CMS Manual System

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

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SUBJECT: Revisions to State Operations Manual (SOM), 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: March 3, 2017
IMPLEMENTATION DATE: March 3, 2017

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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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:

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

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

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III. Information Gathering

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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 (refer 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-Survey 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, subspecialty, 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*; and*

- 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.

VI. Exit Conference

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

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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 (https://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 §*493.1361*)
   - 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))

§493.5 Categories of Tests by Complexity

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

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

(1) Waived tests.

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

(3) Tests of high complexity.

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

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

(1) Certificate of registration or registration certificate.

(2) Certificate of waiver.

(3) Certificate for PPM procedures.

(4) Certificate of compliance.

(5) Certificate of accreditation.

§493.15 Laboratories Performing Waived Tests

§493.15(a) Requirement

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

§493.15(b) Criteria

Test systems are simple laboratory examinations and procedures which--

(1) Are cleared by FDA for home use;

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

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

D1000

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

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

Interpretive Guidelines §493.15(c)

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

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

§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 manufacturer's recommendations for the waived test system. Some manufacturers produce tests that can be run as a waived test or a moderate complexity test. Any laboratory with a 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.

§493.19 Provider-*p*erformed *m*icroscopy (PPM) *p*rocedures

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

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

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

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

(i) A physician during the patient's visit on a specimen obtained from his or her own

patient or from a patient of a group medical practice of which the physician is a member or an employee.

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

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

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

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

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

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

(6) Limited specimen handling or processing is required.

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

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

(2) All potassium hydroxide (KOH) preparations.

(3) Pinworm examinations.

(4) Fern tests.

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

(6) Urine sediment examinations.

(7) Nasal smears for granulocytes.

(8) Fecal leukocyte examinations.

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

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

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

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

(e) Laboratory requirements

Laboratories eligible to perform PPM examinations must--

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

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

§493.20 Laboratories performing tests of moderate complexity

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

Interpretive Guidelines §493.20

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

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

(c) If the laboratory also performs waived tests, compliance with subparts H, J, K, and M of this part is not applicable to the waived tests. However, the laboratory must comply with the requirements in §§493.15(e), 493.1773, and 493.1775.

§493.25 Laboratories performing tests of high complexity

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

Interpretive Guidelines §493.25

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

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

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

(d) If the laboratory also performs waived tests, the requirements of subparts H, J, K, and M are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§493.15(e), 493.1773 and 493.1775.

§493.37 Requirements for a certificate of waiver

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

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

(b) Laboratories issued a certificate of waiver--

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

Interpretive Guidelines §493.37(b)(1)

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

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

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

(d) In accordance with subpart R of this part, HHS will suspend or revoke or limit a laboratory's certificate of waiver for failure to comply with the requirements of this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.
Interpretive Guidelines §493.37(d)

See the Adverse Action section of the SOM beginning at §6250 for enforcement procedures.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) The notification requirements of §493.53;

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

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

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

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

§493.49 Requirements for a certificate of compliance

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

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

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

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

(2) Remits the certificate fee specified in subpart F of this part; and
(3) Meets the applicable requirements of this subpart and subparts H, J, K, M, and Q of this part.

(b) Laboratories issued a certificate of compliance--

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

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

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

(ii) To evaluate complaints;

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

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

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

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

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

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

(e) In the event of a noncompliance determination resulting in an HHS action to revoke, suspend or limit the laboratory's certificate of compliance, HHS will--

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

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

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

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

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

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

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

(1) Basis for denial of the application; and

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

Interpretive Guidelines §493.49(h)(2)

See the Appeals section of the SOM beginning at §6300 for instructions on denial of a certificate application.

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

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

§493.51 Notification requirements for laboratories issued a certificate of compliance

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

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.

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

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

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

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

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

(1) Ownership;
(2) Name;

(3) Location; or

(4) Director

Interpretive Guidelines §493.53(b)

See the section of the SOM beginning at §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.

§493.57 Requirements for a registration certificate

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

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

Interpretive Guidelines §493.57

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

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

(1) Complies with the requirements of §493.55;

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

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

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

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

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

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

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

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

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

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

Interpretive Guidelines §493.57

See the Appeals section of the SOM beginning at §6300 for instructions on denial of a certificate of accreditation application.

