CMS Manual System

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Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 140 **Date: May 29, 2015**

SUBJECT: Revisions to Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services

I. SUMMARY OF CHANGES: Revisions have been made to reflect comments and recommendations from regional office and State Agency surveyors, professional and accrediting organizations, other Health and Human Services components, and a GAO audit. Changes have also been made to include partial deletions of certain subsections affected and to reflect the recent publication of regulations and updates in technologies within the field of laboratory medicine. Standard level headings have been added to all D-tags for ease of use by surveyors.

NEW/REVISED MATERIAL - EFFECTIVE DATE: May 29, 2015
IMPLEMENTATION May 29, 2015

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

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R	Appendix C/D8201 (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:
R	Appendix C/D8203 (c) The laboratory must comply with the basic inspection requirements of §493.1773
R	Appendix C/D8301 §493.1777/Standard; Inspection of laboratories that have requested or have been issued a certificate of compliance
R	Appendix C/D8303 (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.
R	Appendix C/D8305 (c) Provider-performed microscopy procedures. The inspection sample for review may include testing in the subcategory of provider-performed microscopy procedures.
R	Appendix C/D8307 (d) Compliance with basic inspection requirements. The laboratory must comply with the basic inspection requirements of §493.1773.

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2015 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements

	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

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

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

Table of Contents

A. SURVEY PROTOCOLS

Introduction

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

Survey protocols and interpretive guidelines are established pursuant to pertinent sections of the Social Security Act, the Public Health Service Act, the Clinical Laboratory Improvement Amendments (CLIA) of 1988, and the CLIA regulations at 42 CFR Part 493 to provide guidance to personnel conducting surveys of laboratories. The protocols and guidelines clarify and/or explain the Federal requirements for laboratories and are required for use by all surveyors assessing laboratory performance based on these Federal requirements. The same survey protocols are used by the *Centers for Medicare & Medicaid Services (CMS) R*egional *O*ffice (RO) and/or State Agency (SA) surveyors.

The following protocols represent an outcome-oriented method to be used to conduct the survey. The focus of the survey is to assess how the laboratory monitors its operations and ensures the quality of its testing. The intended use of these protocols is to promote consistency in the approach to the survey process, and to ensure that a laboratory's operations are reviewed in a practical, efficient, and effective manner so that at the completion of the survey there is sufficient information to make compliance determinations. While the purpose of the protocols and guidelines is to provide direction in preparing for the survey, conducting the on-site survey, analyzing, evaluating, and documenting survey findings, the surveyor's professional judgment is the most critical element in the survey process.

CMS's objective is not only to determine the laboratory's regulatory compliance but also to assist regulated laboratories in improving patient care by emphasizing those aspects of the regulatory provisions that have a direct impact on the laboratory's overall test performance. CMS promotes the use of an educational survey process, especially on initial laboratory inspection, to help laboratories understand and achieve the quality system concepts. It is the surveyor's objective, using professional judgment, to determine, based on observation of the laboratory's (past and current) practices, interviews with the laboratory's personnel, and review of the laboratory's relevant documented records, whether it is producing quality test results (i.e., accurate, reliable, and timely). The primary objective of the survey process is to determine whether or not the laboratory meets the CLIA requirements. The surveyor meets this objective by employing an outcome-oriented survey process or approach, the intent of which is to focus the surveyor on the overall performance of the laboratory and the way it monitors itself, rather than on a methodical evaluation of each standard-level regulatory requirement.

Surveyors **must** make every effort to minimize the impact of the survey on laboratory operations, patient care activities, and to accommodate staffing schedules and departmental workloads as much as possible. In facilities providing direct patient care *(e.g., physician offices, clinics, residential care facilities, and hospitals),* surveyors must

avoid interrupting or interfering with patient care. Surveyors must respect patient privacy and confidentiality at all times in all survey settings.

Provider-Performed Microscopy (PPM) procedures are moderate complexity tests subject to routine *biennial* surveys except when the laboratory holds a certificate for PPM procedures.

When performing a survey on a facility that conducts PPM procedures, the appropriate requirements at 42 CFR Part 493, Subparts C, H, J, K, M, and Q apply. (Refer to Section IX for information concerning conducting surveys of laboratories holding a certificate for PPM Procedures.)

SOM section 1018A addresses surveys of federally owned entities which includes Indian Health laboratories.

For information concerning conducting surveys of waived testing, refer to Section IX.

The Outcome-Oriented Survey Process *(OOSP)*

The principal focus of the outcome-oriented survey is the effect (outcome) of the laboratory's practices on patient test results and/or patient care. The *OOSP* is intended to direct the surveyor to those requirements that will most effectively and efficiently assess the laboratory's ability to provide accurate, reliable, and timely test results.

In the outcome-oriented survey process, the surveyor reviews and assesses the overall functioning of the laboratory and evaluates the laboratory's ability to perform quality testing; that is, the surveyor evaluates the laboratory's quality system. The quality system requirements in the Introduction to Subpart K and the General Laboratory, Preanalytic, Analytic, and Postanalytic Quality Assessment requirements are appropriate guides for the surveyor to organize the review.

In the outcome-oriented survey process, emphasis is placed on the laboratory's quality system as well as the structures and processes throughout the entire testing process that contribute to quality test results. The surveyor selects a cross-section of information from all aspects of the laboratory's operation for review to assess the laboratory's ability to produce quality results. The surveyor reviews the cross-section of information to verify that the laboratory has established and implemented appropriate ongoing mechanisms for monitoring its practices, and identifying and resolving problems effectively.

If the findings from the review of the laboratory's ongoing mechanisms for ensuring quality test results are sufficient to make the determination of compliance and if the evaluation does not warrant a more in-depth review, the surveyor concludes the survey and asks if the laboratory has any questions about CLIA requirements.

NOTE: Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, includes guidelines and instructions for *the listed* regulatory

requirements and encompasses all types of laboratory facilities. *Surveyors should take care, therefore, to* only *cite to the* portions *of this document that are* applicable to the laboratory operations *and the complexity* of testing performed.

I. Identifying Sources of Information

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

A. Scheduling Surveys

There are three activities associated with scheduling surveys:

- *The intention to survey which is the in-office formulation of a work plan,*
- *Announcing the survey, which is notifying the laboratory (when applicable) of the survey date and time, and*
- *Performing the survey, which is the actual on-site inspection.*

For efficiency when scheduling, attempt to cluster surveys geographically to include initials, recertifications, complaints and validations. Extenuating circumstances require RO review. In instances where the State requires a laboratory survey at a different time frame than CLIA, the State must meet both survey scheduling requirements as efficiently as possible. For example, the State requires a survey before the laboratory can operate in that State. The SA can survey the laboratory for compliance with the State requirements, and return in the appropriate time frame to survey for compliance with the CLIA requirements.

1. *Initial Surveys: In order to permit observation of actual testing during the initial survey, schedule the initial survey to occur at least 90 days after the data entry of the CMS Form-116, but no later than 12 months after the data entry of the CMS Form-116. For example, the CMS Form-116 data entry date is May 10, 2006. The initial survey should be conducted between August 8, 2006 (90th day after May 10, 2006) and May 9, 2007 (365th day after May 10, 2006.) If after the 90 days, a representative from the laboratory states that laboratory testing is not being performed because equipment is not ready, etc., advise the laboratory that the CLIA number will be terminated until such time testing is being performed. If there is suspicion that the laboratory is being operated in a manner that constitutes a risk to human health, schedule an unannounced survey. An unannounced survey is an optionany time there is suspicion of risk to human health.*
2. *Recertification Surveys: Schedule the recertification survey to occur at least 6 months (180 days) prior to the expiration date of the laboratory's current certificate, but no earlier than 12 months prior to the expiration date of the current certificate. For example, the current certificate expiration date is December 31, 2006. The recertification survey should be conducted between December 31, 2005 and July 3, 2006.*

Establish a date and time for the survey once the schedule has been completed. If a laboratory operates more than one shift *or has separate* location*s*, schedule survey hours to include a representative cross-section of shifts or locations, as necessary.

To enhance survey effectiveness and efficiency, except in the case of complaints *or other instances in which you would conduct an unannounced survey,* consider mailing the following forms to the laboratories before the scheduled survey date. Request the laboratory to complete the forms and either return them to the SA or hold them for review during the *on-site* survey.

- Laboratory Personnel Report (CLIA), Form CMS-209 (required) with directions for completing or updating information, adding new personnel or changes in positions or status; and

- Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, Form CMS-116 (required) with signature of current owner/operator/director. (*For counting test volumes, r*efer to Section IX: Additional Information.)

Request the following information be accessible and retrievable at the time of survey:

- Standard operating procedure manual with all test procedures (e.g., package inserts and supplemental information, as necessary);

- Reference laboratories' client services manual, if applicable;

- Records of tests referred to other laboratories;

- Personnel records, including:

    a. Diplomas, certificates, degrees;

    b. Training and experience;

    c. Continuing education;

    d. Competency assessment;

    e. Duties/responsibilities; and

    f. Personnel changes.

- Quality control records, including:

    a. Remedial action information;

b. Calibration and calibration verification records;

c. Statistical limits; and

d. Instrument maintenance and function checks records.

- *All proficiency* testing (PT) *records*, including:

  a. Test runs with PT results;

  b. Direct printouts;

  c. Remedial actions for unsatisfactory results*;*

  d. Copies of the signed PT attestation forms provided by the PT program; and

  e. For nonwaived tests and procedures that are not listed in Subpart I, verification of test or procedure accuracy twice yearly.

- Quality system assessment plan and documentation:

  For each of the systems:

  a. Policies and procedures to monitor, assess, and correct identified problems;

  b. Documentation of ongoing assessment activities, including:

     1. Review of the effectiveness of corrective actions taken;

     2. Revision of policies and procedures to prevent recurrence of problems *and address complaints*; and

     3. Discussion of assessment reviews with staff.

- Safety information; and

- Patient testing records:

  a. Requisition (patient charts may be used);

  b. Work records (direct printouts); and

  c. Patient test reports (patient charts may be used).

B. Announced and/or Unannounced Surveys

Section 353(g)(1) of the Public Health Service Act provides for either announced or unannounced surveys, *but it is generally CMS's policy to use announced surveys.* Complaint or revisit surveys must be conducted on an unannounced basis. *For either an initial CLIA survey or recertification CLIA survey, an unannounced survey may be performed after one appointment is cancelled by the laboratory.* For announced surveys, allow up to *two* weeks' notice. *Refer to SOM, Chapter 6, §6106 for additional guidance regarding announced and/or unannounced surveys.*

When applicable, the laboratory may be notified by telephone or mail. Notification **may** include the actual date and time of the survey. *Use this communication to notify the laboratory about the potential consequences of cancelling an appointment.* Request that the laboratory notify the RO or SA, as appropriate, if its laboratory operations are not conducted during usual hours of operation or only on specific days and times. Surveys are to be conducted during the laboratory's routine hours of operation. Confirm the laboratory's certificate type and advise the laboratory to notify the SA of any changes that would necessitate a different certificate. If the laboratory has applied for a certificate of accreditation, ask the laboratory to provide documentation (e.g., written verification from the accreditation organization) of its accreditation status *prior to going on-site, when possible*.

C. Pre-Survey Preparation

Prior to each survey, review the laboratory's file, including the CLIA-database information. To determine the size of the survey team and the expected time required for the survey, consider the number of sites under the certificate, the scope and volume of testing, and the test complexity.

1. **Personnel -** *Consult the annual laboratory registry to assist with determining whether the director/owner has had a laboratory certificate revoked within the last two years*. Include the completed or updated Form CMS-209 in each survey package. Use this information during the *on-site* survey to evaluate positions currently held by employees in accordance with the requirements. Focus on new personnel since the last survey.

2. **Services Offered** - Review the CLIA application, the list of tests and specialties/subspecialties, and any correspondence from the laboratory to determine the complexity of tests performed. Ascertain whether the laboratory has changed *analytes,* specialties *or subspecialties, or* added/deleted tests or *procedures* since the last survey.

3. **PT -** Review PT records to ensure that the laboratory is enrolled and participating in an approved program for each PT *listed in Subpart I*, specialty, subspecialty, *analyte or test* for which testing is performed. Note any unacceptable, unsatisfactory, or unsuccessful scores and any specialty, subspecialty, *analyte or*

test that is not evaluated by the proficiency testing program provider. Use this information to target particular tests for review during the survey.

4. **File Review**--Evaluate the laboratory's ability to maintain compliance between surveys by reviewing its file for:

    - Previous survey results and plans of correction by noting patterns, number, nature of deficiencies, and dates of correction;

    - Enforcement action(s) taken or in progress, e.g., limitations of the certificate or voluntary withdrawal of a specialty, subspecialty, analyte *or* test due to unsuccessful proficiency testing or loss of qualified personnel; and

    - Complaint allegations noting frequency, significance, severity and, if substantiated, the resolution.

II. Entrance Interview

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

The entrance interview sets the tone for the entire survey. Be prepared, positive, courteous, and make requests, not demands. Upon arrival, present the appropriate identification, introduce other team members, inform the facility's administrator, director, or supervisor of the purpose of the survey, the time schedule, and explain the survey process. Identify a contact person and establish a communication level based on the degree of technical knowledge of the contact person.

If the laboratory consists of multiple testing sites, verify all information concerning testing performed at each site. If one or more sites do not meet the multiple site exceptions in the regulations (42 CFR §§493.35(b), 493.43(b) and 493.55(b)), explain the reason and have the owner/operator/director complete Form CMS-116 for each applicable site. (Refer to Section IX for information concerning conducting surveys of multiple testing sites under one certificate.)

Inform the laboratory that the survey will include a tour of the facility, record review, observation, and interviews with personnel involved in the *preanalytic*, analytic, and *postanalytic* phases of the testing process. Establish personnel availability and discuss approximate time frames for survey completion. Determine whether the deficiencies, when identified, are to be discussed with testing personnel, and explain that an exit conference may be held to discuss survey findings. Refer to the SOM, Chapter 6, §§6124 and 6126, for additional information regarding the exit conference.

Request that the laboratory collect any documents, records, or information that may be needed to complete the survey, and solicit and answer any questions the laboratory may have concerning the survey process.

III. Information Gathering

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

The technique for information gathering includes observation, interviews, and record review and these are usually performed concurrently. The information gathering process is critical in the determination of quality laboratory testing. Gather sufficient information to evaluate the laboratory's operations without being overly intrusive or gathering excessive information. As each laboratory is unique in the services offered, the order of gathering information may be different for each survey. The timing for observing testing and the availability of staff for interview may determine the sequence of the survey.

Consider the laboratory's compliance history (*including, but not limited to*, deficient practices and Plans of Correction). Verify the correction *of* all previously cited deficiencies *and continued compliance with CLIA regulations.* Pay particular attention to deficiencies that the laboratory has failed to correct. Refer to enforcement requirements *at* 42 CFR Part 493, Subpart R, if needed.

