and employed as a technical supervisor of high complexity testing as of the effective date of the final rule December 28, 2024, to continue to be qualified under the new provisions provided the individuals remain continuously employed in their position after the effective date of December 28, 2024. To be considered "continuously employed," in their position, the individual may have no more than 6 months of break in employment in their position in a two-year period.

Note 1 to paragraphs (b) through (i): The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

D6112
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

The technical supervisor is responsible for the technical and scientific oversight of

the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

Interpretive Guidelines §493.1451

In a specialty in which neither the director nor the general supervisor can qualify to provide **technical** supervision, the laboratory may engage the services of a qualified person either on a part-time or full-time basis for this service. The technical supervisor is not required to be on the premises full-time or at all times tests are being performed in his/her specialty(ies). However, the technical supervisor must be available to provide consultation and is required to spend an amount of time in the laboratory sufficient to supervise the technical performance of the staff in his/her specialty(ies). There should be documentation, such as a log book or notes from training which indicate the technical supervisor performs his/her assigned duties. The technical supervisor is responsible for evaluating the capabilities of the testing personnel and the general supervisor's testing performance.

D6113
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(a) The technical supervisor must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and

D6114
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(b) The technical supervisor is responsible for--

(b)(1) Selection of the test methodology that is appropriate for the clinical use of the test results;

D6115
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(b)(2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

D6116
(Rev.)

§493.*1451* Standard: Technical supervisor responsibilities.

(b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

Interpretive Guidelines §493.1451(b)(3)

Any laboratory testing patient specimens for the Human Papillomavirus (HPV) must enroll and successfully participate in a CMS-approved proficiency testing program for HPV beginning in 2008. Laboratories should refer to Subpart H for further information. The laboratory's CLIA certificate must include the subspecialty of Virology. The laboratory must also be in compliance with all the CLIA regulations governing the preanalytic, analytic, and postanalytic phases of testing including proficiency testing and personnel requirements.

D6117
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

D6118
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

D6119
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

D6120
(Rev.)

§493.*1451* Standard: Technical supervisor responsibilities.

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

Interpretive Guidelines §493.1451(b)(7)

In some instances, in-service training may be specifically related to an instrument or test, or may be very general in nature. The laboratory may establish its own format, content, and schedule or provide training on an as-needed basis. This is acceptable provided the laboratory does not have deficiencies related to test performance.

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

Interpretive Guidelines §493.1451(b)(8)

The technical supervisor is responsible for assessing the competency of the testing personnel, and the 6 *(six)* competency assessment *procedures* are found under the technical supervisor responsibilities. Depending on the situation, non-compliance can be cited at General Laboratory Systems (D5209/§493.1235), laboratory director *(*D6103/§493.1445*)*, or technical supervisor *(D6120-D6129/§493.1451(b)(8)-§493.1451(b)(9))*.

In order to be able to perform competency assessment, the individual must meet the regulatory qualifications of a TS, and performance of competency assessment should be delegated in writing to the individual.

Probes §493.1451(b)(8)

What mechanism is used to ensure that testing personnel are following the laboratory's policies and procedures? When approved by the director, these policies and procedures may include manufacturer's instructions.

D6121
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

The procedures for evaluation of the competency of the staff must include, but are

not limited to--

(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

D6122
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(b)(8)(ii) Monitoring the recording and reporting of test results;

D6123
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

D6124
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

D6125
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

D6126
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(b)(8)(vi) Assessment of problem solving skills; and

D6127

(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

Interpretive Guidelines §493.1451(b)(9)

The regulations allow laboratory director/technical supervisor to delegate the competency assessment (CA) to the general supervisor (GS). The technical supervisor remains responsible for the evaluations and documentation of CA.

In order to be able to perform competency assessment, the individual must meet the regulatory qualifications of TS or GS, and performance of competency assessment should be delegated in writing to the individual. These individuals may or may not appear on the CMS-209 as a TS or GS.

D6128
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

D6129
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(c) In cytology, the technical supervisor or the individual qualified under §493.1449(*e*)(2)--

(c)(1) May perform the duties of the cytology general supervisor and the cytotechnologist, as specified in §§493.1471 and 493.1485, respectively;

D6130
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(c)(2) Must establish the workload limit for each individual examining slides;

§493.1451(c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary;

D6131
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(c)(4) Must perform the functions specified in §493.1274(d) and (e);

D6132
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(c)(5) Must ensure that each individual examining gynecologic preparations participates in an HHS approved cytology proficiency testing program, as specified in §493.945 and achieves a passing score, as specified in §493.855; and

D6133
(Rev.)