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

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

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

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

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

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

§493.821 Condition: Microbiology

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

D2074

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

§493.835 Standard; Syphilis serology

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

D2121

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

§493.851 Standard: Hematology

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

D2122

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

§493.851 Standard: Hematology

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

D2123

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

§493.851 Standard: Hematology

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

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

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

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

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

D2127
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.851 Standard: Hematology

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

D2128
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.851 Standard: Hematology

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

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

D2153
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.859 Standard: ABO Group and D (Rho) Typing

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

D2154
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.859 Standard: ABO Group and D (Rho) Typing

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

D2164
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.861 Standard: Unexpected *a*ntibody *d*etection

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

D2165

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

§493.861 Standard; Unexpected *a*ntibody *d*etection

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

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

§493.861 Standard; Unexpected *a*ntibody *d*etection

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

§493.861 Standard; Unexpected *a*ntibody *d*etection

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

D2173

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

§493.863 Standard: Compatibility testing

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

D2182

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

§493.865 Standard: Antibody *i*dentification

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

D3001

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

§493.1101 Standard: Facilities

(a) The laboratory must be constructed, arranged, and maintained to ensure the following:

(a)(1) The space, ventilation, and utilities necessary for conducting all phases of the testing process.

Interpretive Guidelines §493.1101(a)(1)

Work areas should be arranged to minimize problems in specimen handling, examination and testing, and the reporting of test results.

Workbench space should be sufficient for test performance, well lit, and have water, gas, suction, and, electrical outlets as necessary. Instruments, equipment, and computer

systems should be placed in locations where their operation is not affected adversely by physical or chemical factors, such as heat, direct sunlight, vibrations, power fluctuations or fumes from acid or alkaline solutions. Equipment tops should not be used as workbench space.

Determination of proper lighting is subjective since the regulations do not specify the foot-candles or other measures of light intensity required. Ensure that lighting or background is appropriate for visual interpretation of test results (e.g., macroscopic evaluation of hemagglutination reactions or strep screen; dark background with reflected light for reading K-B disk diffusion AST). When citing deficiencies, document the circumstances in which lighting adversely or may adversely affect test performance or personnel safety.

Determine that the laboratory has a system to ensure its ventilation system properly removes vapors, fumes, and excessive heat, when appropriate, for the type of testing done in the laboratory.

Ensure that an adequate, stable electrical source is maintained at each location (e.g. outlets, not extension cords) and meets the power requirements for each piece of equipment.

D3015

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

§493.1103 Standard: Requirements for transfusion services

A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities.

Interpretive Guidelines §493.1103

A "facility that provides transfusion services" is any entity that may store and/or administer blood and blood products to patients.

Subpart K--Quality System for Nonwaived Testing

§493.1200 Introduction

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

(a) Each laboratory that performs nonwaived testing must establish and maintain written policies and procedures that implement and monitor a quality system~~s~~ for all phases of the total testing process (that is, preanalytic, analytic, and postanalytic) as well as general laboratory systems.

(b) The laboratory's quality systems must include a quality assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates and resolves problems.

(c) The various components of the laboratory's quality system are used to meet the requirements in this part and must be appropriate for the specialties and subspecialties of testing the laboratory performs, services it offers, and clients it serves.

D5002

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

§493.1201 Condition: Bacteriology

If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1261, and §§493.1281 through 493.1299.

***Interpretive* Guidelines §493.1201**

Tests or procedures to detect an antigen are categorized in this subspecialty where the antigen is detected or identified. For example, tests or procedures for identifying Group A Streptococcus are categorized in Bacteriology.

D5004

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

§493.1202 Condition: Mycobacteriology

If the laboratory provides services in the subspecialty of Mycobacteriology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1262, and §§493.1281 through 493.1299.

***Interpretive* Guidelines §493.1202**

Tests or procedures to detect an antigen are categorized in the subspecialty where the antigen is detected or identified. For example, the procedures to identify Mycobacteria are categorized in Mycobacteriology.