A. Organizing the Survey

Consider the following variables when making determinations for organizing the survey and the areas to be reviewed:

- Purpose of the Survey:

    a. Initial or recertification (*r*efer to SOM Chapter 6, §§6112-6114 regarding CLIA recertification using the Alternative Quality Assessment Survey (AQAS)):

    b. Complaint;

    c. Follow-up; and/or

    d. Validation.

- Pre-*S*urvey Information:

    a. Problematic PT;

    b. Previous survey deficiencies;

    c. Complaints; and/or

    d. Enforcement actions.

- Size and Organization of the Laboratory:

    a. Type of instruments/test procedures;

    b. Type of information system(s);

    c. Number of supervisors and testing personnel;

    d. Number of testing sites;

    e. Scheduling of testing (e.g., Stat, daily, weekly shifts);

    f. Number of specialties/subspecialties;

    g. Test volume;

    h. Record availability; and/or

    i. Type of patients/clients served.

B. Observation of Facilities and Processes

Observe the laboratory's physical layout. These observations should include specimen collection and processing, "prep" and clean-up areas, testing and reporting areas, and storage areas. Whenever possible, observe specimen processing and test performance, noting information which would precipitate revisiting an area, interviewing personnel, or requesting records for review. Observe and verify that reagents, kits, and equipment correlate with test menu, clients served and results reported. Also observe whether staffing *and space* appear adequate for test volume. Schedule the survey date/time to observe personnel performing specimen processing, testing, and reporting of results in each specialty/subspecialty of service. If it is not possible to observe testing, ask for a verbal walk-through of the procedure. Do not distract staff when observing operations and personnel activities.

Focus observations on:

- Specimen integrity;
- Quality control performance;
- Skills and knowledge of personnel regarding:

    a. Performance of testing;

    b. Evaluation of test results;

c. Identification and resolution of problems; and

- Interactions of personnel regarding:

a. Availability of supervisor to staff;

b. Communication among personnel *at all levels within the laboratory and with clients; and*

c. *Interaction of laboratory director in laboratory's operations*.

At all times respect patient privacy and do not interfere with patient care and confidentiality.

C. Interviews

Interview the staff to confirm observations and obtain additional information, as necessary. Obtain information to identify personnel interviewed, such as name or code. Ask open-ended questions, e.g., probes from the guidelines, and if necessary, repeat or restate the response given by the staff to confirm what was said.

During the interview of personnel, evaluate their knowledge and skills for performing tests, identifying problems and the methods for corrective and remedial actions. Interviews should include as many staff members as necessary to form a judgment as to the ability of staff to perform their duties. Determine *the validity of any* allegations prior to leaving the laboratory. Do not cite deficient practices without verification. Conduct a follow-up investigation, if appropriate, of allegations that cannot be substantiated during the present survey, e.g., falsified test results or referral of PT specimens to another laboratory for testing.

D. Record Review

Gather relevant information that will reflect the laboratory's ability to provide quality testing from all areas of the laboratory including records encompassing the time period since the last certification survey. Determine all new tests, new test methods, and new equipment added since the prior survey and review documentation relevant to as many of these factors as possible when reviewing laboratory records. The amount of records selected and reviewed is not intended to be statistically valid, but rather a representative cross-section of various records. Avoid predictable patterns of gathering information (e.g., same tests or time periods). Do not allow the laboratory to select the records for review. Consider the types of clients and/or facilities that the laboratory serves, e.g., nursing homes, pediatric, dialysis units, public health clinics, and cancer clinics. Choose a variety of patient records across the laboratory's spectrum of clients. When test information must be gathered from medical records, be considerate when handling these records, as they contain confidential information. If possible, review medical records in the presence of office or laboratory personnel with consideration for confidentiality.

Subpart K delineates the laboratory's responsibility for performing its own internal reviews. This is an excellent starting point for an outcome-oriented survey. Review a cross-section of information selected from records of quality system assessment activities within each of the four systems. Review a cross-section of information *while* simultaneously assessing the laboratory's ability to provide quality test results as well as its ability to identify and correct problems. Refer to the quality system assessment portions of the regulations as a guide for organizing your selection and review of information to assess the laboratory's overall compliance. Investigate further any problems identified but not addressed by the laboratory's quality system assessment. If the laboratory is failing to monitor (or effectively monitor) its own system and correct its problems, you can direct the laboratory to the requirements and the relevant sections for its particular setting.

Make copies of any records needed to support deficient practice *findings*.

Ensure that reviews of PT (Subpart H), Facility Administration (Subpart J), Quality System (Subpart K), and Personnel (Subpart M) include the following:

1. PT

   Laboratories must be appropriately enrolled and *participating* in a CMS approved PT program(s) for each *Subpart I* specialty *and* subspecialty *that they perform. Laboratories also must perform biannual PT that meets 42 CFR 493.1236(c)(1) for any nonwaived tests that they conduct, that do not fall under Subpart I. Verify that both requirements have been met for the* entire period of time the laboratory has been performing each test *or procedure* (not just shortly before the survey).

   If the laboratory has unacceptable *PT scores* or unsatisfactory performance in *a* specialty, subspecialt*y*, *analyte or test* since the last survey, review the specific record, corrective action, and any other data such as education and training of staff associated with PT remediation. Include both patient test results and QC records which were assayed in the same run as the failed PT in the review. In addition:

   - Verify that the laboratory has reported results under the appropriate methodology/instrumentation used for test performance, e.g., automated vs. manual hematology;

   - Verify that the laboratory did not engage in inter-laboratory communications *regarding the PT sample(s) prior to the event cut-off date;*

   - *Verify that the laboratory did not refer its PT samples for testing prior to the event cut-off date;*

- Verify that PT samples were handled, prepared, processed, examined, tested, and reported, to the extent practical, in the same manner as patient samples. *PT samples must not be sent to another laboratory for analysis prior to the event cut-off date.*

- For tests where there is no PT available and/or those *nonwaived* tests performed by the laboratory that are not included in *Subpart I*, determine *whether* the laboratory verifies the accuracy of each test *or procedure* at least twice a year.

2. Facility Administration

Review records for the appropriate retention times and *ensure* the laboratory adheres to appropriate safety, arrangement, space, ventilation, and contamination procedures. If the facility provides transfusion services, verify that the arrangement is current, the blood products are stored appropriately, and transfusion reactions are investigated and reported to the appropriate authorities in a timely manner.

3. Quality System

General Laboratory, Preanalytic, Analytic, and Postanalytic System Quality Assessment–

Using the patient test requisitions, test records, test results, and test reports or, as applicable, patient charts, review all phases of the laboratory testing processes, including instructions for specimen storage. If possible, when reviewing individual patient test results, correlate test requisition(s) or medical record information with final report(s). Refer to Postanalytic Systems Quality Assessment for guidance in reviewing and correlating patient test results. After determining the patient population serviced by the laboratory, e.g., geriatrics, public health clinics, dialysis units, health fairs, and hospitals, review the following:

- A cross-section of patient test results encompassing all specialties and subspecialties of testing performed in the laboratory in sufficient numbers to determine if results vary significantly from expected population norms;

- Worksheets or instrument printouts, looking for outliers, trends, etc., when tests are performed in batches;

- Several worksheets, instrument printouts, or medical records over time for tests performed at random;

- Test results that are disproportionately abnormal or normal; and

- The correlation of initial test results and/or test results of various analytes of a patient over time.

Review QC practices and evaluate whether the laboratory is following its own QC protocols or those procedures specified by the manufacturer. Review QC results, including outliers, shifts, trends, and corrective actions taken, when necessary.

Refer to the establishment and verification of performance specifications at 42 CFR *§*493.1253 for guidance in reviewing the laboratory's policies and criteria for adding a new method, test system or analyte to its test menu.

Correlate reported patient test data with QC data and/or quality systems assessment records to ensure proper performance and documentation of controls. Review original test data (instrument printouts or computer files). Verify that patient results have not been reported when QC data was unacceptable according to the laboratory's protocol.

Consider the following in relation to the laboratory's patient population:

- New methodologies and equipment;
- QC and calibration materials used;
- Source and availability of QC limits;
- Evaluation and monitoring of QC data; and
- Corrective action for QC failures.

4. Personnel

The scope of the review of personnel records (qualifications, training, and competency) will be related to the type of survey, type and complexity of testing performed, and the observations and findings of the survey. For **initial** CLIA certification surveys, evaluate the qualifications and experience of the laboratory director and each technical consultant, technical supervisor, clinical consultant, general and cytology supervisor, and cytotechnologist. Evaluate the qualifications, *training* and experience of a cross-section of testing personnel.

For CLIA **recertification** surveys, it is not necessary to review personnel *qualification* records of individuals previously evaluated unless there have been changes in the individual's position and/or the laboratory's test menu since the last survey. Focus on any new laboratory director, technical consultant, technical supervisor, clinical consultant, general and cytology supervisor, cytotechnologist, and testing personnel. Refer to subpart M for additional information concerning personnel training, experience, competency, qualifications *and responsibilities*.

IV. Assessing Outcome or Potential Outcome

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

If the information gathered indicates that the laboratory has established, implemented, and maintained appropriate ongoing mechanisms for ensuring quality test results by monitoring, evaluating, and resolving any problems in its practices, and findings do not warrant a more in-depth review, conclude the survey. However, if an assessment of the laboratory's performance cannot be made based on the cross-section of information collected, it may be necessary to expand the cross-section (e.g., number of sites, observations, or number of records). If the findings reveal potential problem areas with any test procedures, ensure the review is sufficient in breadth and depth to substantiate whether a negative or potentially negative outcome exists. If a problem or potential problem related to patient test results is found, determine the nature and seriousness of the problem.

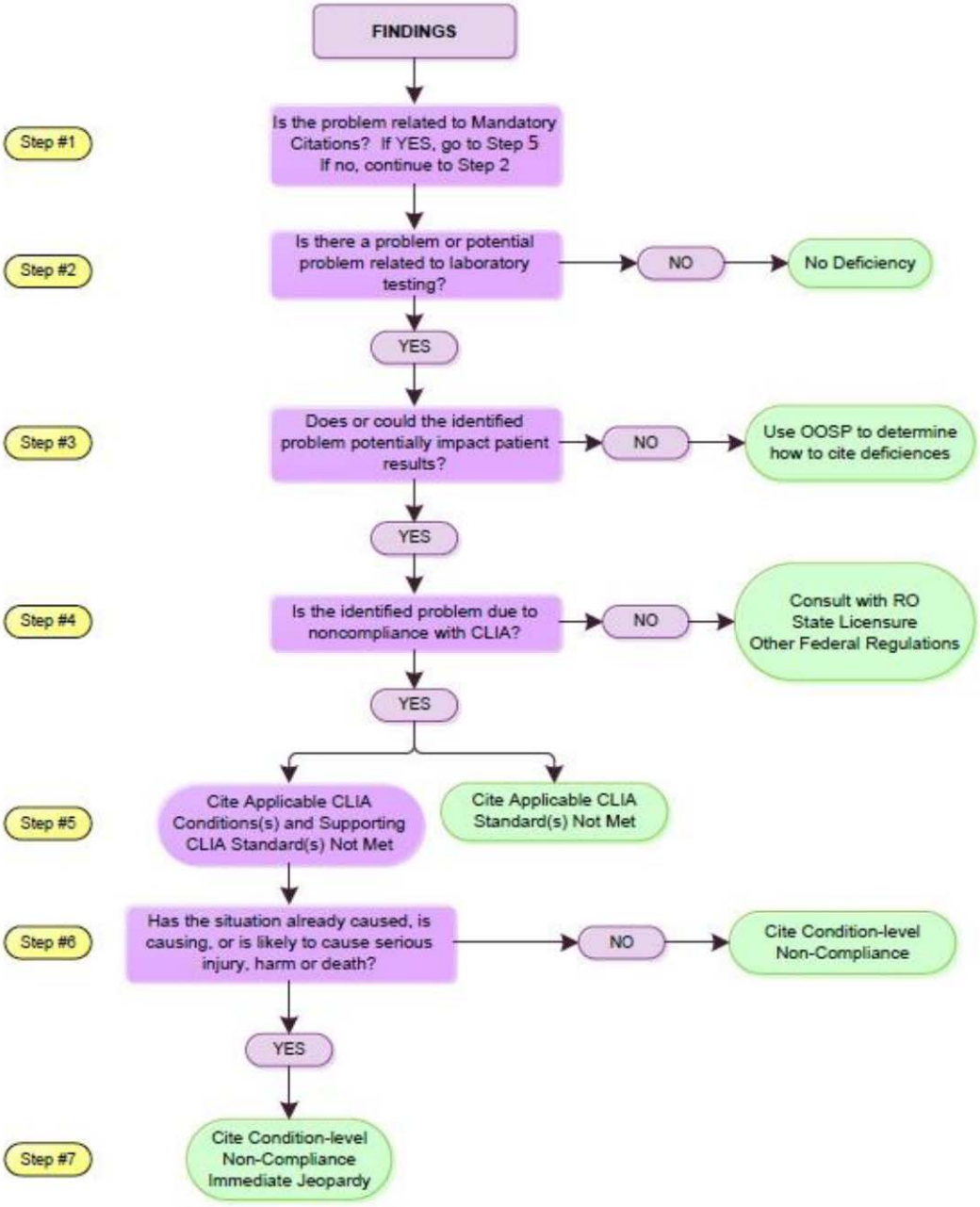
The survey process allows the freedom to increase or decrease the number and types of records reviewed, the personnel interviewed, and the observations made as individual needs are identified.

Analyze the findings for the degree of severity, pervasiveness, *comparison with historical* survey *results*, frequency of occurrence, and impact on delivery of services, i.e., accuracy, reliability, and timeliness of test results. *A single* occurrence of a deficiency directly related to a potential adverse impact on patient testing may be cited. On the other hand, some preliminary findings may have so slight an impact on outcome that they do not warrant a citation. *However, there are four CLIA Condition-level requirements the surveyor must cite if non-compliance is found, regardless of the presence or absence of any negative outcome or potential harm (see VII D. Mandatory Citations).*

Figure 4-1, steps one through four, presents the decision process for whether or not to cite deficiencies during a survey. After a preliminary finding is established by the surveyor, the first step is to determine whether or not it is a mandatory citation. If yes, go to step #5; if no, go to step #2. Step 2 is to determine the problem or potential problem is related to laboratory testing. If the answer is no, then no deficiency is cited. On the other hand, if the answer to this question is yes, then the third step is to determine if the identified problem does or could potentially impact patient test results. If the surveyor determines there is no impact or potential impact to patient test results, then the surveyor uses the OOSP to determine whether deficiencies should be cited. If the surveyor concludes that there is an impact or potential impact to patient test results, then the fourth step is to determine if the problem may be the result of, or otherwise related to, noncompliance with CLIA regulatory requirements. If yes, then the surveyor must cite a deficiency. If no, then consult with the RO on whether other Federal regulations are applicable. If the laboratory is subject to a State Licensure Program, consult with the State Agency supervisor for further instruction.

Note: Any condition-level deficiency is an actionable deficiency. Any standard-level deficiency that has an impact or potential impact on patient test results is also an actionable deficiency.