§493.1451 Standard: Technical supervisor responsibilities.

(c)(6) If responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.

D6134
(Rev.)

§493.1453 Condition: Laboratories performing high complexity testing; clinical consultant.

The laboratory must have a clinical consultant who meets the requirements of §493.1455 of this subpart and provides clinical consultation in accordance with §493.1457 of this subpart.

Interpretive Guidelines §493.1453

The Condition of clinical consultant is not met when the clinical consultant:

- Position is not filled;

- Is not qualified; or
- Does not fulfill the clinical consultant responsibilities.

D6135
(Rev.)

§493.1455 Standard: Clinical consultant qualifications.

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must--

(a) Be qualified as a laboratory director under §493.1443(b)(1), (2), or *(3)* or, for the subspecialty of oral pathology, §493.1443(b)(*5*); or

(b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

D6136
(Rev.)

§493.1457 Standard: Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.

D6137
(Rev.)

§493.1457 Standard: Clinical consultant responsibilities.

The clinical consultant must--

(a) Be available to provide consultation to the laboratory's clients;

D6138
(Rev.)

§493.1457 Standard: Clinical consultant responsibilities.

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

D6139
(Rev.)

§493.*1457* Standard: Clinical consultant responsibilities.

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

Probe §493.1457(c)

Has the clinical consultant reviewed the reports to ensure that test results include patient information required for specific patient interpretations?

Has the clinical consultant reviewed the reports to ensure that the correct reference range is listed (i.e. the race-free equation is being used to calculate the estimated glomerular filtration rate (eGFR))?

D6140
(Rev.)

§493.1457 Standard: Clinical consultant responsibilities.

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

D6141
(Rev.)

§493.1459 Condition: Laboratories performing high complexity testing; general supervisor.

The laboratory must have one or more general supervisors who are qualified under §493.1461 of this subpart to provide general supervision in accordance with §493.1463 of this subpart.

Interpretive Guidelines §493.1459

The Condition of general supervisor is not met when the general supervisor:

- Position is not filled;
- Is not qualified; or

- Does not fulfill the general supervisor responsibilities.

D6142
(Rev.)

§493.1461 Standard: General supervisor qualifications.

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

Interpretive Guidelines §493.1461

The type of experience required under this regulation is **clinical** in nature. This means examination and test performance on human specimens for purposes of obtaining information for the diagnosis, treatment, and monitoring of patients, or for providing information to others who will do the diagnosing and treating of the patient's condition.

Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is considered acceptable experience. Research experience is also acceptable experience if it is obtained while performing tests on human specimens. A year of laboratory training and experience is equivalent to 2080 hours and could extend over more than one 12 calendar-month period.

If all testing personnel have associate degrees, but none meet the training or experience requirement for general supervisor, the duties of the general supervisor must be fulfilled by an appropriately qualified individual. This individual need not be on-site at all times.

D6143
(Rev.)

§493.*1461* Standard: General supervisor qualifications.

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) The general supervisor must be qualified as a--

(b)(1) Laboratory director under §493.1443; or

(b)(2) Technical supervisor under §493.1449.

(c) If the requirements of paragraph (b)(1) *or* (2) of this section are not met, the individual functioning as the general supervisor must--

(c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical *or medical* laboratory science, or medical technology from an accredited institution; and

(c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or

(c)(2)(i) Qualify as testing personnel under §493.1489(b)(*3*); and

(c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

(c)(3) Meet the requirements at § 493.1443(b)(3) or § 493.1449(c)(4) or (5); or

(c)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

Interpretive Guidelines §493.1461(c)(4)

The grandfathering provision will allow individuals already qualified and employed as a general supervisor of high complexity as of the effective date of the final rule December 28, 2024, to continue to be qualified under the new provisions provided the individuals remain continuously employed in their position after the effective date of December 28, 2024. The individual may have no more than 6 months of break in employment in their position in a two-year period.