D5006

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

§493.1203 Condition: Mycology

If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1263, and §§493.1281 through 493.1299.

Interpretive **Guidelines §493.1203**

Tests or procedures to detect an antigen are categorized in the subspecialty where the antigen is detected or identified. For example, tests for the identification of fungi are categorized in Mycology.

D5008

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

§493.1204 Condition: Parasitology

If the laboratory provides services in the subspecialty of Parasitology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1264, and §§493.1281 through 493.1299.

Interpretive **Guidelines §493.1204**

Tests or procedures to identify an antigen are categorized in the subspecialty where the antigen is detected or identified. For example, procedures to identify a parasite are categorized in the subspecialty of Parasitology; however, procedures to detect or identify an antibody to the parasite are categorized in the subspecialty of General Immunology.

D5010

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

§493.1205 Condition: Virology

If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1265, and §§493.1281 through 493.1299.

Interpretive **Guidelines §493.1205**

Tests or procedures to identify the virus (antigen) are categorized in the subspecialty when the antigen is detected or identified. For example, tests or procedures to detect herpes are categorized in the subspecialty of Virology. Tests or procedures to detect antibodies to Herpes are categorized in the subspecialty of General Immunology.

GENERAL LABORATORY SYSTEMS

D5200

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

§493.1230 Condition: General laboratory systems

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in §§493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in §493.1239 for each specialty and subspecialty of testing performed.

Interpretive **Guidelines §493.1230**

Significant deficiencies cited under this condition may indicate deficiencies under personnel responsibilities. Use D5200 when significant deficiencies are identified that have the potential to adversely affect patient testing, are systemic and pervasive throughout the laboratory, and are not limited to any one specialty or subspecialty.

The requirements in this section address those general operational functions that are not specific to any one specialty or subspecialty.

D5215

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

§493.1236 Standard: Evaluation of proficiency testing performance

(b)(2) Any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

Interpretive **Guidelines §493.1236(b)(2)**

The laboratory must have a mechanism for routine review of its proficiency testing results that are evaluated by its PT providers. This includes a review of its actual PT

results against the PT provider's participant summary results for the particular PT event and when any of the following occur:

- The PT program assigned an artificial score of 100% (e.g., results not evaluated or scored);

- A zero score for nonparticipation; if the laboratory did not test the specimen, it must document what other means were used to assess the accuracy of the test for the PT event that was missed; or

- The PT provider notifies the laboratory that its results were not evaluated (given a score of "0") due to missing the return deadline.

Probes §493.1236(b)(2)

Has the laboratory reviewed its test menu to determine if it tests any analyte(s) that are not listed in subpart I?

§493.1236(c) At least twice annually, the laboratory must verify the accuracy of the following:

D5219

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

§493.1236 Standard: Evaluation of proficiency testing performance

(c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

Interpretive **Guidelines §493.1236(c)(2)**

Laboratory tests or procedures that are not compatible may include new or emerging technologies for which PT is not yet available.

Probes §493.1236(c)(2)

How does the laboratory verify accuracy of tests not included under subpart I or tests for which compatible PT samples are not available (e.g., blind testing of materials with known values, other external assessment programs, split samples with another laboratory instrument or method, comparison with Kodachrome slides from a reference source)?

D5221

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

§493.1236 Standard: Evaluation of proficiency testing performance

(d) All proficiency testing evaluation and verification activities must be documented.

Interpretive **Guidelines §493.1236(d)**

Documentation must include review of all unsatisfactory scores and the corrective action taken.

PREANALYTIC SYSTEMS

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.

D5303

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

§493.1241 Standard: Test request

(b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.

Interpretive Guidelines §493.1241(b)

Review the laboratory's policy for requesting written orders within 30 days of the oral requests. If no written order was received, verify the laboratory has documentation showing the attempt.

D5307

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

§493.1241 Standard: Test request

(d) The patient's chart or medical record may be used as the test requisition or authorization but must be available to the laboratory at the time of testing and available to CMS or a CMS agent upon request.

Probes §493.1241(d)

When the patient's chart or medical record is used as the test requisition does it provide all the information necessary to ensure accurate testing and reporting of results?