Figure #4-1 Decision Algorithm for Laboratory Citations



V. Regulatory Compliance Decision

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

After all necessary information has been collected and *the surveyor determines whether any identified laboratory testing-related problems do (or could) negatively impact patient test* outcomes*, and, if so, whether such problems are due to non-compliance with CLIA, the surveyor will need to determine whether CLIA-related non-compliance driven issues constitute* a condition- level deficiency. Review the findings and decide if additional information and/or documentation are necessary to substantiate *and document a standard- or condition-level* deficient practice.

The number of deficiencies *generally* does not *correlate* to whether a *laboratory should be* found out of compliance *with a standard or condition. Standard-level deficiencies require: (1) the documentation of the nature and extent of the deficiencies, if any, with respect to a particular function, i.e., the creation of a list of the deficient practices; and (2) the surveyor to assess the need for improvement in relation to the prescribed conditions, i.e., review standard-level deficiencies to determine condition-level non-compliance. With the exception of the four mandatory condition-level citations discussed in subsection VII.D. below, c*onsider a condition out of compliance *as a result of* one or more deficiencies if, in your judgment, the deficiency(ies) constitutes a significant or a serious problem that adversely affects patient test results/patient care, or has the potential for adversely affecting patient test results/patient care.

Determining Immediate Jeopardy

Immediate jeopardy is defined in 42 CFR §493.2 as "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." *The three components of immediate jeopardy are seriousness, immediacy and harm*. (See 42 CFR §493.1812 providing the enforcement actions to be taken when deficiencies pose immediate jeopardy.) Refer to *Figure 4-1* for guidance in determining *whether to issue condition (and/or standard) citations and what enforcement actions to pursue.*

Figure 4-1, steps four through six, presents the decision steps for citing deficiencies in relation to patient outcome.

In step four, the surveyor cites applicable CLIA Conditions, Mandatory CLIA Citations and/or supporting CLIA Standards that are not met by the laboratory. Upon citing Condition(s), step five is to determine whether the situation already caused, is causing, or likely to cause serious injury, harm or death. If yes, step 6 is to proceed with citing Immediate Jeopardy (IJ) along with the Condition-level non-compliance. If the surveyor concludes no IJ is present, proceed with citing Condition(s) as identified under Step four.

As one works one's way through the chart (Figure 4-1), they would ask:

- What is the seriousness of the problem in relation to patient outcome?

    a. Does/*could* the problem result in inaccurate test results?

    b. Is/*might* the situation *be* one in which immediate corrective action is necessary because the laboratory's noncompliance has already caused, *is causing* or is likely to cause serious injury, harm, or death to individuals served by the laboratory or to the health or safety of the general public?

- What are the regulatory considerations?

    a. Are *CLIA* regulatory *condition or standard level* deficiencies identified?

    b. Do the deficiencies pose an immediate jeopardy to patient health and welfare?

    c. Is/*are* there *any deficiencies subject to* enforcement *actions under the CLIA regulations?*

VI. Exit Conference

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

The purpose of the exit conference is to *provide an overview of* your findings with the laboratory. *It* is not meant to be *an exhaustive discussion of your findings*. It is the continuation of the educational survey process and is the first opportunity for the laboratory to present additional information in response to the findings. Acknowledge staff cooperation and operational support, as appropriate, before addressing the non-compliance issues.

If immediate jeopardy or condition-level deficiencies are identified, inform the laboratory of the seriousness of the problem(s)/finding(s) and indicate that they are not final *until receipt of the written statement of deficiencies Form (CMS-2567).* Consider the following when conducting an exit conference:

- Conduct the exit conference with the facility's administrator, director, consultant, or supervisor, and/or other invited staff;

- Describe the *laboratory practices* that *do* not *appear to be* in compliance *with the regulatory requirements* and the findings that substantiate these *potential* deficiencies;

- Provide the laboratory an opportunity to discuss and provide additional information regarding *potential* deficiencies. It is the laboratory's responsibility to determine the corrective action(s) necessary to remedy the problem(s). *Inform the laboratory that they will receive a written statement of deficiencies (Form CMS-2567) with the final deficiencies cited;*

- Provide instructions and the time frame for submitting a plan of correction *in response to finalized deficiency findings* as referenced in SOM Chapter 6, §6130;

- Refer to SOM Chapter 6, §6126, for additional information on the exit conference including the presence of counsel, taping of the exit conference, and situations that would justify refusal to conduct or continue an exit conference. If a tape is made of the exit conference, get a copy before you leave;

- Inform the facility of your intended recommendation to the RO to certify, recertify, or deny certification of the laboratory; and

- At the exit interview, inform the laboratory (director/administrator/supervisor) of changes in test volumes which may result in fee changes.

VII. Development of the Statement of Deficiencies

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

Choose the most appropriate regulatory *citation and corresponding D-tag* when documenting a deficiency. *For example, if* deficient practices are a result of failure of the laboratory to properly perform quality assessment, cite the deficiency using the quality assessment requirements. *Note, however, where a laboratory does not have a quality assessment program, one should cite the quality assessment requirements and the laboratory director at D6021and/or D6094 for not ensuring that the quality assessment programs are established and maintained to ensure the quality of laboratory services provided.* If deficient practices are *the result of a laboratory's* failure to perform *(*or perform correctly*)* certain *specific* tasks or requirements, then cite the deficiency in the specific area of the regulation such as personnel, general laboratory systems, preanalytic systems, analytic systems or postanalytic systems. Supporting information for documenting deficiencies should be complete, clear, and concise. Write deficiency statements in terms that allow a reasonably knowledgeable person to understand the aspects of the requirements that are not met. Avoid writing the same deficiency in several places. Write your statement of evidence following the format described in the Principles of Documentation *Guidelines (http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html).*

For some cited deficiencies, the Automated Survey Processing Environment (ASPEN) system may request that you list the appropriate specialty or subspecialty identifier code(s) for each *D-tag*. Use the list provided on Form CMS-1557 that identifies the code number for each specialty and subspecialty (e.g., the code number for the specialty of hematology is 400). **This is applicable to standard and condition-level deficiencies**.

A. Citing Standard-Level Deficiencies

If *standard-level* noncompliance has been identified, cite the most specific standard available. For instance, if the deficient practice(s) is related to control procedures:

- Cite the appropriate *D-tag (D5501 – D5773) for* the specialty/subspecialty standards under 42 CFR *§§493.1261 through 493.1278*, which are Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Routine Chemistry, Hematology, Immunohematology, Histopathology, Cytology, Clinical Cytogenetics, and Histocompatibility if such standard is available; OR

- Use the appropriate *D-tag (D5401 – D5485; D5775 – D5793) for* 42 CFR §§493.1251 through 493.1256 and 42 CFR §§493.1281 through 493.1289, if an appropriate *D-tag* is NOT available in the specialty/subspecialty standards.

EXAMPLE: A laboratory performs fluid cell counts using a hemocytometer. The laboratory failed to perform manual fluid cell counts in duplicate. Use D5543.

EXAMPLE: A rheumatologist performs rheumatoid factor (RF) titers. The rheumatologist failed to include control materials for the RF titer. Use D5451.

Where there are underlying standards, condition-level deficiencies can only be cited when standard-level deficiencies have been identified. Remember to cite to standard-level deficiencies when such deficiencies support a finding of condition-level deficiencies.

B. Citing Condition-Level Deficiencies

When the deficient practice is of such a serious nature that correction *is a condition for allowing the laboratory to continue with patient testing,* cite the most appropriate condition and document the finding using the format in the Principles of Documentation. As stated in the Principles of Documentation, the laboratory must correct *all* standard-level deficiencies that are used to support the condition-level noncompliance *finding* before the *laboratory can be found back in compliance with the* condition.

Options within Subpart K

- Specialty and Subspecialty conditions--Use these conditions when *serious* deficiencies are *identified within the* specialty or subspecialty. D5002 - D5042.

- General Laboratory Systems--Use this condition when *serious* deficiencies are *identified within* general laboratory systems. D5200.

- Preanalytic--Use *this condition* when *serious* deficiencies are *identified within* the *preanalytic* phase of testing. D5300.

- Analytic--Use *this condition* when *serious* deficiencies are *identified within the* analytic phase of testing. D5400.

- Postanalytic--Use *this condition* when *serious* deficiencies are *identified within* the postanalytic phase of testing. D5800.

  NOTE: *A serious deficiency is based on the nature and extent of the deficient practice.*

C. Choosing the Appropriate Condition

Review the regulatory language at each of the conditions, noting the requirements that must be met for the condition to be in compliance. For example: The condition of Bacteriology *at* 42 CFR §493.1201 *(D5002)* states the laboratory must meet the requirements at 42 CFR §*§*493.1230 *(D5200)* through 493.1256 *(D5485),* 493.1261 *(D5501 – D5507)* and 493.1281 *(D5775) through* 493.1299 *(D5893)* (covering General Laboratory Systems, Preanalytic Systems, Analytic Systems, and Postanalytic Systems). Serious problems in one or more of these areas can cause the condition of Bacteriology to be out of compliance.

In comparison, the condition statement for Preanalytic Systems *at* 42 CFR §493.1240 (D5300) states the laboratory must meet the requirements at 42 CFR §§493.1241 *(D5301 – D5309),* 493.1242 *(D5311 – D5317),* and 493.1249 *(D5393)* for each specialty or subspecialty of testing. Serious preanalytic deficiencies that are pervasive throughout the laboratory (not related to specific specialties or subspecialties) could cause the condition of Preanalytic Systems to be out of compliance. Caution: An enforcement action based on noncompliance with the condition of General Laboratory Systems, Preanalytic Systems, Analytic Systems or Postanalytic Systems *could* be a revocation or a suspension of the *CLIA* certificate and *would* not *necessarily* be a limitation of the CLIA certificate for one or more specialties.

Standard-level deficiencies written in one subpart cannot be the basis for a condition in another subpart. Deficiencies in Proficiency Testing or Personnel would not be the basis for the condition of Bacteriology to be out of compliance. It is not uncommon for a surveyor to identify issues that crossover between subparts of the regulations. *Cite deficiencies* at the appropriate area of the regulations *that describes the problem.* For example, failures in proficiency testing may be caused by an error in specimen identification, test system malfunction, or lack of training for staff. *Consider citing the most appropriate citation for the laboratory to come into compliance. Avoid citing multiple citations for the same deficiency* unless each *citation* focuses on a different aspect of the *deficiency* (instrument malfunction vs. staff training, *or quality system vs. laboratory director responsibilities, as discussed above*).

The surveyor must consider the deficiencies cited when determining the conditions out of compliance, and also the potential enforcement actions should the laboratory not correct the deficiencies. The organization of the regulations and conditions allows the surveyor

to write a condition out of compliance according to specialty/subspecialty or to the Systems of testing (General Laboratory Systems, Preanalytic Systems, Analytic Systems, or Postanalytic Systems).

EXAMPLE *1*:

A laboratory has one or more standard-level deficiencies related to Bacteriology testing in Preanalytic Systems 42 CFR §493.1241 through 493.1249 (D5301-D5393), Quality Control Procedures 42 CFR § 493.1256 (D5441-D5485) and the Bacteriology subspecialty 42 CFR § 493.1261 (D5501-D5507). The surveyor may determine the condition of Bacteriology 42 CFR § 493.1201 (D5002) is out of compliance based on the deficiencies written under all three systems, Preanalytic, Analytic and Postanalytic. Even though the laboratory conducts testing in other specialty or subspecialty areas, by citing the deficiencies under the condition of Bacteriology, the certificate could be limited for the subspecialty of Bacteriology instead of the entire CLIA certificate being affected.

EXAMPLE *2*:

A laboratory is cited for one or more standard-level deficiencies in Preanalytic Systems 42 CFR §493.1241 through 493.1249 (D5301-D5393) and the deficiencies are related to practices in all the specialties and subspecialties offered by the laboratory. The surveyor determines the condition of Preanalytic Systems is out of compliance. If the laboratory does not correct the condition-level deficiency in Preanalytic Systems, the enforcement action is against the certificate and not a limitation of a specialty or subspecialty.

EXAMPLE *3*:

A laboratory has deficiencies in Bacteriology in the Control Procedures 42 CFR §493.1256 (D5441-D5485), the Bacteriology subspecialty 42 CFR §493.1261 (D5501-D5507), and Routine Chemistry deficiencies in the Control Procedures 42 CFR §493.1256 (D5441-D5485). All deficiencies are within the Analytic System. The surveyor may determine the condition of Bacteriology 42 CFR §493.1201 (D5002) is out of compliance based on the deficiencies cited in Control Procedures 42 CFR §493.1256 (D5441-D5485) and also deficiencies in subspecialty areas for Bacteriology 42 CFR §493.1261 (D5501-D5507).

And the surveyor may determine the condition of Routine Chemistry 42 CFR §493.1210 (D5016) is out of compliance based on deficiencies cited related to Control Procedures 42 CFR §493.1256 (D5441-D5485). Even though the D-tags used to determine condition-level noncompliance in Routine Chemistry are cited in the Control Procedures area, the appropriate condition to mark out of compliance is the applicable subspecialty of Routine Chemistry.

If the laboratory performs testing in only the subspecialties of Bacteriology and Routine Chemistry, and if the deficient practices are pervasive, the surveyor may write the condition of Analytic Systems 42 CFR §493.1250 (D5400) out of compliance.

When a specialty or subspecialty condition is out of compliance, the enforcement action chosen may be a limitation to the certificate for the specialty or subspecialty out of compliance. This approach allows the laboratory to continue testing in those specialties and subspecialties in which compliance was determined. A condition-level deficiency in one of the Systems (General Laboratory Systems, Preanalytic Systems, Analytic Systems, or Postanalytic Systems) indicates a pervasive situation through all specialties and subspecialties offered by the laboratory.

D. Mandatory Citations

There are four CLIA Condition-level requirements the surveyor must cite if non-compliance is found, regardless of the presence or absence of any negative outcome or potential harm. The four CLIA Condition-level requirements are: proficiency testing enrollment, proficiency testing referral, unsuccessful proficiency testing participation and issues related to personnel qualifications.

Table VII-1 provides guidance to surveyors for citing the four mandatory CLIA Condition-level citations. Citations should include the Condition citation and the corresponding D-tag. Where appropriate, surveyors should also provide any Standard - level citations under the condition as well as the standard-level D-tag for those standard-level citations.

The mandatory Condition-level citations and D-tags and the Standard-level citations and D-tags that correspond to the three mandatory PT conditions are:

1. *Enrollment in Proficiency Testing (D2000) (42 CFR §493.801)*
   No minimum standard-level D-tag required. This is the ONLY mandatory Condition-level citation where no Standard-level D-tag is cited in conjunction with the Condition-level D- tag.