(d) For blood gas analysis, the individual providing general supervision must--

(d)(1) Be qualified under §§493.1461(b)(1) or (2), or 493.1461(c); or

(d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or

(d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and

Interpretive Guidelines §493.1461(d)(3)(i)

NOTE: Many blood gas systems are categorized as moderate complexity tests; therefore, only moderate complexity personnel requirements are applicable. To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity tests), refer to the *"FDA CLIA Complexity Database" at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.*
Test systems, assays, and examinations not yet classified are considered high complexity.

(d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis.

(e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed:

(e)(1) In histopathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or (*f*)(1);

(e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or § 493.1449(f)(2);

(e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or § 493.1449(*f*)(3); and

(e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or (*g*).

Interpretive Guidelines §493.1461(e)

In the case of gross examinations, the technical supervisor may delegate to individuals qualified under §493.1489 the responsibility for the physical examination/description, including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures for which a specific written protocol has been developed. *The delegation should be in writing.*

The technical supervisor is ultimately responsible for the diagnosis related to the gross examination and must sign the examination report. The technical supervisor is not required to provide direct on-site supervision but is responsible for the accuracy of all test results reported. All physical examinations/descriptions of tissue including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures including dissection, inking, marking, and specific orientation for diagnostic interpretation performed in the absence of the technical supervisor by individuals qualified under §493.1489 should be reviewed within 24 hours by the technical supervisor. All microscopic tissue examinations must be performed by individuals qualified under §493.1449(b), (*f*) or (*g*), as appropriate.

There should be documentation of the identity of the personnel performing the grossing portion of the test. The name does not necessarily need to be included in the final report because the final report is under the responsibility of the technical supervisor. The decision to include the name/initials of the person grossing in the final report is a laboratory decision, and does not fall under the CLIA requirements. The grossing information should be recorded and maintained to show who performed the test, somewhere in the test record. During a Mohs procedure the surgical test requisition may be the surgical report. D5787 §493.1283(a)(4)

D6144
(Rev.)

§493.1463 Standard: General supervisor responsibilities.

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

Interpretive Guidelines §493.1463
Interview several testing personnel to elicit information about the duties they perform and the degree of supervision they receive.

D6145
(Rev.)

§493.1463 Standard: General supervisor responsibilities.

(a) The general supervisor--

(a)(1) Must be accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor;

D6146
(Rev.)

§493.1463 Standard: General supervisor responsibilities.

(a)(2) Is responsible for providing day-to-day supervision of high complexity test performance by a testing personnel qualified under §493.1489;

D6147
(Rev.)

§493.1463 Standard: General supervisor responsibilities.

(a)(3) Except as specified in paragraph (c) of this section, must be onsite to provide direct supervision when high complexity testing is performed by any individuals qualified under §493.1489(b)(5); and

D6148
(Rev.)

§493.1463 Standard: General supervisor responsibilities.

(a)(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

D6149
(Rev.)

§493.1463 Standard: General supervisor responsibilities.

(b) The director or technical supervisor may delegate to the general supervisor the responsibility for--

(b)(1) Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

D6150
(Rev.)

§493.1463 Standard: General supervisor responsibilities.

(b)(2) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;

D6151
(Rev.)

§493.1463 Standard: General supervisor responsibilities.

(b)(3) Providing orientation to all testing personnel; and

(b)(4) ***Evaluating and documenting the competency of all testing personnel.***

D6152
(Rev.)

§493.1463 Standard: General supervisor responsibilities.

(c) Exception. For individuals qualified under §493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (a)(3) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.

D6153
(Rev.)

§493.1467 Condition: Laboratories performing high complexity testing; cytology general supervisor.

For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of §493.1469 of this subpart, and provides supervision in accordance with §493.1471 of this subpart.
Interpretive Guideline §493.1467

The Condition of cytology general supervisor is not met when the cytology general supervisor:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the cytology general supervisor responsibilities.

D6155
(Rev.)

§493.1469 Standard: Cytology general supervisor qualifications.

The cytology general supervisor must be qualified to supervise cytology services. The general supervisor in cytology must possess a current license issued by the State in which the laboratory is located, if such licensing is required, and must--

(a) Be qualified as a technical supervisor under §493.1449 (b) or (*e*); or

(b)(1) Be qualified as a cytotechnologist under §493.1483; and

(b)(2) Have at least 3 years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.

Interpretive Guidelines §493.1469(b)(2)

In addition to screening slides in a laboratory, the 3 years of full-time experience as a cytotechnologist can be fulfilled if the individual has been:

- Teaching in schools of cytotechnology;
- Teaching cytotechnology for residency programs in academic institutions; or
- Participating in research directly related to cytotechnology, which includes screening slides, library research, and documentation.