D5309

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

§493.1241 Standard: Test request

(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

Interpretive Guidelines §493.1241(e)

The laboratory must have an ongoing mechanism to ensure the accuracy of manual entries by personnel into an LIS.

How does the laboratory ensure that all individuals who enter data including clerical staff correctly match patient information?

D5313

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

§493.1242 Standard: Specimen submission, handling, and referral

(b) The laboratory must document the date and time it receives a specimen.

Interpretive Guidelines §493.1242(b)

When a sample is collected and a test is performed during the course of a patient's visit, the date and time recorded in the patient "sign-in" log may be used as the date and time of receipt into the laboratory.

D5315

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

§493.1242 Standard: Specimen submission, handling, and referral

(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

Interpretive Guidelines §493.1242(c)

Some examples of laboratories meeting equivalent requirements are those of the Veterans Administration (VA), the Department of Defense (DOD) facilities, and CLIA-exempt laboratories.

Probes §493.1242(c)

How does the laboratory ensure that the reference laboratory has and maintains a current CLIA certificate?

D5317

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

§493.1242 Standard: Specimen submission, handling, and referral

(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

Interpretive Guidelines §493.1242(d)

Ensure the laboratory has provided written instructions to each client that sends specimens/test requests. The instructions may contain information on specimen handling (e.g., collection, preservation, storage, transport, testing schedule times and how to obtain additional assistance for unusual circumstances).

D5391

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

§493.1249 Standard: Preanalytic systems quality assessment

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at §§493.1241 through 493.1242.

Interpretive Guidelines §493.1249(a)-(c)

Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the 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 **Preanalytic System** includes assessing practices/issues related to test requests, specimen submission, handling and referral.

Some examples include: monitoring the frequency of specimen handling problems (such as the use of an improper blood collection tube, inadequate mixing of blood specimens with anticoagulant after collection), and delays in specimen transport; identifying clients who repeatedly refer unacceptable specimens or improperly complete requisition forms and documentation of *the laboratory's* efforts to reduce the recurrence of these problems.

Review assessment policies, procedures and reports to verify that the laboratory has a system in place to ensure continuous improvement. Corrective action reports are one indication that the laboratory is monitoring and evaluating laboratory performance and the quality of services.

Probes §493.1249(a)-(c)

When a laboratory uses off-site drawing facilities, what policies or procedures does the laboratory use to ensure proper accountability or tracking of patient specimens from time of collection to receipt by the laboratory performing the tests?

Does the laboratory perform periodic or spot checks for accurate transfer of information (e.g., manual entries by personnel from test orders to test requisition or into an LIS)? For referral specimens, how does the laboratory check for transcription errors when patient test information is transcribed from the laboratory's original requisition form to the reference laboratory's requisition?

What actions does the laboratory take if test requisitions from one or more clients are consistently incomplete, illegible or contain incorrect information?

What actions does the laboratory take if specimens received from one client are consistently unsatisfactory for testing (e.g., specimens for Cytology)? Has the laboratory's efforts to reduce the recurrence of these problems been documented and effective?

D5393

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

§493.1249 Standard: Preanalytic systems quality assessment

(b) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff.

§493.1249(c) The laboratory must document all preanalytic systems quality assessment activities.

Interpretive **Guidelines §493.1249(c)**

The steps taken by the laboratory to identify and correct problems and prevent their recurrence must be documented. All laboratory policies amended due to its QA activities must also be noted.

ANALYTIC SYSTEMS

D5405

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

§493.1251 Standard: Procedure manual

(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

D5409

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

§493.1251 Standard: Procedure manual

(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in §493.1105(a)(2).

D5415

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

§493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following:

(1) Identity and when significant, titer, strength or concentration.

(2) Storage requirements.

(3) Preparation and expiration dates.

Interpretive Guidelines §493.1252(c)(3)

Expiration dates for test kits and/or reagents may differ due to date opened or storage conditions (e.g., refrigerator, room temperature). Verify that laboratory personnel are aware of these differences and document the appropriate expiration date.

(4) Other pertinent information required for proper use.

D5417

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

§493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

Interpretive Guidelines §493.1252(d)

In citing deficiencies, for outdated or deteriorated materials, indicate whether these materials have been used for patient testing. Also, look for contamination, drying or other signs of deterioration. This is as important as checking expiration dates.