2. *Proficiency Testing Referral (D2000) (42 CFR §493.801)*
   - *At a minimum cite the Standard at D2013 (42 CFR §493.801(b)(4))*

3. *Successful Participation in Proficiency Testing (D2016) (42 CFR §493.803)*
   - *At a minimum cite the Standard at any of the following as applicable: D2028, D2037, D2046, D2055, D2064, D2074, D2084, D2085, D2096, D2097, D2107, D2108, D2118, D2119, D2130, D2131, D2162, D2163, D2172, D2181, D2190 or D2191.*

The mandatory Condition-level citations and D-tags, and the potential standard-level citations and D-tags that correspond to the Condition-level personnel qualifications, are:

1. *Laboratory Director PPM (D5980) (42 CFR §493.1355)*
   - *At a minimum cite the Standard at D5981(42 CFR §493.1357)*

2. *Testing Personnel PPM (D5990) (42 CFR §4931361)*
   - *At a minimum cite the Standard at D5991(42 CFR §493.1363)*
3. *Laboratory Director Moderate Complexity Testing (D6000) (42 CFR §493.1403)*
   - *At a minimum cite the Standard at D6003(42 CFR §493.1405)*
4. *Technical consultant Moderate Complexity Testing (D6033) (42 CFR §493.1409)*
   - *At a minimum cite the Standard at D6035(42 CFR §493.1411)*
5. *Clinical Consultant Moderate Complexity Testing (D6056) (42 CFR §493.1415)*
   - *At a minimum cite the Standard at D6057(42 CFR §493.1417)*
6. *Testing Personnel Moderate Complexity Testing (D6063) (42 CFR §493.1421)*
   - *At a minimum cite the Standard at D6065(42 CFR §493.1423)*
7. *Laboratory Director High Complexity Testing (D6076) (42 CFR §493.1441)*
   - *At a minimum cite the Standard at D6078(42 CFR §493.1443)*
8. *Technical Supervisor High Complexity Testing (D6108) (42 CFR §493.1447)*
   - *At a minimum cite the Standard at D6111(42 CFR §493.1449)*
9. *Clinical Consultant High Complexity Testing (D6134) (42 CFR §493.1453)*
   - *At a minimum cite the Standard at D6135(42 CFR §493.1455)*
10. *General Supervisor High Complexity Testing (D6141) (42 CFR §493.1459)*
    - *At a minimum cite the Standard at D6143(42 CFR §493.1461)*
11. *Cytology General Supervisor (D6153) (42 CFR §493.1467)*
    - *At a minimum cite the Standard at D6155(42 CFR §493.1469)*
12. *Cytotechnologist (D6162) (42 CFR §493.1481)*
    - *At a minimum cite the Standard at D6164(42 CFR §493.1483)*
13. *Testing Personnel High Complexity Testing (D6168) (42 CFR §493.1487)*
    - *At a minimum cite the Standard at D6171(42 CFR §493.1489(b))*

Table VII-1

MANDATORY CITATIONS

IF YOU FIND NON-COMPLIANCE WITH. . .		YOU MUST AT LEAST CITE THE *STANDARD* AT D-TAG. . .	YOU MUST AT LEAST CITE THE *CONDITION* AT D-TAG. . .
Non-enrollment in Proficiency Testing 42 CFR § 493.801			D2000
Proficiency Testing Referral 42 CFR § 493.801(b)(4)		D2013	D2000
Unsuccessful Participation in Proficiency Testing 42 CFR § 493.803		D2028, D2037, D2046, D2055, D2064, D2074, D2084, D2085, D2096, D2097, D2107, D2108, D2118, D2119, D2130, D2131, D2162, D2163, D2172, D2181, D2190, OR D2191	D2016
Personnel Qualifications – Subpart M	Laboratory Director PPMP	D5981	D5980
	Testing Personnel PPMP	D5991	D5990
	Laboratory Director Moderate Complexity Testing	D6003	D6000
	Technical Consultant Moderate Complexity Testing	D6035	D6033
	Clinical Consultant Moderate Complexity Testing	D6057	D6056
	Testing Personnel Moderate Complexity Testing	D6065	D6063
	Laboratory Director High Complexity Testing	D6078	D6076
	Technical Supervisor High Complexity Testing	D6111	D6108
	Clinical Consultant High Complexity Testing	D6135	D6134
	General Supervisor High Complexity Testing	D6143	D6141
	Cytology General Supervisor	D6155	D6153
	Cytotechnologist	D6164	D6162
	Testing Personnel High Complexity Testing	D6171	D6168

E. Allegation of Compliance (AOC)/Plan of Correction (POC)

When Condition-level noncompliance is determined by the RO or State Agency surveyor, an AOC is requested.

When a Standard-level noncompliance is determined by the RO or a State Agency surveyor, a POC is requested.

The maximum timeframe for a correction of a standard-level deficiency is 12 months after the last day of the survey; however, depending on the type and seriousness of the deficiency(ies), the acceptable timeframe may be much shorter than 12 months.

There are four elements that are required to be submitted with a POC. Those four elements are:

a. *Documentation describing the corrective actions that have been taken for patients that were identified by the survey and subsequent analysis as having been affected by the deficient practice(s);*
b. *An explanation as to how the laboratory has identified other patients who may have been affected by the deficient practice(s);*
c. *A description of the correction(s) that have been put into place and/or the systemic changes that have been made to ensure that the deficient practice does not recur; and*
d. *How the corrective actions are being monitored to ensure the deficient practice does not recur.*

When Condition-level noncompliance is determined by the RO or a State Agency surveyor, an AOC is requested.

In addition to the above four elements, the AOC is a statement or documentation that is:

a. *Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;*
b. *Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation: and,*
c. *Indicates resolution of the problem(s)*

VIII. Survey Report Documentation and Data Entry

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

Following each survey, as applicable, complete the following additional documentation. This information remains in the official file, either at the SA or RO. Also include Forms CMS-209, appropriate ownership information (completed by the laboratory) and the Alternative Quality Assessment Survey (AQAS) form (completed by the laboratory, if applicable) in the official file.

Form CMS-1557, Survey Report Form (CLIA);

Form CMS-2567, Statement of Deficiencies and Plan of Correction;

Form CMS-2567B, Post Certification Revisit Report;

Form CMS-1539, Certification and Transmittal;

Form CMS-670, Survey Team Composition and Workload Report; and

Form CMS-562, Medicare/Medicaid/CLIA Complaint Form.

Following the survey, enter into the *CLIA database* any revisions, additions, or deletions to the application (Form CMS-116) information. Refer to the CLIA Systems Users Guide for specific information and instruction. Enter into the data system the Certification Kit, which consists of:

Form CMS-1539, Certification and Transmittal;

Form CMS-1557, Survey Report Form (CLIA) - pages 1 and 2;

Form CMS-2567, Statement of Deficiencies and Plan of Correction; and

Form CMS-670, Survey Team Composition and Workload Report.

Enter into the data system, when applicable:

Form CMS-562, Medicare/Medicaid/CLIA Complaint Form.

Form CMS -668B has been developed to assess the survey process from the viewpoint of the laboratory. Leave this form with all laboratories that receive either an *on-site* survey or the AQAS. The laboratory will complete this form *and return it to CO.*

IX. Additional Information

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

A. Counting Tests

Total annual volume for waived tests, if any, should be recorded on the CLIA application (Form CMS-116) in the waived testing section. The total annual volume for nonwaived tests, including PPM procedures, should be reported on the form in the Nonwaived Testing section by specialty and subspecialty. Only tests that are **ordered** and **reported** should be included in the laboratory's test volume(s). Calculations (e.g., A/G ratio, MCH, MCHC, HCT, and T7), QC tests, and PT assays should not be counted.

- For chemistry tests, each non-calculated analyte is counted separately (e.g., Lipid Panel consisting of a total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides equals 4 tests).

- For complete blood counts, each measured individual analyte that is ordered and reported is counted separately. Differentials count as one test.

- For urinalysis, microscopic and macroscopic examinations each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.

- For microbiology, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per test request from each specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification. Each gram stain or acid-fast bacteria (AFB) smear requested from the primary source is counted as one. For example, if a sputum specimen has a routine bacteriology culture and gram stain, a mycology test, and an AFB smear and culture ordered, this would be counted as five tests. For parasitology, the direct smear and the concentration and prepared slide are counted as one test.

- For allergy testing, each allergen is counted as one test.

- *For flow cytometry, each measured individual analyte (e.g. T cells, B cells, CD4, etc.) that is ordered and reported should be counted separately. .*

- For *manual* gynecologic and nongynecologic cytology, each slide (not case) is counted as one test. *Refer to D5643 for counting non-gynecological slide preparations using liquid-based slide preparatory techniques. Refer to D5665 for counting gynecologic cytology slide preparations when using automated and semi-automated screening devices.*

- For immunohematology, each ABO, Rh, antibody screen, cross match, or antibody identification is counted as one test.

- For histocompatibility, each HLA typing (including disease associated antigens) is counted as one test, each HLA antibody screen is counted as one test and each HLA cross match is counted as one test. For example, a B-cell, a T-cell, and an auto-crossmatch between the same donor and recipient pair would be counted as 3 tests.

- For histopathology, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special

stains, including immunohistochemistry, performed on slides to the total number of specimen blocks prepared by the laboratory.

- For cytogenetics, the number of tests is determined by the number of specimen types processed on each patient (e.g., a bone marrow and a venous blood specimen received on one patient are counted as two tests). *NOTE: For all other genetic tests, the number of tests is determined by the number of results reported in the final report.*

- *Genetics tests should be placed in the specialty or subspecialty where they fit best, according to the methodology of the test*.

B. Conducting Surveys of Multiple Testing Sites under One Certificate

1. *Multiple sites will be permitted to operate under a single certificate when the sites meet one of the multiple site exceptions at 42 CFR §§ 493.35(b), 493.43(b), or 493.55(b). Each site performing testing under a* single certificate must meet all applicable requirements of 42 CFR Part 493. Each site is subject to a survey; *however, the primary on-site should be one of the locations included in the initial CLIA certification survey*. Select a representative portion of the remaining locations for on-site survey.

   When choosing the representative sample for multiple site surveys, consider the following:

   - Types of testing performed;
   - Types of clients and/or facilities served, e.g., pediatric, geriatric, residential/emergency care, or health assessment screens;
   - Location(s) participating in PT; and
   - Problems or complaints identified either at the primary or other testing sites.

2. Temporary testing sites, including mobile units, should be inspected using the criteria listed above. Refer to the SOM Chapter 6, §6034 to assist with determining what constitutes a mobile unit and §6036.3 for temporary testing sites. Every effort should be made to schedule the survey to coincide with testing at temporary locations. (Refer to 42 CFR §§493.35(b)(1),493.43(b)(1),493.55(b)(1))

3. Refer to the SOM Chapter 6, §6036.2 for additional information on laboratories performing limited public health testing. These entities should be inspected using the above criteria (Refer to 42 CFR §§ 493.35(b)(2), 493.43(b)(2), 493.55(b)(2))

4. In a hospital laboratory, multiple test sites under one certificate should be inspected using the criteria listed above. (Refer to 42 CFR §§ 493.35(b)(3), 493.43(b)(3), 493.55(b)(3))

Many Home Health Agencies (HHAs) *may be certified with multiple sites under one certificate. A parent HHA may apply for one CLIA certificate as long as these sites are under one HHA Medicare provider number, i.e., parent location. Medicare designates these multiple locations using the term parent location for the main location and the additional sites as branches. Hospices may also be certified with one certificate for multiple sites. Refer to the SOM Chapter 6, §6008 for additional information on HHAs and hospices.*

A laboratory having multiple sites under one certificate is required to enroll in only one PT program(s) for *the primary test system/procedure for* each specialty, subspecialty, analyte *or* test used under that certificate even though the same *specialty*, *subspecialty*, analyte or *test* may be *used* at multiple locations using different test systems *or procedures and different* personnel. *Ensure* that PT records indicate the location at which the tests were performed, and that all other locations have been compared with the system selected for PT, as specified in 42 CFR §493.1281(a).

A condition may be considered out of compliance *even if* deficiencies *are only* found at *a subset of the sites operating under the single certificate.*

C. Conducting Surveys of Waived Tests

In **any** laboratory holding a CLIA certificate, waived tests **are not** subject to routine survey. A survey of waived tests may be conducted **only** when authorized by the RO to:

- 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.*

D. Conducting Surveys of Certificate for PPM Procedures

If a laboratory holds a "Certificate for PPM Procedures," do not conduct a certification or recertification survey of these facilities. However, a survey may be conducted as specified in 42 CFR Part 493, Subpart Q (i.e., *randomly) after RO consultation to*:

- *Determine if* the laboratory is *testing outside its certificate*;

- Collect information regarding the appropriateness of tests specified as PPM;
- *Investigate a complaint from the public; and*
- Determine *if the laboratory is operating and if* testing is performed in a manner that does not constitute an imminent and serious risk to public *health.*

Bear in mind in those instances in which you are performing a survey of PPM procedures, that the appropriate requirements in 42 CFR Part 493 Subparts H, J, K, M, and Q will apply. Furthermore, regardless of the certificate held, in instances in which a survey is occurring in a laboratory with a Certificate of Compliance or Certificate of Accreditation, which has conducted PPM testing, that testing may be included in the sample for the patient testing review portion of the survey.

X. Reporting Complaints

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

The SA/RO investigates allegations of non-compliance that are related to CLIA requirements in laboratories. A complaint about a laboratory should be reported to the appropriate SA or RO contact. The complete list of SA/RO contacts can be found on the CLIA website at www.cms.hhs.gov/clia. ***The RO is responsible for coordinating the responses to all complaints.***

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

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

"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.

"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.

"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.

"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.

"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.

"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.

"Midlevel practitioner" means a nurse midwife, nurse practitioner, 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.

"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).

"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.

"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 either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the National Committee for the Clinical Laboratory Standards (NCCLS). In instances where definitive or reference methods are not available or a specific method’s results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group (“peer” group) may be used. If the method group is less than 10 participants, “target value” means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

Interpretive Guidelines §493.2

The National Reference System for the Clinical Laboratory (NRSCL) no longer exists. The National Committee for the Clinical Laboratory Standards (NCCLS) is now known as the Clinical Laboratory Standards Institute (CLSI).

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

(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)

See §6030 of the 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 §§6002 and 6022 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.

D1000

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

§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 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. *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 the RO 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;

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

§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 the RO 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 Certificate of Waiver 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 manufacture'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 Certificate of Waiver 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. See S&C-04-05.

***NOTE**: It is never acceptable for a laboratory operating under a Certificate of Waiver 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 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*.

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Subpart B--Certificate of Waiver

§493.35 Application for a certificate of waiver

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

(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)

See §6030 of the SOM for instructions on handling a laboratory operating without a CLIA certificate.

(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 the RO to determine which State conducts the inspection. *See §6034 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.

See §6008 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 §*6036.2* 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.*

See §6008 of the SOM for assistance in determining whether laboratories under the same ownership can file a single application.

(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 the RO 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 your RO 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)

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.

§493.39 Notification requirements for laboratories issued a certificate of waiver

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

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

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

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

Interpretive Guidelines §493.39(a) and (b)

See §§6006 and 6030 of the SOM for instructions on handling a laboratory operating without an appropriate CLIA certificate.

See *§6032 of the SOM for applicable instructions on handling changes in ownership, name, location or director.*

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

(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)
See §6030 of the SOM for instructions on handling a laboratory operating without a CLIA certificate.