D6156
(Rev.)

§493.1471 Standard: Cytology General Supervisor Responsibilities.

The technical supervisor of cytology may perform the duties of the cytology general supervisor or delegate the responsibilities to an individual qualified under §493.1469.

Interpretive Guidelines §493.1471

The delegation of responsibility should be in writing.

D6157
(Rev.)

§493.1471 Standard: Cytology general supervisor responsibilities.

(a) The cytology general supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

D6158
(Rev.)

§493.1471 Standard: Cytology general supervisor responsibilities.

(b) The cytology general supervisor must--

(b)(1) Be accessible to provide on-site, telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of cytology;

D6159
(Rev.)

§493.1471 Standard: Cytology general supervisor responsibilities.

(b)(2) Document the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified under §493.1274(c));

D6160
(Rev.)

§493.1471 Standard: Cytology general supervisor responsibilities.

(b)(3) For each 24-hour period, document the total number of slides he or she examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

D6161
(Rev.)

§493.1471 Standard: Cytology general supervisor responsibilities.

(b)(4) Document the number of hours spent examining slides in each 24-hour period.

D6162
(Rev.)

§493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist.

For the subspecialty of cytology, the laboratory must have a sufficient number of cytotechnologists who meet the qualifications specified in §493.1483 to perform the functions specified in §493.1485.

D6163
(Rev.)

§493.1483 Standard: Cytotechnologist qualifications.

Each person examining cytology slide preparations must meet the qualifications of §493.1449 (b) or (*e*), or--

D6164
(Rev.)

§493.1483 Standard: Cytotechnologist qualifications.

(a) Possess a current license as a cytotechnologist issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(b)(1) Have graduated from a school of cytotechnology accredited by the *Commission on Accreditation of Allied Health Education Programs (CAAHEP); or*

(b)(2) Be certified in cytotechnology by a certifying agency approved by HHS; or

(b)(3) Notwithstanding any other provision of this section, an individual is considered qualified as a cytotechnologist under this section if they were qualified and serving as a cytotechnologist in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

Interpretive Guidelines §493.1483(b)(3)

The grandfathering provision will allow individuals already qualified and employed as a cytotechnologist as of the effective date of the final rule December 28, 2024, to continue to be qualified under the new provisions provided the individuals remain continuously employed in their position after the effective date of December 28, 2024. The individual may have no more than 6 months of break in employment in their position in a two-year period.

D6165
(Rev.)

§493.1485 Standard: Cytotechnologist *r*esponsibilities.

The cytotechnologist is responsible for documenting--

(a) The slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified in §493.1274(c));

D6166
(Rev.)

§493.1485 Standard: Cytotechnologist responsibilities.

(b) For each 24-hour period, the total number of slides examined or reviewed in the

laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

D6167
(Rev.)

§493.1485 Standard: Cytotechnologist responsibilities.

(c) The number of hours spent examining slides in each 24-hour period.

D6168
(Rev.)

§493.1487 Condition: Laboratories performing high complexity testing; testing personnel.

The laboratory has a sufficient number of individuals who meet the qualification requirements of §493.1489 of this subpart to perform the functions specified in §493.1495 of this subpart for the volume and complexity of testing performed.

Interpretive Guidelines §493.1487

The Condition of Testing Personnel is not met when the testing personnel:

- Are not qualified; or
- Do not fulfill the testing personnel responsibilities.

The criteria used to determine the adequacy of the testing personnel involves evaluating testing personnel responsibilities, ensuring that these responsibilities are specified by the director in writing and are appropriate to ensure compliance with the reporting and recordkeeping requirements, quality control monitoring, quality assessment activities, and proficiency testing participation. Cite this deficiency only when problems are found in areas that can be directly related to insufficient numbers of testing personnel. (Use D6101 to relate the finding regarding insufficient personnel to director responsibilities.)

D6170
(Rev.)

§493.1489 Standard: Testing personnel qualifications.

Each individual performing high complexity testing must--

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

D6171
(Rev.)

§493.1489 Standard: Testing personnel qualifications.