D5419

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

§493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies

(e) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.

Interpretive Guidelines §493.1252(e)

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

§493.1253 Standard: Establishment and verification of performance specifications

(a) Applicability. Laboratories are not required to verify or establish performance specifications for any test system used by the laboratory before April 24, 2003.

Interpretive Guidelines §493.1253(a)

The requirements of §493.1253 apply to each nonwaived test system (i.e., moderate and high complexity) introduced into the laboratory on or after April 24, 2003. This includes the following:

- A test system that is introduced into the laboratory for the first time to measure an analyte that the laboratory has not previously measured;
- A test system introduced for the first time into the laboratory for a test that the

laboratory currently performs on an alternative test system (e.g., instrument A has been used to perform cholesterol testing, now instrument B will be used);

- An analyte added to a test system that can measure multiple analytes which the laboratory has been using for patient testing but has not previously reported patient results for this particular analyte; and

- A modification to a test system that the laboratory has been using for patient testing (e.g., the laboratory reduces the specimen and/or reagent volumes).

When multiple instruments (including the same make and model, e.g., point-of-care instruments) are used to perform the same test, the laboratory must verify or establish, as applicable, performance specifications for each instrument.

Refer to requirements in subpart M, for training and competency of personnel.

Specific information regarding testing for agents of emergent public health significance and alternative methods /procedures for establishing performance specifications may be found at www.aphl.org.

NOTE: Public health testing performed on environmental (non-human) samples is not subject to CLIA.

D5425

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

§493.1253 Standard: Establishment and verification of performance specifications

(b)(3) Determination of calibration and control procedures. The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

Interpretive Guidelines §493.1253(b)(3)

Through the verification/establishment process, the laboratory defines the frequency for calibration and control performance as well as the type, number, and concentration of calibration and control materials used to monitor, detect error, and evaluate method performance. The frequency for calibration and control performance must not be less than the frequency specified in the manufacturer's instructions.

In establishing the calibration and quality control frequency, the laboratory must consider:

- Test system instrument/reagent stability, including relocation;

- Frequency with which the test is performed;
- Technique dependence of the method;
- Frequency of quality control failures; and
- Training, experience, and competency of technical personnel.

For additional criteria in determining calibration and quality control frequency refer to §§493.1255 and 493.1256.

D5427

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

§493.1253 Standard: Establishment and verification of performance specifications

(c) Documentation. The laboratory must document all activities specified in this section.

Interpretive Guidelines §493.1253(c)

The actual measurement(s) taken, reactions and/or observations must be recorded.

Acceptable formats for documentation may vary.

§493.1254 Standard: Maintenance and *f*unction *c*hecks

§493.1254(a) Unmodified manufacturer's equipment, instruments, or test systems. The laboratory must perform and document the following:

Interpretive Guideline §493.1254(a)

When a laboratory introduces a new test system, the laboratory may determine, depending on the outcome of the performance specifications, that additional measures are necessary in order to ensure accurate and reliable test results.

D5439

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

§493.1255 Standard: Calibration and calibration verification procedures

(b) Perform and document calibration verification procedure -

(b)(1) Following the manufacturer's calibration verification instructions;

(b)(2) Using the criteria verified or established by the laboratory under §493.1253(b)(3)--

(b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and

(b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and

(b)(3) At least once every 6 months and whenever any of the following occur:

(b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.

(b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance.

(b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.

(b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

Interpretive Guidelines §493.1255(b)

The calibration verification requirements may be met by verifying the procedure using a high-level material such as a control, calibration material, or patient specimen and diluting it to cover the reportable range if allowed by the manufacturer.

Control activities routinely used to satisfy the requirement for §493.1256 do **not** satisfy the calibration verification requirements.

EXCEPTIONS:

1. Laboratories must perform and document calibration procedures following the manufacturer's test system instructions, using calibration materials provided or specified, and at a frequency that is recommended by the manufacturer. Where the manufacturer does not provide such instruction, the laboratory may calibrate using 3 or more levels of calibration materials that include a low, mid, and high value at least every 6 months.