(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 the RO to determine which State conducts the inspection. See §6034 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.
See §6008 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)

See *§6036.2* of the SOM *for information on* limited public health testing.

See §6008 of the SOM for assistance in determining whether laboratories under the same ownership can file a single application.

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

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 or *a* certificate of waiver prior to performing patient testing.

See §§6006 and 6030 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)

See the Appeals section of the SOM beginning at §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.

§493.51 Notification requirements for laboratories issued a certificate of compliance

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

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 §6016 and §6032 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 Adverse Action section of the SOM beginning at §6256 for instructions on handling laboratories that are going out of business or voluntarily withdrawing from all testing.

Subpart D--Certificate of Accreditation

§493.55 Application for registration certificate and certificate of accreditation

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

(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, the ROs are notified and the approved organizations and programs are published as a notice in the FEDERAL REGISTER.

See *§§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 §6030 of the SOM for instructions on handling a laboratory operating without a CLIA certificate.

(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 the RO to determine which State conducts the inspection. See §6034 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.

See §6008 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 *§6036.2* of the SOM for the definition of limited public health testing.

See §6008 of the SOM for assistance in determining whether laboratories under the same ownership can file a single application.

(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 the RO 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.

§493.61 Requirements for a certificate of accreditation

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

(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 the section of the SOM regarding Special Procedures for Accredited and CLIA-exempt laboratories beginning at §§6152 and 6200 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. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

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 §6016 and §6032 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 Adverse Action section of the SOM beginning at §6256 for instructions on handling laboratories that are going out of business or voluntarily withdrawing from all testing.

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

Subpart H – General Guidelines

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

By law, proficiency testing (PT) programs are evaluated initially for CMS approval and annually thereafter for re-approval. After review, Central Office (CO) 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 http://www.cms.gov/clia.* The RO is responsible for *ensuring that their SAs are aware of the approved program listing for the current year.* Address questions related to the currently approved PT programs to the RO.

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 the RO,* who discusses the findings with CO. CO 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 CO to provide technical *advice*.

D2000

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

§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.

NOTE: If a laboratory has not enrolled for one or more tests that it performs and the tests are listed in Subpart I, cite ONLY D2000, Enrollment and testing of samples; do **not** cite D2016, Successful Participation.

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 Certificate of Waiver. 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 the RO for guidance and resolution.

D2001

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

§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)

For late enrollment, refer to Laboratory Director Responsibilities (D6015 Moderate Complexity or D6088 High Complexity).

D2003

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

§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)

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).

D2004

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

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

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

§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 that 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. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

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

§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. 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.

D2010

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

§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

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

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

(b)(3)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)(3)

Handle allegations of inter-laboratory communications or referral of proficiency testing specimens as a complaint and investigate using the complaint investigation procedures outlined in §6136 of the SOM. Immediately contact the RO if you find evidence to support these kinds of allegations.

D2013

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

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

(b)(4) 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)(4)

The regulation refers to referral of PT specimens *to another laboratory for analysis.*

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 bar on owner/operator) apply equally to all PT testing samples and results.

Do not solicit a Plan of Correction from a laboratory when it has been determined that the laboratory intentionally referred its PT samples to another laboratory for analysis. Immediately notify the RO recommending revocation of the certificate (a statutory requirement) and forward to the RO all documentation necessary to support the findings.

D2015

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

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

(b)(5) 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)(5)

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. 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.

(b)(6) 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)(6)

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

§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.*

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, RO CLIA laboratory consultants 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, notify the laboratory and instruct them 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 RO concurrence.* No on-site review is required to initiate this action.

The laboratory *must* submit an acceptable plan of remedial action, listing projected 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 plan. Satisfactory participation in the next PT event would provide verification that the laboratory's remedial action, training and/or technical assistance were successful. The remedial action plan should demonstrate that the laboratory will correct its problems within 3 months, although special circumstances may be considered. *If* a laboratory refuses to take acceptable training and/or technical assistance actions (including failure to submit an acceptable plan of remedial action, or failure to complete its plan), sanction action *may be initiated with concurrence from the RO*.

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. 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:

A laboratory scores 60% on a testing event in mycobacteriology. On the next testing event, the laboratory fails to participate in mycobacteriology. The citations are D2030 (§493.825), D2037 (§493.825) and D2016 (§493.803). *(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.)*

Example:

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 §§493.841(f), and 493.803. *(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.)*

When recommending to the RO 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.

D2017

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

§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 Report #155 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.

D2021

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

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

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

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

§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.

D2030

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

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

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

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

§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.

D2039

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

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

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

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

§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.

D2048

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

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

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

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

§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.

D2057

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

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

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

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

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

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

D2067

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

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

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

§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.

D2075

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

§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.

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

§493.837 Standard; General immunology

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

D2077

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

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

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

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

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

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

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.

D2088

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

§493.841 Standard; Routine chemistry

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

D2089

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

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

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

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

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

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

§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.

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

§493.843 Standard; Endocrinology

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

D2100

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

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

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

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

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

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

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

§493.845 Standard; Toxicology

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

D2111

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

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

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

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

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

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

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.

D2122

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

§493.849 Condition: Hematology

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

D2123

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

§493.849 Condition: 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. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.849 Condition: 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. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.849 Condition: 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. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

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

§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.

D2133

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

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

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

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

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

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

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

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

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

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

§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

D2147

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

§493.855 Standard; Cytology: gynecologic examinations

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

D2148

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

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

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

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

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

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.

D2155

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

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

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

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

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

§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.

D2165

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

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

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

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

§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.

D2174

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

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

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

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

§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.

D2183

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

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

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

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

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

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

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

§493.1101 Standard: Facilities

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

§493.1101 Standard: Facilities

(a)(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.

D3005

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

§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

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

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

§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 the Regional Office (RO) 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.

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

§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?

D3017

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

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

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

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

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

§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, notify the FDA at:

Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)
Director, Office of Compliance and Biologics Quality
Attn: Fatality Program Manager (HFM-650)
1401 Rockville Pike
Rockville, MD 20852-1448

Voicemail: 301-827-6220

E-mail: fatalities2@cber.fda.gov

Fax: 301-827-6748

NOTE: Send the RO 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.

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

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

§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.

D3031

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

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

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

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

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

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

§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.*

For test reports from histopathology, oral pathology, or cytology that require personnel identifiers or an authorized signature (which may be electronic), the copy must include evidence of the identifiers or signature(s).

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?

(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.

D3043

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

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

§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.

D5012

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

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

§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.

Interpretive Guidelines §493.1208

Tests or procedures to detect or identify antibodies to a bacteria, virus, parasite, etc., are categorized under the subspecialty of General Immunology.

D5016

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

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

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

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

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

§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.

D5040

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

§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.

D5200

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

§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.

Interpretative 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.

D5203

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

§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., aliquotting), 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 should be determined according to the test methodology utilized by the laboratory. Review 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, and incorrect reporting of results?

D5205

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

§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?

Does the laboratory have a mechanism to refer complaints or problems to its reference laboratory(s), or other offices or agencies, when appropriate? Does the laboratory document this activity?

D5207

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

§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 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 handling requirements, is adequate.

D5209

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

§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 deficiencies at this location 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 is the only individual testing and/or reporting 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. This also applies if the LD is also performing patient testing and/or reporting patient test results. When dealing with a LD, cite deficiencies at this location 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, 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

Testing personnel in PPM laboratories, including mid-level practitioners, are required to undergo competency assessment that includes the six procedures found in §493.1413(b)(8). Use D5209 or appropriate Technical Consultant D-tag (D6046 through D6052) relating to competency assessment.

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)?

D5213

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

§493.1236 Standard: Evaluation of proficiency testing performance

(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).*

D5217

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

§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).

D5291

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

§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)-(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, and other laboratories ordering tests, and other non-laboratory areas or departments 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 identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be **written** as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor 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.

An example would be monitoring the type and number of complaints received by the laboratory such as a particular client continuously complaining about the laboratory's failure to promptly respond to STAT test requests. The laboratory must have documentation that the complaint was investigated and appropriate action taken to correct the problem.

Verify that the laboratory has a system in place for monitoring and evaluating confidentiality of patient information.

Probes §493.1239(a)

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

§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.

D5300

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

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

§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.

D5305

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

§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)?

D5311

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

§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?

D5400

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

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

§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)

*P*rocedures 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) and Armed Forces Institute of Pathology (AFIP) 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. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§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 aliquotted 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. Use 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 becomes inoperable.

Interpretive Guidelines §493.1251(b)(14)

Laboratory information systems (LIS) procedures must be available to operators. Instructions should identify the individual(s), either by name or position, to notify if the LIS goes down or if a system error occurs.

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?

D5407

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

§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 and AFIP 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.

D5411

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

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

§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.

(b)(2) Temperature.

(b)(3) Humidity.

(b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

Interpretive Guidelines §493.1252(b)

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 and should be assessed by the laboratory for appropriateness and monitoring. 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.

Temperature-controlled spaces, equipment, and instruments must be monitored and results documented for acceptable temperature ranges. Corrective action is needed when acceptable temperature ranges are exceeded. Use *D5781 when corrective action not documented*.

Continuous monitoring of temperatures by a recording thermograph is acceptable provided the data and time of use are annotated. The charts must be retained to document that temperatures were within the limits established by the laboratory.

In lieu of manual temperature recording, it is acceptable for temperatures to be maintained and monitored internally by the instrument, provided either test results are flagged or not generated when the temperature range for test performance is exceeded.

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 the 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?

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

§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.

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.

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 b*een 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. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§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.

D5427
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§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.

D5429

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

§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 usually divided into two parts:

- Unscheduled repairs when needed; and
- Scheduled preventive maintenance (PM), which is performed to prevent breakdowns or malfunctions, to prolong the life of an instrument and to maintain optimum operating characteristics.

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.

A service contract does not negate the laboratory's responsibility for performing other routine maintenance not included in the maintenance contract. 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. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

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

§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)

A laboratory's maintenance program is usually divided into two parts:

- Unscheduled repairs when needed; and
- Scheduled preventive maintenance (PM) which is performed to prevent breakdowns or malfunctions, to prolong the life of an instrument and to maintain optimum operating characteristics.

Probes §493.1254(b)(1)

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

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

§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.

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.

Test method calibration *procedures 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 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. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§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. 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.*

3. 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).

4. 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. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

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

§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.**

Interpretive Guidelines §493.1256(d)

Considerations for establishing equivalent quality testing

If the laboratory chooses to implement *a* reduced QC frequency for multiple instruments (*i.e.,* the same make*s* and model*s* used to perform the same test*s*) a successful evaluation process must be performed for each instrument for which the *reduced* QC frequency applies. *Further information on the evaluation process can be found on the Equivalent Quality Control Procedures section below (Options 1-3).*

NOTE: The regulations require laboratories to follow test system manufacturer's instructions for performing the testing. This means the laboratory must perform and follow the manufacturer's package insert as approved or cleared by the FDA.

Advancements in laboratory technology have led to test systems that often include internal monitoring systems (electronic, internal, procedural controls, etc.). Electronic controls only monitor the electrical or electronic components of the test system. Internal or procedural controls may only monitor a portion of the analytic process, such as sample addition, instrument/reagents interaction, or test completion. These advancements may allow laboratories flexibility in determining control procedures that provide equivalent quality procedures to the traditional daily testing of two levels of external control materials. However, under no circumstances may the laboratory reduce the frequency of testing external control materials to less than that specified by the manufacturer's test system instructions.

NOTE: Since the purpose of control testing is to detect immediate errors and monitor performance over time, increasing the interval between control testing (i.e., weekly, or monthly) will require a more extensive evaluation of patient test results when a control

failure occurs (see §493.1282). **The director must consider the laboratory's clinical and legal responsibility for providing accurate and reliable patient test results versus the cost implications of reducing the quality control testing frequency**.

Identifying Sources of Error

As a first step, the laboratory must determine the test system's sources of error. The test system instructions (product insert) may contain this information. If this information is not provided, the laboratory should contact the manufacturer to obtain this information in writing and include it in the procedure manual.

Test Systems with Internal and/or Procedural Controls

If internal *and*/or procedural controls are provided as part of the test system, the following information must be determined by the laboratory:

- Whether the internal/procedural control(s) monitor all components of the test system. This information may be included in the package insert. If not, the laboratory must contact the test system's manufacturer to obtain written documentation identifying the components of the test system monitored by the internal/procedural controls and include this information in the laboratory's procedure manual;

- If all components are not monitored, identify those components of the test system that are monitored by the internal/procedural control(s);

- Have a mechanism for monitoring those components of the test system not monitored by the internal/procedural control(s); and

- Evaluate the affect of adverse environmental conditions and the influence of operator variance and techniques.

NOTE: Although manufacturers may assist laboratories by providing quality control instructions, the laboratory is ultimately responsible for the performance of appropriate quality control procedures, including the documentation and interpretation of quality control data. Under subpart M, the director is responsible for ensuring that quality control (use D6020 or D6093 as appropriate) and quality assessment (use D6021 or D6094 as appropriate) programs are established and maintained to *ensure* the quality of laboratory services, including the identification of failures in quality as they occur (use D6022 and D6094).

Equivalent Quality Control Procedures

The equivalent quality control procedures described below **may only be used** for laboratory testing subject to the following control procedure requirements:

- §493.1256(d)(3)(i-iii) – control requirements for quantitative, qualitative and semi-quantitative procedures

- §493.1256(d)(3)(iv) -- test procedures that include an extraction phase (*Option* 1 and 2 below)

- §§493.1267 - 493.1269 – control requirements for routine chemistry and hematology (*Option 1* and 2 below)

As further technological advances are made and additional data becomes available, CMS will, as appropriate, revise the equivalent quality control procedures and/or the eligibility requirements for test procedures that may use equivalent quality control.

***Option* 1. Test Systems with Internal/Procedural Control(s) that Monitor the Entire Analytic Process**

If a test system uses one or more internal/procedural control(s) to monitor *all* of its analytic components **and** the laboratory using the test system successfully completes the evaluation process described below to demonstrate test system stability over time, the laboratory may use the equivalent quality control procedures described below in lieu of performing the applicable procedures specified in the regulations at §493.1256(d)(3)(i)-(iv) and the applicable specialty and subspecialty requirements listed for routine chemistry and hematology at §§493.1267 - 493.1269.

Evaluation Process: The laboratory must perform the test system's internal control procedure(s) in accordance with the manufacturer's instructions (but **not** less frequently than once each day of testing) **and** test two levels of external control material daily for **10 consecutive days of testing.**

- If the internal and external control results are acceptable throughout the evaluation process, the laboratory may reduce the frequency of testing two levels of external control material from daily to **once per calendar month unless the manufacturer requires more frequent and/or additional external control testing.** The laboratory must continue to perform and monitor the internal control(s) in accordance with the manufacturer's instructions, but not less frequently than once each day of testing.