(b) Meet one of the following requirements:

(b)(1) ***Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or***

(b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution;

(b)(2)(ii) Be qualified under the requirements of § 493.1443(b)(3) or §493.1449(c)(4) or (5); or

Interpretive Guidelines §493.1489(b)(2)(ii)

Individuals may qualify under §493.1489(b)(2)(ii). Individuals qualifying at these cross references, § 493.1443(b)(3) or § 493.1449(c)(4) or (5), only need to meet the education requirements for the equivalent degrees.

For the education equivalent qualification requirements at § 493.1443(b)(3), the individual must have an earned doctoral degree, 16 semester hours of earned doctoral level coursework or an approved thesis in biology/chemistry/MT/CLS/MLS.

For the education equivalent qualification requirements at § 493.1449(c)(4), the individual must meet either § 493.1449(c)(4)(i)(B)(2) or (c)(4)(i)(C)(2). The individual must have an earned bachelor's degree, 16 semester hours of earned graduate level coursework in biology/chemistry/MT/CLS/MLS.

For the education equivalent qualification requirements at § 493.1449(c)(5), the individual must have at least 120 semester hours or equivalent.

EXCEPTION: Individuals with a Bachelor of Nursing degree may qualify as testing personnel for high complexity glucometer testing only.

This limited exception allows qualified individuals with a Bachelor of Nursing degree to perform high complexity glucometer testing. The exception is strictly limited to high complexity glucometer testing only.

Bachelor of Nursing degree holders working under this exception are explicitly prohibited from performing any other types of high complexity testing procedures unless they meet the personnel requirements for high complexity testing personnel. Nurses who

have the appropriate science coursework in chemical, biological, clinical or medical laboratory science, or medical technology, may qualify under § 493.1489(b)(2)(ii) or § 493.1489(b)(3) – (5).

Laboratories should maintain documentation that specifically identifies which personnel are authorized to perform which tests. These individuals should be listed on the Form CMS 209 and have competency testing performed.

(b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or—

(b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—

(b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—

(b)(3)(ii)(A)(1) Twenty-four (24) semester hours of medical laboratory technology courses; or

(b)(3)(ii)(A)(2) Twenty-four (24) semester hours of science courses that include—

(b)(3)(ii)(A)(2)(i) Six (6) semester hours of chemistry;

(b)(3)(ii)(A)(2)(ii) Six (6) semester hours of biology; and

(b)(3)(ii)(A)(2)(iii) Twelve (12) semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(b)(3)(ii)(B) Have laboratory training that includes:

(b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or

(b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or

(b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

Interpretive Guidelines §493.1489(b)(4)

Ensure that the military discharge paperwork (i.e., DD Form 214) reflects the occupational specialty and includes weeks of training. The occupational specialty must be related to the laboratory and must be at least 50 weeks long.

(b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

Interpretive Guidelines §493.1489(b)(5)

The grandfathering provision will allow individuals already qualified and employed high complexity testing personnel as of the effective date of the final rule December 28, 2024, to continue to be qualified under the new provisions provided the individuals remain continuously employed in their position after the effective date of December 28, 2024. The individual may have no more than 6 months of break in employment in their position in a two-year period.

(b)(6) For blood gas analysis—
(b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or

(b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or

(b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution.

Interpretive Guidelines §493.1489(b)(6)

This requirement applies only to performance of blood gas analysis procedures which are categorized as high complexity.

NOTE: Some blood gas systems are categorized as moderate complexity tests. Therefore, only moderate complexity personnel requirements are applicable to them. To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity tests), refer to the *"FDA CLIA Complexity Database" at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.*
Test systems, assays, and examinations not yet classified are considered high complexity.

(b)(7) For histopathology, meet the qualifications of §493.1449(b) or (*f*) to perform tissue examinations.

Interpretive Guidelines §493.1489(b)(7)

The tests in histopathology include both gross examination (macroscopic), and microscopic examination of the slide(s) with evaluation and diagnostic interpretation, and diagnostic findings reported.

In the case of gross examinations, the technical supervisor may delegate to individuals qualified under §493.1489 the responsibility for the physical examination/description, including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures for which a specific written protocol has been developed. The technical supervisor is ultimately responsible for the diagnosis related to the gross examination and must sign the examination report. The technical supervisor is not required to provide direct on-site supervision but is responsible for the accuracy of all test results reported. All physical examinations/descriptions of tissue including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures performed in the absence of the technical supervisor by individuals qualified under §493.1489 should be reviewed within 24 hours by the technical supervisor. All microscopic tissue examinations must be performed by individuals qualified under §493.1449(b), (*f*) or (*g*), as appropriate.