2. *If the laboratory performs a calibration protocol using 3 or more levels of calibration materials that include a low, mid, and high value at least every 6 months, the calibration verification requirement is met.*

3. For automated cell counters, the calibration verification requirements are considered met if the laboratory follows the manufacturer's instructions for instrument operation and tests 2 levels of control materials each day of testing provided the control results meet the laboratory's criteria for acceptability. This exception does not apply to centrifugal hematology test systems.

4. For automated chemistry analyzers, the calibration verification requirements are considered met if the laboratory follows the manufacturer's instructions for instrument operation and routinely tests three levels of control materials (lowest level available, mid-level, and highest level available) more than once each day of testing, the control material results meet the laboratory's criteria for acceptability and the control materials are traceable to National Institute of Standards and Technology (NIST) reference materials.

Calibration materials, proficiency testing samples with known results, or control materials with known values may be used to perform calibration verification. For these materials, the laboratory must define acceptable limits for the difference between the measured value obtained, versus the actual concentration of the materials.

NOTE: PT samples can only be used after the event cut-off date.

"Calibration material" means a solution that has a known amount of analyte weighed in, has a value determined by repetitive testing using a reference/definitive test method or is traceable to National Institute of Standards and Technology (NIST) reference material, if possible.

If a manufacturer provides reagents for a test where all of the reagents for a test are packaged together, calibration verification is not required for each additional reagent package with the same lot number that is received in the same shipment. For example, if the laboratory receives 12 packs of reagents and the laboratory has verified calibration for at least one of the 12 packs of reagents, then the laboratory does not have to verify calibration for the remaining 11 packs of reagents provided that all 12 packs of reagents have the same lot number and were received on the same shipment to the laboratory. However, this exception does not override the requirement to perform calibration verification as specified at 493.1255(b)(3).

5. Calibration verification is not required on:
   - Instruments that are factory or manufacturer calibrated and/or
   - Tests that are considered non-quantitative (e.g., Prothrombin time and Activated Clotting Time, which are measured in units of time)

When reviewing the laboratory's maintenance and function check records as required in §493.1254, determine whether the laboratory performed calibration verification when major maintenance occurred or critical parts were replaced.

The actual measurement(s) taken, reactions and/or observations must be recorded.

Probes §493.1255(b)

If a laboratory does not perform calibration verification after a complete change of reagents, what data does the laboratory have to document that changing reagent lot numbers does not affect the reportable range of patient test results, and does not adversely affect control results?

D5445

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

§493.1256 Standard: Control procedures

(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--

(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at §§493.1261 through 493.1278.

(d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section.

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

Interpretive Guidelines §493.1256(d)

INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)

INTRODUCTION

§493.1250 provides for HHS' approval of a procedure that provides equivalent quality testing as an alternative to meeting the Analytic Systems requirements in §493.1251 - §493.1283. CMS has *approved* use of an equivalent quality control procedure, which permits laboratories to develop and customize laboratory-specific quality control procedures for their healthcare setting(s). This procedure is termed Individualized Quality Control Plan (IQCP).

An IQCP is composed of three parts: a Risk Assessment (RA), a Quality Control Plan (QCP), and a Quality Assessment (QA) plan. The RA is the identification, evaluation, and documentation of potential failures and errors in a testing process. The QCP documents a laboratory's standard operating procedure that describes the practices,

resources, and procedures to control the quality of a test process. The QA consists of the laboratory's written policies and procedure for the ongoing monitoring of the effectiveness of their IQCP.

IQCP is only available for select quality control requirements, which are identified below in Table 1 "Eligibility for IQCP."

When the manufacturers' instructions do not address quality control or those instructions are less stringent than the regulatory control procedures for Analytic Systems (see Table 1), the laboratory needs to follow the regulatory requirements or develop an IQCP. Laboratories have the flexibility to follow all regulatory requirements as written or customize their control procedures using the IQCP procedure. Whichever option is selected laboratories are not permitted to establish quality control procedures that are less stringent than those specified by the manufacturer of the test system.