- If **any** internal or external control result is unacceptable during the evaluation process *or* after the laboratory has reduced the frequency for testing external control materials, the laboratory must repeat the unacceptable internal and/or external control.

    a. If the repeat control result(s) are within range, no further corrective action is necessary and the laboratory may, as applicable, resume the evaluation process or continue the reduced frequency of external control testing.

b. If the repeat control result(s) are not acceptable, the laboratory must identify the problem, take appropriate corrective action and follow the requirements at §493.1282(b)(2) before reporting patient test results. **The laboratory must restart and successfully complete the evaluation process before reducing the frequency of testing external control materials.**

- All evaluation process and corrective action activities must be documented.

NOTE: If a laboratory's **existing** QC data for the test system meets the evaluation process protocol described above, the laboratory may reduce the frequency for testing external control materials as specified above.

The laboratory must perform calibration verification (§493.1255), as applicable, and test external control materials (§493.1256) with each complete change of reagents, with each new lot number or shipment of reagents, following major preventive maintenance, or replacement of critical parts that may influence test performance. If the calibration verification and external control results are acceptable, the laboratory may continue monthly external control and daily internal control testing.

For each test, the following ongoing assessment activities are also required**:**

- Proficiency testing:
    - Results must demonstrate acceptable/satisfactory performance as specified in subpart H;
    - Acceptable performance must be demonstrated for testing for which proficiency testing is not required or proficiency testing materials are not available (§493.1236);
- Analytic system quality assessment (§493.1289) activities must demonstrate problems are not occurring; and
- Competency assessment evaluations must demonstrate testing personnel are accurately performing testing as specified in subpart M.

If unacceptable results are obtained for any of the above assessment activities, the laboratory must investigate, identify the problem, document the corrective action(s) taken, and **restart** the evaluation process.

Option **2. Test Systems with Internal/Procedural Control(s) that Monitor a Portion of the Analytic Process**

Some internal/procedural controls monitor only certain components of the test system. Although the test system's manufacturer may suggest other mechanisms to monitor the

component(s) not checked by the internal/procedural controls, the laboratory is ultimately responsible for ensuring that all components of the analytic process are monitored. The laboratory may use the equivalent quality control procedures listed below in lieu of performing the applicable procedures specified in the regulations at §493.1256(d)(3)(i)-(iv) and the applicable specialty and subspecialty requirements listed for routine chemistry and hematology at §§493.1267-493.1269, when it can demonstrate the test system's stability over time. This may be substantiated by successfully completing the evaluation process described below.

Evaluation Process: The laboratory must perform the test system's internal control procedure(s) in accordance with the manufacturer's instructions (but **not** less frequently than once each day of testing) and test two levels of external control material daily for **30 consecutive days of testing**.

- If the internal and external control results are acceptable throughout the evaluation process, the laboratory may reduce the frequency of testing two levels of external control material from daily to **once per calendar week unless the manufacturer requires more frequent and/or additional external control testing**. The laboratory must continue to perform and monitor the internal control(s) in accordance with the manufacturer's instructions, but not less frequently than once each day of testing.

- If **any** internal or external control result is unacceptable during the evaluation process or after the laboratory has reduced the frequency for testing external control materials, the laboratory must repeat the unacceptable internal and/or external control.

    - If the repeat control result(s) are within range, no further corrective action is necessary and the laboratory may, as applicable, resume the evaluation process or continue the reduced frequency of external control testing.

    - If the repeat control result(s) are **not** acceptable, the laboratory must identify the problem, take appropriate corrective action and follow the requirements at §493.1282(b)(2) before reporting patient test results. **The laboratory must restart and successfully complete the evaluation process before reducing the frequency of testing external control materials.**

- All evaluation process and corrective action activities must be documented.

NOTE: If a laboratory's **existing** QC data for the test system meets the evaluation process protocol described above, the laboratory may reduce the frequency for testing external control materials as specified above.

The laboratory must perform calibration verification (§493.1255), as applicable, and test external control materials (§493.1256) with each complete change of reagents, with each new lot number or shipment of reagents, following major preventive maintenance, or replacement of critical parts that may influence test performance. If the calibration verification and external control results are acceptable, the laboratory may continue weekly external control and daily internal control testing.

For each test, the following ongoing assessment activities are also required:

- Proficiency testing:
    - Results must demonstrate acceptable/satisfactory performance as specified in subpart H;
    - Acceptable performance must be demonstrated for testing for which proficiency testing is not required or proficiency testing materials are not available (§493.1236);
- Analytic system quality assessment (§493.1289) activities must demonstrate problems are not occurring; and
- Competency assessment evaluations must demonstrate testing personnel are accurately performing testing as specified in subpart M.

If unacceptable results are obtained for any of the above assessment activities, the laboratory must investigate, identify the problem, document the corrective action(s) taken and **restart** the evaluation process.

Option **3. Test Systems without Internal/Procedural Control(s)**

Test systems without internal/procedural controls subject to the extraction phase control requirements at §493.1256(d)(3)(iv) or the specialty or subspecialty requirements at §§493.1261 - 493.1278 are not eligible *to use this* option.

Advancements in laboratory technology have led to the production of test systems that are capable of maintaining stable performance specifications over time and are minimally influenced by adverse environmental conditions and operator variance. While the test system manufacturer should provide the laboratory with written documentation of the test system's stability (which may be included as part of the package insert or operator manual, and must be maintained by the laboratory), the laboratory is responsible for ensuring that all components of the analytic process are monitored. This may be accomplished by testing, at a minimum, two levels of external control material daily. The laboratory may use the equivalent quality control procedures described below in lieu of performing the applicable procedures specified in the regulations at §493.1256(d)(3)(i)-(iii), when it can demonstrate the test system's stability over time.

This may be substantiated by successfully completing the evaluation process described below.

Evaluation Process: The laboratory must perform the test system's control procedures in accordance with the manufacturer's instructions **and**, at a minimum, test two levels of external control material daily for **60 consecutive days of testing**. Because the test system's performance **may** be affected by operator variance, all personnel who will perform the test must participate in the evaluation.

- If the external control results are acceptable throughout the evaluation process, the laboratory may reduce the frequency of testing two levels of external control material from daily to **once per calendar week unless the manufacturer requires more frequent and/or additional external control testing.**

- If **any** external control result is unacceptable during the evaluation process or after the laboratory has reduced the frequency for testing external control material, the laboratory must repeat the unacceptable external control.

    - If the repeat control result(s) are within range, no further corrective action is necessary and the laboratory may, as applicable, resume the evaluation process or continue the reduced frequency of external control testing.

    - If the repeat control result(s) are **not** acceptable, the laboratory must identify the problem, take appropriate corrective action and follow the requirements at §493.1282(b)(2) before reporting patient test results. **The laboratory must restart and successfully complete the evaluation process before reducing the frequency of testing external control materials.**

- All evaluation process and corrective action activities must be documented.

NOTE: If a laboratory's **existing** QC data for the test system meets the evaluation process protocol described above, the laboratory may reduce the frequency for testing external control materials as specified above.

The laboratory must perform calibration verification (§493.1255), as applicable, and test external control materials (§493.1256) with each complete change of reagents, with each new lot number or shipment of reagents, following major preventive maintenance, or replacement of critical parts that may influence test performance. If the calibration verification and external control results are acceptable, the laboratory may continue weekly external control testing.

For each test, the following ongoing assessment activities are also required:

- Proficiency testing:
    - Results must demonstrate acceptable/satisfactory performance as specified in subpart H;
    - Acceptable performance must be demonstrated for testing for which proficiency testing is not required or proficiency testing materials are not available (§493.1236);
- Analytic system quality assessment (§493.1289) activities must demonstrate problems are not occurring; and
- Competency assessment evaluations must demonstrate testing personnel are accurately performing testing as specified in subpart M.

If unacceptable results are obtained for any of the above assessment activities, the laboratory must investigate, identify the problem, document the corrective action(s) taken and **restart** the evaluation process.

§493.1256 Standard: Control procedures

(d)(3) At least once each day patient specimens are assayed or examined perform the following for--

Interpretive Guidelines §493.1256(d)(3)

Laboratories *generally need to* follow manufacturers' test system instructions for control performance and meet the requirements in this section. The laboratory must determine if more extensive (e.g., number, frequency) control testing is necessary. Use D5425.

Immunology:

Determine which immunological methods the laboratory uses and how the laboratory tests quality control materials to check each test component of the test system. Examples of test systems that have multiple components are:

- Complement Fixation (CF);
- Hemagglutination inhibition (HAI);
- Radio-immunoassay (RIA);
- Enzyme immunoassay (EIA);

- Indirect immunofluorescence (IFA);
- Fluorescence Polarization Immunoassay (FPIA);
- Radioimmunoprecipitin assay (RIPA); and
- Radioallergosorbent test (RAST).

Use D5449 or D5451, as appropriate.

Syphilis Serology:

For FTA-ABS tests, does the laboratory employ:

- Reactive control serum in Phosphatase Buffered Solution (PBS);
- Reactive control serum in sorbent;
- Minimally reactive control (1+);
- Non-specific serum control in PBS;
- Non-specific serum control in sorbent;
- Non-specific staining control of PBS; and
- Non-specific staining control of sorbent?

For MHATP or HATTS tests, does the laboratory employ:

- Reactive reference control material;
- Non-reactive reference control material;
- Unsensitized erythrocyte with each specimen;
- Unsensitized erythrocyte with buffer;
- Sensitized erythrocyte with buffer;
- Unsensitized erythrocyte with each reactive control serum; and
- Unsensitized erythrocyte with non-reactive control serum?

Use D5451*as appropriate.*

Probes §493.1256(d):

What data does the laboratory have to support its frequency of testing quality control samples?

How does a mobile laboratory evaluate instrument and reagent stability following relocation to determine the frequency of testing quality control samples?

D5447

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

§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.

D5453

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

§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.

D5471

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

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

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

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

§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 it's 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. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§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.

D5485

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

§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 periodically issue guidance regarding emergent public health issues such as Ebola (see S&C:15-08-CLIA Information for Clinical Laboratories Concerning Possible Ebola Virus Disease).* 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 mechanisms employed to ensure accurate test results. Laboratories are encouraged to use multiple mechanisms (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.

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

(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 mechanism 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), 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.

D5507

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

§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.

When testing is performed daily, for each antimicrobial agent/organism combination, 1 out of every 20 consecutive results may be out of the acceptable range. Any more than 1 out-of-control result in 20 consecutive tests requires corrective action.

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	Non-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*

Non-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.

When testing is performed daily, for each antimicrobial agent/organism combination, 1 out of every 20 consecutive results may be out of the acceptable range. Any more than 1 out-of-control result in 20 consecutive tests requires corrective action.

§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 when shipments of reagents, disks, stains, or antisera for identification systems were opened or when the laboratory prepared these materials.

D5511

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

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

§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 when shipments of reagents, disks, stains, or antisera for identification systems were opened or when the laboratory prepared these materials.

D5517

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

§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.

D5523

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

§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.

D5527
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§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 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.

D5531

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

§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.

D5543

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

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

§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 nonmanual 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 ÷ 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?

D5551

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§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. 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. 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).
http://www/fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm25829.htm.

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.

A minor crossmatch when the donor unit has not been screened for unexpected antibodies. Because all blood collected in FDA registered facilities is required to be screened for unexpected antibodies, this requirement is rarely applicable.

(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

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§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(a) Syphilis testing;
- §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

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§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. No expired blood should 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 must 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)?

D5559

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

§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):

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):

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

§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?

D5607

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

§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.

D5615

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

§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.

D5631

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

§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:

D5639

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

§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?

D5651

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

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

§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.

D5659

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

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

§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.

D5667

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

§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, the actual measurements, reactions, and/or observations and 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 two years, for example: five year retrospective review, 10 percent rescreens, cytology/histology correlations, cytotechnologist's performance evaluations, individual's 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 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?

D5683

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

§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

Culture Type	**Minimum Number of Spreads Counted per Patient**	**Minimum Number of Cells Analyzed per Patient**
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)?

§493.1278 Standard: Histocompatibility

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

(a) General. The laboratory must meet the following requirements.

Interpretive Guidelines **§493.1278(a):**

When condition-level deficiencies in Histocompatibility are identified in any or all phases of testing, cite *D5042*.

D5753

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

§493.1278 Standard: Histocompatibility

(c) Disease-associated studies. The laboratory must check each typing for disease-associated HLA antigens using control materials to monitor the test components and each phase of the test system to ensure acceptable performance.

Interpretive Guidelines §493.1278(c)

Disease association studies are single or limited antigen typings usually performed by serologic typing methods and more rarely performed by flow cytometric methods.

Positive and negative controls must be run with each test.

Control cells must be tested with each lot and shipment of reagents. Use D5753.

For serologic typings, the control cells should include at least two cells known to express the specified antigen and two cells known to express cross-reacting antigens that might

be confused with the specific antigen. Control cells should also include at least two cells lacking the specific and cross-reacting antigen.

For typing sera acceptability, use D5745.

D5761

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

§493.1278 Standard: Histocompatibility

(d)(7) As applicable, have available and follow written criteria and procedures for antibody identification to the level appropriate to support clinical transplant protocol.

Probe §493.1278(d)(7)

Do the laboratory's policies specify when antibody reactivity (positive antibody screen) will be further characterized, (i.e., identification of antibody directed against specific HLA antigens) and the procedures to be used for antibody identification?

D5781

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

§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.

D5785

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

§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 for a test system's reagents *falls outside the acceptable limits*?

D5801

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

§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).

Note: An example of an electronic system that a laboratory or health care provider can contract with is Direct, which provides secure, authenticated, encrypted transport of laboratory test results to an authorized person, their personal representative, and others responsible for using the test results. Laboratories utilizing Direct, in addition to fully supporting the Direct Implementation Guide for Delivery Notification, and meeting all other relevant CLIA requirements, would meet the CLIA regulations for an adequate electronic system for sending test results to the final report destination (§493.1291(a)).

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?*

§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.

D5805

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

§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 generated at a later date.

(c)(4) The test performed.

Interpretive Guidelines §493.1291(c)(4)

For tests that have not been FDA-cleared or approved (including test systems not subject to FDA clearance or approval, methods developed in-house, standardized methods such as textbook procedures, and FDA-cleared or approved test systems modified by the laboratory), the test report must include the statement "The performance characteristics of this test were determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration".

The disclaimer for Analyte Specific Reagents (ASR) should state ["This test was developed and its performance characteristics determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration"]. The ASR disclaimer on the test report is required by the FDA *under 21 CFR, Part 809.30(*e) "Restrictions on the sale, distribution and use of analyte specific reagents."

In either case, 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: site of culture; 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 "sex and/or age specific" normal ranges 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 and any mutations on the test report.

For DNA or nucleic acid based genetic tests, the laboratory should include the test method(s) employed and mutation(s) detected 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), 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?

§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.

D5809

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

§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, or new "normal" *ranges or units of measure available to its clients*.

§493.1291(e) Probes

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

§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 Guidance §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?*

D5813

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

§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?

D5817

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

§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 the interpretations of the codes are available to the authorized person using the test results.