D6173
(Rev.)

§493.1495 Standard: Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance and for reporting test results.

Interpretive Guidelines §493.1495

The tests in histopathology include gross examination (macro), microscopic slide evaluation and interpretation with diagnostic reporting.

D6174
(Rev.)

§493.1495 Standard: Testing personnel responsibilities.

(a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

D6175
(Rev.)

§493.1495 Standard: Testing personnel responsibilities.

(b) Each individual performing high complexity testing must--

(b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

D6176
(Rev.)

§493.1495 Standard: Testing personnel responsibilities.

(b)(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;

D6177
(Rev.)

§493.1495 Standard: Testing personnel responsibilities.

(b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

D6178
(Rev.)

§493.1495 Standard: Testing personnel responsibilities.

(b)(4) Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

D6179
(Rev.)

§493.1495 Standard: Testing personnel responsibilities.

(b)(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;

Interpretive Guidelines §493.1495(b)(5):

If, during the survey, testing personnel demonstrate an inability to identify a problem that adversely affects a patient test result, cite *D6102* §493.1445(e)(12) under the director responsibilities.

Some examples of problems that may adversely affect patient test results may include:

- A pleural fluid that is mislabeled as a urine specimen and, therefore, is cultured as

a urine culture;

- Performing a potassium on a hemolyzed sample; or
- Tests are incubated at 37°C when the manufacturer's instructions require 25°C incubation.

D6181
(Rev.)

§493.1495 Standard: Testing personnel responsibilities.

(b)(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications; and

D6182
(Rev.)

§493.1495 Standard: Testing personnel responsibilities.

(b)(7) Except as specified in paragraph (c) of this section, if qualified under §493.1489(b)(5), perform high complexity testing only under the onsite, direct supervision of a general supervisor qualified under §493.1461.

D6183
(Rev.)

§493.1495 Standard: Testing personnel responsibilities.

(c) Exception. For individuals qualified under §493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (b)(7) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.

Subpart Q--Inspection

D8100
(Rev.)

§493.1771 Condition: Inspection requirements applicable to All CLIA-certified and CLIA-exempt laboratories.

(a) Each laboratory issued a CLIA certificate must meet the requirements in §493.1773 and the specific requirements for its certificate type, as specified in §§493.1775 through 493.1780.

(b) All CLIA-exempt laboratories must comply with the inspection requirements in §§493.1773 and 493.1780, when applicable.

D8101
(Rev.)

§493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.

(a) A laboratory issued a certificate must permit CMS or a CMS agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part. A CLIA-exempt laboratory and a laboratory that requests, or is issued a certificate of accreditation, must permit CMS or a CMS agent to conduct validation and complaint inspections.

Interpretive Guidelines §493.1773(a)

If for any reason a facility denies entry to or does not permit you to conduct a survey, the following steps should be taken:

- Explain your authority to conduct the survey and the consequences of failure to permit a survey;
- If necessary, consult with your supervisor or the *CMS*; and
- For failure to permit entry into or inspection of the laboratory, use D8101.

If the laboratory continues to refuse a survey, refer to Subpart R – Enforcement Procedures beginning at §493.1800 and the Adverse Action section of the SOM at 6250.

Conduct complaint surveys on an unannounced basis.

The CLIA application will solicit the laboratory's hours of operation. For complaint or

revisit surveys, you may phone the laboratory to confirm the hours of testing prior to a survey without revealing your identity or the scheduled date.

Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible; accommodate staffing schedules and workloads as much as possible. In facilities providing direct patient care, e.g., physician's offices, clinics, residential care facilities, hospitals, respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.

Maintain documentation for all on-site follow-up surveys in the laboratory's official file.

D8103
(Rev.)

§493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.

(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following:

Interpretive Guidelines §493.1773(b)-(c)

The regulations **do not** require a laboratory to maintain records on-site. During the survey, the laboratory must be able to retrieve copies of all records and necessary information upon request. Determine what constitutes a reasonable timeframe based on the information requested.

(b)(1) Test samples, including proficiency testing samples, or perform procedures.

(b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part.

(b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process (preanalytic, analytic, and postanalytic).

(b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following:

(b)(4)(i) Specimen procurement and processing areas.

(b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports.

(b)(4)(iii) Testing and reporting areas.