LABORATORY DIRECTOR RESPONSIBILITIES

Under subpart M, the laboratory director is responsible for ensuring that quality control (use D6020 or D6093 as appropriate) and quality assessment (use D6021 or D6094 as appropriate) programs are established and maintained to assure the quality of laboratory services, including the identification of failures in quality as they occur (use D6022 or D6094).

The laboratory director is responsible for deciding whether a laboratory will seek to meet its CLIA quality control obligations through IQCP, and if the laboratory director decides to do so, the laboratory director is also responsible for ensuring that the QCP the laboratory develops meets the IQCP requirements.

The laboratory director must consider the laboratory's clinical and legal responsibility for providing accurate, reliable and timely patient test results (§493.1407 or §493.1445) prior to implementing a QCP that is less stringent than the applicable Analytic Systems control regulations listed in Table 1, Eligibility for IQCP.

REGULATORY CONSIDERATIONS WHEN USING IQCP

All CLIA regulations, other than those specifically designated as eligible for IQCP in Table 1, Eligibility for IQCP, continue to be in force and must be followed.

Table 1, Eligibility for IQCP, lists those specialties/subspecialties and general regulations which are designated as "eligible" for IQCP, that is, those specialties/subspecialties and general regulations for which the laboratory has the flexibility to develop control procedures using the IQCP procedure. Table 1 also lists those specialties/subspecialties and specialty/subspecialty regulations which are not eligible for IQCP.

- The first column lists the CLIA specialties/subspecialties: Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Syphilis Serology, General Immunology, Routine Chemistry, Urinalysis, Endocrinology, Toxicology, Hematology, Immunohematology, Clinical Cytogenetics, Radiobioassay, Histocompatibility, Pathology, Histopathology, Oral Pathology and Cytology.

- The second column indicates whether or not each specialty/subspecialty is eligible for IQCP. The specialties/subspecialties eligible for IQCP are; Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Syphilis Serology, General Immunology, Routine Chemistry, Urinalysis, Endocrinology, Toxicology, Hematology, Immunohematology, Clinical Cytogenetics, Radiobioassay and Histocompatibility. The specialties/subspecialties not eligible for IQCP are; Pathology, Histopathology, Oral Pathology and Cytology.

- The third column lists the general regulations that *are eligible for IQCP* and may be applied to the eligible specialty/subspecialties listed in column one: §493.1256(d)(3)-(5) and §493.1256(e)(1)-(4).

- The fourth column lists the specialty/subspecialty regulations that are eligible for IQCP:§493.1261, §493.1262, §493.1263, §493.1264, §493.1265, §493.1267(b),(c), §493.1269, and §493.1278(b)(6),(c),(d)(6),(e)(3).

- The fifth column lists the specialty/subspecialty regulations that are not eligible for IQCP: §493.1267(a),(d), §493.1271, §493.1276, §493.1278(a),(b)(1-5),(d)(1-5),(d)(7),(e)(1-2),(f),(g), §493.1273 and §493.1274.

Table 1: Eligibility for IQCP

CLIA Specialty/ Subspecialty	**Eligible for IQCP?**	**General Regulations Eligible for IQCP**	**Specialty/ Subspecialty Regulations Eligible for IQCP**	**Specialty/ Subspecialty Regulations <u>NOT</u> Eligible for IQCP**
Bacteriology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1261	N/A
Mycobacteriology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1262	N/A
Mycology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1263	N/A
Parasitology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1264	N/A

Virology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1265	N/A
Syphilis Serology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
General Immunology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Routine Chemistry	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1267(b),(c)	§493.1267(a), (d)
Urinalysis	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Endocrinology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Toxicology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Hematology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1269	N/A
Immunohematology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	§493.1271
Clinical Cytogenetics	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	§493.1276
Radiobioassay	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Histocompatibility	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1278(b)(6), (c), (d)(6), (e)(3)	§493.1278(a), (b)(1-5), (d)(1-5), (d)(7), (e)(1-2), (f), (g)
Pathology	No	None (Not eligible for IQCP)	N/A	N/A
Histopathology	No	None (Not eligible for IQCP)	N/A	§493.1273
Oral Pathology	No	None (Not eligible for IQCP)	N/A	N/A
Cytology	No	None (Not eligible) for IQCP)	N/A	§493.1274

Probe(s) §493.1256(d)

For each test system, does the laboratory perform quality control testing procedures as specified in the manufacturer's instructions? Use D5411.