D5819

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

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

§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 to the authorized person, their agent (if applicable) and 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. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

(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 Guidance §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

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§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, and other laboratories ordering tests, and non-laboratory areas or departments 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, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor the corrective action(s) to ensure the action(s) taken has 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 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.

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.

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 (http://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.

D5981

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§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, 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.

D6003

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§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

When qualifying a Laboratory Director, please 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. The certificate of a laboratory which has been excluded from participation under the Medicare program under title XVIII of the Social Security Act [42 U.S.C.A. § 1395 et seq.] because of actions relating to the quality of the laboratory shall be suspended for the period the laboratory is so excluded."*

(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 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 possess qualifications that are equivalent to those required for such certification; or**

Interpretive Guidelines §493.1405(b)(1)(ii)

Board certified means the individual has completed all the designated board's requirements, including the examination. If the director is named in a current edition of "The Official American Board of Medical Specialties (ABMS) Directory of Board Certified Medical Specialists (published by ABMS by Elsevier, 11830 Westline Industrial Drive, St. Louis, Missouri 63146, 1-866-856-8075) as appropriately board certified, this may be accepted as evidence of certification without needing further documentation. You may make a notation of this in the laboratory's file.

Qualifications that are equivalent for certification include board eligibility (i.e., the individual meets all education, training or experience requirements to take the

examination, but has not actually taken and successfully completed the examination.) An individual who wishes to qualify as a director must supply evidence of this eligibility status. The designated boards, upon request, send a letter to the individual confirming his/her eligibility status. Note that some boards set time restrictions for taking the examination. For purposes of the regulations, the individual must meet the education, training or experience required by the board to be eligible to take the examination and must have confirmation of eligibility status.

(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. [Ref: S&C-05-44] 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)

The type of experience required under this regulation is **clinical** in nature. This means directing or supervising personnel who examine and perform tests on human specimens for the purpose of providing information that is used in diagnosing, treating, and monitoring a patient's condition. This experience may include the laboratory director personally examining and performing tests on patient specimens. 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 laboratory director should have documentation, e.g., signed procedure manuals, test reports, worksheets and workcards, that indicates the director assumes the responsibilities in §493.1407.

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.

Ophthalmologists with a doctor of medicine (MD) degree are qualified to direct moderate complexity laboratories, provided they have had at least one year of experience directing or supervising moderate complexity laboratories, or have obtained at least 20

CMEs in laboratory practice commensurate with the laboratory director's responsibilities in §493.1407. [Ref: S&C-05-44]

(b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or

(b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in §493.1407; or

Interpretive Guidelines §493.1405(b)(2)(ii)(B)

The 20 CMEs must be obtained prior to qualifying as a laboratory director. The CME 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 CPT coding would not fulfill this requirement.

For a list of some CME 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 CMEs, verify they include the laboratory director responsibilities detailed in §493.1407.

(b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

Interpretive Guidelines §493.1405(b)(2)(ii)(C)

The residency program should provide the director the knowledge in principles and theories of laboratory practice including: quality control and quality assessment, proficiency testing, the phases of the total process (i.e., preanalytic, analytic and postanalytic), as well as, general laboratory systems, facility administration, and development and implementation of personnel policy and procedure manuals. This training should also include hands-on laboratory testing.

(b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and

Interpretive Guidelines §493.1405(b)(3)

See §493.2 for the definition of an accredited institution.

(b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or

(b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing;

(b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution;

(b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and

(b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or

(b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution;

(b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and

(b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing;

(b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under §493.1406; or

Interpretive Guidelines §493.1405(b)(6)

For tests of moderate complexity, individuals qualify as laboratory directors, if on February 28, 1992, they previously qualified, or could have qualified under the Federal regulations, published on March 14, 1990, as a laboratory director. After February 28, 1992, individuals must meet the requirements at §§493.1405(b)(1)-(5) to qualify as a laboratory director, unless the individual can demonstrate compliance with §493.1405(b)(6), (that is, on February 28, 1992, he or she **could** have qualified as a laboratory director under Federal regulations published on March 14, 1990).

(b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located.

§493.1406 Standard; Laboratory director qualifications on or before February 28, 1992

The laboratory director must be qualified to manage and direct the laboratory personnel and test performance.

(a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and

(b) The laboratory director must:

> **(b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;**
>
> **(b)(2) Be a physician who:**
>
> > **(b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or**
> >
> > **(b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or**
> >
> > **(b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or**
> >
> > **(b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;**
>
> **(b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification;**
>
> **(b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and**
>
> > **(b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of**

Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or

(b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either:

(b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or

(b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or

(b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located.

Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

D6005

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§493.1407 Standard; Laboratory director responsibilities

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

Interpretive Guidelines §493.1407(c)

If the director cannot practically provide personal, *on-site* supervision it must be demonstrated that the director:

- *Provides direction and consultation by telephone or electronic means (e.g. email, text message or fax), as necessary; or*

- Delegates to qualified personnel specific responsibilities as provided in the regulations.

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).

D6006

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§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.

D6010

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§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.

D6030

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§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 and postanalytic activities 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 laboratory and you find that a factor in these problems is poor performance of incompetent staff, cite D6030 or D6103 (laboratory director).

D6031

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

§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 §493.1497(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 new and revised procedures.

D6035

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

§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 possess qualifications that are equivalent to those required for such certification; or**

Interpretive Guidelines §493.1411(b)(1)(ii)

Qualifications that are equivalent for certification include board eligibility, i.e., the individual meets all education, training, or experience requirements to take the examination, but has not actually taken and successfully completed the examination. An individual who wishes to qualify as a technical consultant must supply evidence of this eligibility status. The designated boards, upon request, will send a letter to the individual confirming his/her eligibility status. Note that some boards set time restrictions for taking the examination. For purposes of the regulations, the individual must meet the education, training or experience required by the board to be eligible to take the examination and must have confirmation of eligibility status.

> **(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 one year of laboratory training or experience, or both in non-waived 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) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and**

(b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

Note: **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.**

Interpretive Guidelines §493.1411(b)(3)-(b)(4)

See §493.2 for the definition of an accredited institution.

Some examples of how the one-year requirement for 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.

NOTE: §493.1411(b)(4) requires 2 years of laboratory training or experience and can be met by any combination equivalent to 2 years of laboratory training or experience.

D6038

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

§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.

D6046

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

§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--

All testing personnel must be listed on the CMS Form 209 and must undergo documented competency assessment. The technical consultant/supervisor is responsible for assessing the competency of the testing personnel, and the 6 competency assessment criteria are found under the technical consultant/supervisor responsibilities. Depending on the situation, non-compliance can be cited at General Laboratory Systems (D5209/§493.1235), laboratory director (D6030/§493.1407 or D6103/§493.1445, or technical consultant/supervisor (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.

D6063

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

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

§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

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.

Training may include, but is not limited to, attendance at:

- Seminars given by experts in the field, e.g., a lecture about antibiotic resistance given by the infection control officer of a local hospital;

- On-site or off-site instrument trainings given by a manufacturer, e.g., a week-long training course given at the manufacturer's headquarters, or training by a manufacturer's technical representative on an instrument purchased by a laboratory;

- Technical training sessions, workshops, or conferences given by a professional laboratory organization, e.g., CAP, ASMT, AACC, and ASCT;

- Technical education classes or specialty courses that include hands-on test performance, e.g., parasitology, bacteriology, cytology, given by CDC, a State Health Department, or professional laboratory organizations;

- A formal laboratory training program; or

- Inservices offered by a local hospital laboratory staff, pathologist, or medical technologist to a physician's office personnel.

Documentation may consist of, but is not limited to, letters from training programs or employers, attestation statements by the laboratory director, a log sheet initialed by the attendees indicating attendance at a training session/inservice, certificates from organizations providing the training session, workshop, conference, specialty course.

D6065

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

§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 have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or

Interpretive Guidelines §493.1423(b)(1)

See §493.2 for the definition of an accredited institution.

(b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or

(b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

Interpretive Guidelines §493.1423(b)(3)

Equate similar military courses with different titles. Evaluate the course length and content to *ensure* that it provides effective training for testing personnel. Refer to "A Guide to the Evaluation of Educational Experience in the Armed Services," American Council on Education, Washington, D.C.

(b)(4)(i) Have earned a high school diploma or equivalent; and

Interpretive Guidelines §493.1423(b)(4)

Personnel qualifying under this requirement must have a high school diploma or GED.

Probes §1493.1423(b)(4)

How does the laboratory *ensure* that personnel receiving orientation and training have the necessary skills for properly performing assigned responsibilities?

D6078

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

§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

When qualifying a Laboratory Director, please refer to section 353(i)(3) of the PHS Act 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."

(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 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 possess qualifications that are equivalent to those required for such certification; or**

Interpretive Guidelines §493.1443(b)(1)(ii)

Qualifications that are equivalent for certification include board eligibility, i.e., the individual meets all education, training, or experience requirements to take the examination, but has not actually taken and successfully completed the examination. An individual who wishes to qualify as a director must supply evidence of this eligibility status. The designated boards, upon request, will send a letter to the individual confirming his/her eligibility status. Note that some boards set time restrictions for taking the examination. For purposes of the regulations, the individual must meet the

education, training, or experience as required by the board to be eligible to take the examination and must have confirmation of eligibility status.

(b)(2) 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)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

Interpretive Guidelines §493.1443(b)(2)(i)

The residency program should provide the director the knowledge in principles and theories of laboratory practice including: quality control and quality assessment, proficiency testing, the phase of the total process (i.e., preanalytic, analytic and postanalytic), as well as general laboratory systems, facility administration, and development and implementation of personnel policy and procedure manuals. This training should also include hands-on laboratory testing.

(b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or

Interpretive Guidelines §493.1443(b)(2)(ii)

The type of experience required under this regulation is **clinical** in nature. This means directing or supervising personnel who examine and perform tests on human specimens for the purpose of providing information that is used in diagnosing, treating, and monitoring a patient's condition. This experience may include the laboratory director personally examining and performing tests on patient specimens. 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 laboratory director should have documentation, e.g., signed procedure manuals, test reports, worksheets and workcards, that indicates the director assumes the responsibilities in §493.1445.

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.

(b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and--

(b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or

Interpretive Guidelines §493.1443(b)(3)

See §493.2 for the definition of an accredited institution.

To qualify as a laboratory director of high complexity testing on or after February 24, 2003, individuals possessing a Ph.D. or Dr.P.H. must be board certified by an approved board.

"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)*,

ABHI - American Board of Histocompatibility and Immunogenetics,

ABMG*G* - 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,

NRCC - National Registry for Certified Chemists (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.

An acceptable doctoral degree is a Doctor of Philosophy – Ph.D., Doctor of Science – D.Sc. If acceptable to the board, a Doctor of Dental Surgery – D.D.S., Doctor of Public Health – Dr.P.H.

Laboratory testing of non-human specimens is not acceptable experience, e.g., environmental, animal testing.

(b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least--

(b)(3)(ii)(A) Two years of laboratory training or experience, or both; and

(b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing.

(b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or

Interpretive Guidelines §493.1443(b)(4)

An individual is qualified as a laboratory director if he or she was serving as a laboratory director on or before February 28, 1992. After February 28, 1992, individuals must meet the requirements at §493.1443(b)(1)-(3) to qualify as a laboratory director for high complexity.

In accordance with the regulations, the requirements listed below may be used only for individuals meeting these qualifications and functioning in the position as of February 28, 1992.

The requirements for a laboratory director under 42 CFR 493.1415, published March 14, 1990 (55 FR 9538) are as follows:

(a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and

(b) The laboratory director must:

(b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;

(b)(2) Be a physician who:

(b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties, or

(b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties, or

(b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification, or

(b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for certification;

(b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties, or subsequent to graduation has had 4 or more years of full time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and in addition, either:

(b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or

(b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or

(b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located.

(b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or

Interpretive Guidelines §493.1443(b)(5)

Those individuals qualified after February 28, 1992, as directors solely under State law, will not meet this requirement.

(b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

D6080

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

§493.1445 Standard; Laboratory director responsibilities

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

Interpretive Guidelines §493.1445(c)

If the director cannot practically provide personal, on-site supervision, it must be demonstrated that the director:

- Provides direction and consultation electronically *(e.g., email, text message or fax)* or by telephone, as necessary; or

- Delegates to qualified personnel specific responsibilities as provided in the regulations.

D6084

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

§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 immediate jeopardy exists, inform the director 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) 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.

D6103

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

§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 and postanalytic activities 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 laboratory and you find that a factor in these problems is poor performance of incompetent staff, cite D6030 or D6103 (laboratory director).

D6106

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

§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 new and revised procedures.

D6111

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

§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 or Possesses qualifications that are equivalent to those required for such certification.**

Interpretive Guidelines §493.1449(b)(2)

Qualifications that are equivalent for certification includes board eligibility, i.e., the individual meets all education, training, or experience requirements to take the examination, but has not actually taken and successfully completed the examination. An individual who wishes to qualify as a technical supervisor must supply evidence of this eligibility status. The designated boards, upon request, will send a letter to the individual confirming his/her eligibility status. Note that some boards set time restrictions for taking the examination. For purposes of the regulations, the individual must meet the

education, training or experience required by the board to be eligible to take the examination and must have confirmation of eligibility status.

The tests in histopathology include gross examination (macro) and microscopic slide evaluation and interpretation with diagnostic reporting.

(c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, 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 possess qualifications that are equivalent to those required for such certification; or**

Interpretive Guidelines §493.1449(c)(1)(ii)

NOTE: See Interpretive Guidelines for §493.1449(b)(2)

> **(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 one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or**
>
> **(c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and**

Interpretive Guidelines §493.1449(c)(3)(i)

See §493.2 for the definition of an accredited institution.

> **(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 experience in high complexity testing within the subspecialty of bacteriology; or**
>
> **(c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; 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 experience in high complexity testing within the subspecialty of bacteriology; or

(c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; 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 experience in high complexity testing within the subspecialty of bacteriology.

(d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must--

(d)(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

(d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

Interpretive Guidelines §493.1449(d)(1)(ii)

NOTE: See *Interpretive Guidelines for* §493.1449(b)(2).

(d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or 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 within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

Interpretive Guidelines §493.1449(d)(3)(i)

See §493.2 for the definition of an accredited institution.

(d)(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 experience in high complexity testing within the subspecialty of mycobacteriology; or

(d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(d)(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 experience in high complexity testing within the subspecialty of mycobacteriology; or

(d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(d)(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 experience in high complexity testing within the subspecialty of mycobacteriology.

(e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must--

(e)(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

(e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

Interpretive Guidelines §493.1449(e)(1)(ii)

NOTE: See *Interpretive Guidelines for* §493.1449(b)(2)

(e)(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

(e)(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 experience in high complexity testing within the subspecialty of mycology; or

(e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

Interpretive Guidelines §493.1449(e)(3)(i)

See §493.2 for the definition of an accredited institution.

(e)(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 experience in high complexity testing within the subspecialty of mycology; or

(e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(e)(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 experience in high complexity testing within the subspecialty of mycology; or

(e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(e)(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 experience in high complexity testing within the subspecialty of mycology.