(b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires.

(c) Accessible Records and Data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.

(d) Requirement to Provide Information and Data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

D8105
(Rev.)

§493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.

(e) Reinspection. CMS or a CMS agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results.

(f) Complaint inspection. CMS or a CMS agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part.

(g) Failure to permit an inspection or reinspection. Failure to permit CMS or a CMS agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of this part.

Interpretive Guidelines §493.1773(e-g)

If for any reason a facility denies entry to or does not permit you to conduct a survey, the following steps should be taken:

- Explain your authority to conduct the survey and the consequences of failure to permit a survey;
- If necessary, consult with your supervisor or *CMS*; and
- For failure to permit entry into or inspection of the laboratory, use D8101.

If the laboratory continues to refuse a survey, refer to Subpart R – Enforcement Procedures beginning at §493.1800 and the Adverse Action section of the SOM at 6250.

Conduct complaint surveys on an unannounced basis.

The CLIA application will solicit the laboratory's hours of operation. For complaint or revisit surveys, you may phone the laboratory to confirm the hours of testing prior to a survey without revealing your identity or the scheduled date.

Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible, accommodate staffing schedules and workloads as much as possible. In facilities providing direct patient care, e.g., physician's offices, clinics, residential care facilities, hospitals, respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.

Maintain documentation for all on-site follow-up surveys in the laboratory's official file.

§493.1775 Standard: Inspection of laboratories issued a certificate of waiver or a certificate for provider-performed microscopy procedures.

(a) A laboratory that has been issued a certificate of waiver or a certificate for provider-performed microscopy procedures is not subject to biennial inspections.

Interpretive Guidelines §493.1775(a)

To cite deficiencies related to an inspection of a laboratory holding a certificate of waiver or a certificate of provider performed microscopy procedures, use D8100, D8101 and D8103, as appropriate.

D8201
(Rev.)

(b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at any time during the laboratory's hours of operation to do the following:

Interpretive Guidelines §493.1775(b)

In **any** laboratory holding a CLIA certificate, tests listed on the waived list **are not** subject to routine surveys. A survey for waived tests may be conducted **only** when authorized by *CMS* in one of the following instances:

- To collect information on waived tests;
- To determine whether the laboratory is testing beyond its certificate;
- If a complaint is alleged; or
- You have information that the performance of such tests poses an imminent and serious risk that adversely affects patient test results.

When authorized to perform a survey of waived tests, in addition to the requirements in this subpart, refer to the requirements at §493.15, subpart A, and §§493.35, 493.37 and 493.39, subpart B, of these guidelines.

Section 493.35(d) requires that laboratories performing only waived tests and no other tests must agree to permit inspections by HHS in order to receive a certificate of waiver.

Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible, accommodate staffing schedules and workloads as much as possible. In facilities providing direct patient care, (i.e., physician's offices, clinics, residential care facilities, hospitals, etc.), respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.

(b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health.

(b)(2) Evaluate a complaint from the public.

(b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.

Interpretive Guidelines §493.1775(b)(3)

When a laboratory has failed to obtain a registration certificate before performing and reporting patient results for nonwaived testing, notify *CMS* of a possible action by the Office of the Inspector General (OIG) if the laboratory does not obtain the appropriate certificate or cease the nonwaived testing.

(b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.

D8203
(Rev.)

(c) The laboratory must comply with the basic inspection requirements of §493.1773.

D8301
(Rev.)

§493.1777 Standard: Inspection of *l*aboratories *t*hat *h*ave *r*equested or *h*ave *b*een *i*ssued a *c*ertificate of *c*ompliance.

(a) Initial inspection. (a)(1) A laboratory issued a registration certificate must

permit an initial inspection to assess the laboratory's compliance with the requirements of this part before CMS issues a certificate of compliance.

Interpretive Guidelines §493.1777(a)

If for any reason a facility denies entry to or does not permit you to conduct a survey, take the following steps:

- Explain your authority to conduct the survey and the consequences of failure to permit a survey;
- If necessary, consult with your supervisor or *CMS*; and
- For failure to permit entry into or an inspection of the laboratory, use D8101.

If the laboratory continues to refuse a survey, refer to Subpart R – Enforcement Procedures beginning at §493.1800 and the Adverse Action section of the SOM at 6250.

(a)(2) The inspection may occur at any time during the laboratory's hours of operation.