(f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must--

(f)(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

(f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

Interpretive Guidelines §493.1449(f)(1)(ii)

NOTE: See Interpretive Guidelines for §493.1449(b)(2)

(f)(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

(f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology;

(f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

Interpretive Guidelines §493.1449(f)(3)(i)

See §493.2 for the definition of an accredited institution.

(f)(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 experience in high complexity testing within the subspecialty of parasitology; or

(f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(f)(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 experience in high complexity testing within the subspecialty of parasitology; or

(f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(f)(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 experience in high complexity testing within the subspecialty of parasitology.

(g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must--

(g)(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

(g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

Interpretive Guidelines §493.1449(g)(1)(ii)

NOTE: See *Interpretive Guidelines for* §493.1449(b)(2)

(g)(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

(g)(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 experience in high complexity testing within the subspecialty of virology; or

(g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

Interpretive Guidelines §493.1449(g)(3)(i)

See §493.2 for the definition of an accredited institution.

(g)(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 experience in high complexity testing within the subspecialty of virology; or
(g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(g)(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 experience in high complexity testing within the subspecialty of virology; or

(g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(g)(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 experience in high complexity testing within the subspecialty of virology.

(h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must-

(h)(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

Interpretive Guidelines §493.1449(h)(1)(i)

NOTE: See *Interpretive Guidelines for* §493.1449(b)(2)

(h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(h)(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

(h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or

(h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

Interpretive Guidelines §493.1449(h)(3)(i)

See §493.2 for the definition of an accredited institution.

(h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or

(h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or

(h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology.

(i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must--

(i)(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

(i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

Interpretive Guidelines §493.1449 (i)(1)(ii)

NOTE: See *Interpretive Guidelines for* §493.1449(b)(2)

(i)(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

(i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or

(i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

Interpretive Guidelines §493.1449(i)(3)(i)

See §493.2 for the definition of an accredited institution.

(i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or

(i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or

(i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry.

(j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must--

(j)(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

(j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

Interpretive Guidelines §493.1449 (j)(1)(ii)

NOTE: See *Interpretive Guidelines for* §493.1449(b)(2)

(j)(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

(j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

Interpretive Guidelines §493.1449(j)(3)(i)

See §493.2 for the definition of an accredited institution.

(j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or

(j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or

(j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology.

(k)(1) 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--

(k)(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

(k)(1)(ii) Meet one of the following requirements--

(k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification;

Interpretive Guidelines §493.1449(k)(1)(ii)(A) or (B)

NOTE: See *Interpretive Guidelines for* §493.1449(b)(2)

(k)(2) An individual qualified under §493.1449(b) or paragraph (k)(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 paragraphs (b) or (k)(1)(ii)(A) of this section provided the technical supervisor qualified under §493.1449(b) or paragraph (k)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.

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.*

(l) 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--

(l)(1) Meet one of the following requirements:

(l)(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

(l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;

Interpretive Guidelines §493.1449(l)(1)(i)(B)

NOTE: See *Interpretive Guidelines for* §493.1449(b)(2)

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.

(l)(1)(ii) An individual qualified under §493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens.

(l)(2) For tests in dermatopathology, meet one of the following requirements:

(l)(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--

(l)(2)(i)(B) Meet one of the following requirements:

(l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or

Interpretive Guidelines §493.1449(l)(2)(i)(B)(1),(2), or (3)

NOTE: See *Interpretive Guidelines for* §493.1449(b)(2)

(l)(2)(ii) An individual qualified under §493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens.

(l)(3) For tests in ophthalmic pathology, meet one of the following requirements:

(l)(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--

(l)(3)(i)(B) Must meet one of the following requirements:

(l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or

Interpretive Guidelines §493.1449(l)(3)(i)(B)(1) or (2)

NOTE: See *Interpretive Guidelines for* §493.1449(b)(2)

(l)(3)(ii) An individual qualified under §493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or

(m) 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:

(m)(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--

(m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or

(m)(3) An individual qualified under §493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens.

(n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must--

(n)(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

(n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

Interpretive Guidelines §493.1449(n)(1)(ii)

NOTE: See *Interpretive Guidelines for* §493.1449(b)(2)

(n)(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

(n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or

(n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

Interpretive Guidelines §493.1449(n)(3)(i)

See §493.2 for the definition of an accredited institution.

(n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or

(n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or

(n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay.

(o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either--

(o)(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

(o)(1)(ii) Have training or experience that meets one of the following requirements:

(o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or

(o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and

Interpretive Guidelines §493.1449(o)(2)(i)

See §493.2 for the definition of an accredited institution.

(o)(2)(ii) Have training or experience that meets one of the following requirements:

(o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility.

(p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must--

(p)(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

(p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or

(p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and

Interpretive Guidelines §493.1449(p)(2)(i)

See §493.2 for the definition of an accredited institution.

(p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.

(q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must--

(q)(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

(q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

Interpretive Guidelines §493.1449(q)(1)(ii)

NOTE: See *Interpretive Guidelines for* §493.1449(b)(2)

(q)(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

(q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology.

Note: **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.

D6116

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

§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.

D6120

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

§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)

All testing personnel must be listed on the CMS Form 209 and must undergo documented competency assessment. The technical consultant/supervisor is responsible for assessing the competency of the testing personnel, and the 6 competency assessment criteria are found under the technical consultant/supervisor responsibilities. Depending on the situation, non-compliance can be cited at General Laboratory Systems (D5209/§493.1235), laboratory director (D6030/§493.1407 or D6103/§493.1445, or technical consultant/supervisor D6046-D6055/§493.1413(b)(8)-§493.1413(b)(9)).

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.

D6139

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

§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?

D6143

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

§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 paragraph (b)(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, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and

Interpretive Guidelines §493.1461(c)(1)(i)

See §493.2 for the definition of and guidance for an accredited institution.

(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)(2); and

(c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

(c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under §493.1462 on or before February 28, 1992.

(c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of §493.1462 on or before January 1, 1994.

(c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995--

(c)(4)(i) Meet one of the following requirements:

(c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS.

(c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

(c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or

(c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and--

(c)(5)(i) Be a high school graduate or equivalent; and

(c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992.

(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 "Specific List For Categorization of Laboratory Test Systems, Assays, and Examinations by Complexity" *(http://www.gpo.gov/fdsys/pkg/FR-1995-05-15/pdf/95-11653.pdf).* 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 493.1449(l)(1);

(e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(l) or (2);

(e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(1)(3); and

(e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(m).

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 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), (l) or (m), 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)

§493.1462 General supervisor qualifications on or before February 28, 1992.

To qualify as a general supervisor under §493.1461(c)(3), an individual must have met or could have met the following qualifications as they were in effect on or before February 28, 1992.

(a) Each supervisor possesses a current license as a laboratory supervisor issued by the State, if such licensing exists; and

(b) The laboratory supervisor--

(b)(1) Who qualifies as a laboratory director under §493.1406(b)(1), (2), (4), or (5) is also qualified as a general supervisor; therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor; or
(b)(2)(i) Is a physician or has earned a doctoral degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and

(b)(2)(ii) Subsequent to graduation, has had at least 2 years of experience in one of the laboratory specialties in a laboratory; or

(b)(3)(i) Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and

(b)(3)(ii) Subsequent to graduation has had at least 4 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated specialty in a laboratory; or

(b)(4)(i) Is qualified as a laboratory technologist under §493.1491; and

(b)(4)(ii) After qualifying as a laboratory technologist, has had at least 6 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated laboratory specialty in a laboratory; or

(b)(5) With respect to individuals first qualifying before July 1, 1971, has had at least 15 years of pertinent full-time laboratory experience before January 1, 1968; this required experience may be met by the substitution of education for experience.

D6164

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

§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 Committee on Allied Health Education and Accreditation or other organization approved by HHS; or

(b)(2) Be certified in cytotechnology by a certifying agency approved by HHS; or

(b)(3) Before September 1, 1992--

(b)(3)(i) Have successfully completed 2 years in an accredited institution with at least 12 semester hours in science, 8 hours of which are in biology; and

(b)(3)(i)(A) Have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by HHS; or

(b)(3)(i)(B) Have received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by HHS and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal 6 months of training; or

(b)(3)(ii) Have achieved a satisfactory grade to qualify as a cytotechnologist in a proficiency examination approved by HHS and designed to qualify persons as cytotechnologists; or

(b)(4) Before September 1, 1994, have full-time experience of at least 2 years or equivalent within the preceding 5 years examining slide preparations under the supervision of a physician qualified under §493.1449(b) or (k)(1), and before January 1, 1969, must have--

(b)(4)(i) Graduated from high school;

(b)(4)(ii) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician providing cytology services; and

(b)(4)(iii) Completed 2 years of full-time supervised experience in cytotechnology; or

(b)(5)(i) On or before September 1, 1994, have full-time experience of at least 2 years or equivalent examining cytology slide preparations within the preceding 5 years in the United States under the supervision of a physician qualified under §493.1449(b) or (k)(1); and

(b)(5)(ii) On or before September 1, 1995, have met the requirements in either paragraph (b)(1) or (2) of this section.

D6168

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

§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.)

D6171

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

§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 have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;

Interpretive Guidelines §493.1489(b)(1)

See §493.2 for the definition of an accredited institution.

(b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or--

Interpretive Guidelines §493.1489(b)(2)

"An associate degree in a laboratory science" is interpreted to mean an associate degree in a chemical or biological science.

(b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes--

(b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either--

(b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or

(b)(2)(ii)(A)(2) 24 semester hours of science courses that include--

(b)(2)(ii)(A)(2)(i) Six semester hours of chemistry;

(b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and

(b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(b)(2)(ii)(B) Have laboratory training that includes either of the following:

(b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)

(b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.

(b)(3) Have previously qualified or could have qualified as a technologist under §493.1491 on or before February 28, 1992;

(b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either--

(b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or

(b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);

Interpretive Guidelines §493.1489(b)(4)(ii)

Equate similar military courses with different titles. Evaluate the course length and content to ensure that it provides effective training for testing personnel. Refer to "A Guide to the Evaluation of Educational Experience in the Armed Services," American Council on Education, Washington, D.C.

(b)(5)(i) Until September 1, 1997--

(b)(5)(i)(A) Have earned a high school diploma or equivalent; and

(b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has--

(b)(5)(i)(B)(1) 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)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures;

(b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use;

(b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

(b)(5)(i)(B)(5) A working knowledge of reagent stability and storage;

(b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory;

(b)(5)(i)(B)(7) An awareness of the factors that influence test results; and

(b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and

(b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under §493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995;

Interpretive Guidelines §493.1489(b)(5)(ii)

The laboratory director is responsible for ensuring that 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 D6102.)

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 manual differential, he/she should be able to demonstrate the skills for:

- Proper specimen handling prior to testing, e.g., *ensuring* the specimen is properly drawn, if appropriate, properly labeled, the blood film is made within appropriate timeframes and is one-cell layer thick and without cell distortion;

- Proper test performance according to the laboratory's policies and manufacturer's instructions, e.g., using stains that are not outdated, that lack contamination and precipitation, following staining procedures, including staining order and timing and allowing slide to air dry, identification of cells and interpretation of smear to be consistent with blood count, diagnosis, treatment; 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 panic value, not reporting the test result if inconsistent with blood count and noting an explanation, such as "platelet clumping."

Training may include, but is not limited to, attendance at:

- Seminars given by experts in the field, e.g., a lecture about antibiotic resistance given by the infection control officer of a local hospital;

- On-site or off-site instrument trainings given by a manufacturer, e.g., a week-long training course given at the manufacturer's headquarters, or training by a manufacturer's technical representative on an instrument purchased by a laboratory;

- Technical training sessions, workshops, or conferences given by a professional laboratory organization, e.g., CAP, ASMT, AACC, and ASCT;

- Technical education classes or specialty courses that include hands-on test performance, e.g., parasitology, bacteriology, cytology, given by CDC, a State Health Department, or professional laboratory organizations;

- A formal laboratory training program; or

- In-services offered by a local hospital laboratory staff, pathologist, or medical technologist to a physician's office personnel.

Documentation may consist of, but is not limited to, letters from training programs or employers, attestation statements by the laboratory director, a log sheet initialed by the attendees indicating attendance at a training session/in-service, certificates from organizations providing the training session, workshop, conference, or specialty course.

(b)(6) For blood gas analysis--

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 "Specific List For Categorization of Laboratory Test Systems, Assays, and Examinations by Complexity" *(http://www.gpo.gov/fdsys/pkg/FR-1995-05-15/pdf/95-11653.pdf).* Test systems, assays, and examinations not yet classified are considered high complexity.

(b)(6)(i) Be qualified under §493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5);

(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; or

(b)(7) For histopathology, meet the qualifications of §493.1449 (b) or (l) 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), (l) or (m), as appropriate.

§493.1491 Technologist qualifications on or before February 28, 1992

In order to qualify as high complexity testing personnel under §493.1489(b)(3), the individual must have met or could have met the following qualifications for technologist as they were in effect on or before February 28, 1992. Each technologist must--

(a) Possess a current license as a laboratory technologist issued by the State, if such licensing exists; and

(b)(1) Have earned a bachelor's degree in medical technology from an accredited university; or

(b)(2) Have successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the Secretary, and has successfully completed a course of training of at least 12 months in such a school; or

(b)(3) Have earned a bachelor's degree in one of the chemical, physical, or biological sciences and, in addition, has at least 1 year of pertinent full-time laboratory experience or training, or both, in the specialty or subspecialty in which the individual performs tests; or

(b)(4)(i) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses--

(b)(4)(i)(A) For those whose training was completed before September 15, 1963. At least 24 semester hours in chemistry and biology courses of which--

(b)(4)(i)(A)(1) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and

(b)(4)(i)(A)(2) At least 12 semester hours in biology courses pertinent to the medical sciences; or

(b)(4)(i)(B) For those whose training was completed after September 14, 1963.

(b)(4)(i)(B)(1) 16 semester hours in chemistry courses that included at least 6 semester hours in inorganic chemistry and that are acceptable toward a major in chemistry;

(b)(4)(i)(B)(2) 16 semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and

(b)(4)(i)(B)(3) 3 semester hours of mathematics; and

(b)(4)(ii) Has experience, training, or both, covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him or her with education and training in medical technology equivalent to that described in paragraphs (b)(1) and (2) of this section; or

(b)(5) With respect to individuals first qualifying before July 1, 1971, the technologist--

(b)(5)(i) Was performing the duties of a laboratory technologist at any time between July 1, 1961, and January 1, 1968, and

(b)(5)(ii) Has had at least 10 years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience); or

(b)(6) Achieves a satisfactory grade in a proficiency examination approved by HHS.

D6173

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

§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.

D8101
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§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 RO; 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.

D8105

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

§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 the RO; 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. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

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

(c) The laboratory must comply with the basic inspection requirements of §493.1773.

D8301

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

§493.1777 Standard: Inspection of Laboratories That Have Requested or Have Been Issued a Certificate of Compliance

(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 the RO; 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. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

(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 the RO 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.