D8303
(Rev.)

(b) Subsequent inspections. (1) CMS or a CMS agent may conduct subsequent inspections on a biennial basis or with such other frequency as CMS determines to be necessary to ensure compliance with the requirements of this part.

(b)(2) CMS bases the nature of subsequent inspections on the laboratory's compliance history.

Interpretive Guidelines §493.1777(b)

In **any** laboratory holding a CLIA certificate, tests listed on the waived list are not subject to routine surveys. A survey for waived tests may be conducted only when authorized by *CMS* in one of the following instances:

- To collect information on waived tests;
- To determine whether the laboratory is testing beyond its certificate;
- If a complaint is alleged; or
- You have information that the performance of such tests poses an imminent and serious risk that adversely affects patient test results.

When authorized to perform a survey of waived tests, in addition to the requirements in this subpart, refer to the requirements at §493.15, subpart A, and §§493.35, 493.37 and 493.39, subpart B, of these guidelines.

Section 493.35(d) requires that laboratories performing only waived tests and no other tests must agree to permit inspections by HHS in order to receive a certificate of waiver.

Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible; accommodate staffing schedules and workloads as much as possible. In facilities providing direct patient care, (i.e., physician's offices, clinics, residential care facilities, hospitals, etc.), respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.

D8305
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

(c) Provider-performed microscopy procedures. The inspection sample for review may include testing in the subcategory of provider-performed microscopy procedures.

D8307
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

(d) Compliance with basic inspection requirements. The laboratory must comply with the basic inspection requirements of §493.1773.

D8401
(Rev.)

§493.1780 Standard: Inspection of CLIA-exempt laboratories or laboratories requesting or issued a certificate of accreditation.

(a) Validation inspection. CMS or a CMS agent may conduct a validation inspection of any accredited or CLIA-exempt laboratory at any time during its hours of operation.

Interpretive Guidelines §493.1780

Validation surveys of accredited laboratories will be conducted by the State survey agencies. Refer to special procedures for accredited laboratories in the SOM. *CMS* is responsible for conducting validations of CLIA-exempt laboratories.

(b) Complaint inspection. CMS or a CMS agent may conduct a complaint inspection of a CLIA-exempt laboratory or a laboratory requesting or issued a certificate of accreditation at any time during its hours of operation upon receiving

a complaint applicable to the requirements of this part.

Interpretive Guidelines §493.1780(b)

In **any** laboratory holding a CLIA certificate, tests listed on the waived list **are not** subject to routine surveys. A survey for waived tests may be conducted **only** when authorized by *CMS* in one of the following instances:

- To collect information on waived tests;
- To determine whether the laboratory is testing beyond its certificate;
- If a complaint is alleged; or
- You have information that the performance of such tests poses an imminent and serious risk that adversely affects patient test results.

When authorized to perform a survey of waived tests, in addition to the requirements in this subpart, refer to the requirements at §493.15, subpart A, and §§493.35, 493.37 and 493.39, subpart B, of these guidelines.

Section 493.35(d) requires that laboratories performing only waived tests and no other tests must agree to permit inspections by HHS in order to receive a certificate of waiver.

Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible, accommodate staffing schedules and workloads as much as possible. In facilities providing direct patient care, (i.e., physician's offices, clinics, residential care facilities, hospitals, etc.), respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.

(c) Noncompliance determination. If a validation or complaint inspection results in a finding that the laboratory is not in compliance with one or more condition-level requirements, the following actions occur:

(c)(1) A laboratory issued a certificate of accreditation is subject to a full review by CMS, in accordance with subpart E of this part and §488.11 of this chapter.

(c)(2) A CLIA-exempt laboratory is subject to appropriate enforcement actions under the approved State licensure program.

(d) Compliance with basic inspection requirements. CLIA-exempt laboratories and laboratories requesting or issued a certificate of accreditation must comply with the basic inspection requirements in §493.1773.

Transmittals Issued for this Appendix

Rev #	Issue Date	Subject	Impl Date	CR#
R166SOM	03/03/2017	Revisions to State Operations Manual (SOM), Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services	03/03/2017	N/A
R147SOM	10/06/2015	Revisions to State Operation Manual (SOM), Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services	01/04/2016	N/A
R140SOM	05/29/2015	Revisions to Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services	05/29/2015	N/A
R01SOM	05/21/2004	Initial Release of Pub 100-07	N/A	N/A