If the manufacturer's instructions are less stringent than the CLIA regulatory requirements for control procedures, did the laboratory perform an IQCP or are they following the CLIA regulatory requirements for control procedures?

As stated above, an IQCP must include:

- Risk Assessment (RA)
- Quality Control Plan (QCP)
- Quality Assessment (QA)

Risk Assessment

Risk assessment is the identification and evaluation of potential failures and sources of errors in a testing process.

Risk assessments for IQCP must include, at a minimum, an evaluation of the following five components:

- Specimen
- Test system
- Reagent
- Environment
- Testing personnel

The scope of risk assessments must encompass the entire testing process - preanalytic, analytic, and postanalytic phases - and include, at a minimum, the evaluation of the five risk assessment components listed above for each test for which the laboratory wishes to employ IQCP. Use D5445.

The laboratory director has the responsibility for ensuring that the risk assessment considers the CLIA Quality System requirements at 42 C.F.R. 493, Subpart K for accurate, reliable, and timely test results and that test result quality is appropriate for patient care. Re-evaluation of the RA must be considered by the director or his/her designee when changes occur in any of the following components: specimen, test system, reagent, environment and testing personnel.

Conducting the Risk Assessment

To conduct a risk assessment, the laboratory must identify the sources of potential failures and errors for a testing process, and evaluate the frequency and impact of those failures and sources of error on test quality.

In-house data, established by the laboratory in its own environment and by its own personnel, must be utilized to demonstrate that the stability of the test system as it is used in that laboratory supports the number and frequency of the QC documented in the QCP. Use D5425. Data from verification or establishment of performance specifications, historical (existing) QC data, and data/documentation compiled to meet other existing CLIA Quality System regulations at 42 C.F.R. 493, Subpart K can be included. Published data or data from manufacturers (e.g. package inserts) may be taken into consideration, but may not be used as the sole criteria for decision-making. The laboratory must document all activities completed for the risk assessment,

including data to support their risk assessment decisions. Use D5481. *All* RA documentation must be maintained for at least two years after the corresponding QCP has been discontinued. Use D3029.

NOTE: Manufacturer-provided tools and templates, if available, may be helpful for laboratories implementing IQCP; however, laboratories will need to supplement these materials with laboratory-specific information as part of the Risk Assessment. The manufacturer information is not sufficient in and of itself.

Laboratories must assess information provided by manufacturers as part of the RA, such as the manufacturer's instructions (e.g. intended use, limitations, interferences, recommendations). If additional information is required to conduct the risk assessment, that is not available in the manufacturer's instructions, the laboratory should contact the manufacturer to request the needed information.

The following list contains additional possible sources of information for conducting a risk assessment:

- Regulatory requirements
- Manufacturer's package insert (including intended use, limitations, environmental requirements, QC frequency, specimen requirements, reagent storage, maintenance, calibration, interfering substances, etc.)
- Manufacturer's operator manual
- Troubleshooting guide
- Manufacturers' alerts and bulletins
- Verification or establishment of performance specifications
- Testing personnel qualifications, training and competency records
- QC data
- Proficiency testing data
- QA information, including corrective action
- Scientific publications
- Other information as appropriate

In laboratories with multiple identical devices (same make and model), a single risk assessment may be performed for the test system. However, differences in testing personnel and environments where the device will be used must be taken into consideration when performing the risk assessment; therefore, there may be a need to customize a QCP for each individual location and/or device.

NOTE: Multiple devices may be included in a single QCP; however, performance specifications must be established or verified for each individual device and each analyte.

Probes §493.1256(d)

Does the laboratory's RA support its procedures for testing quality control samples, including the frequency of testing? Use D5445.

Has the laboratory included all five components and all phases of testing in their risk assessment, and have they reasonably identified and evaluated the potential failures and sources of error? Use D5445.

Has the laboratory conducted a risk assessment for each location where testing is performed on multiple numbers of identical devices (i.e. same make, model)?

For example, has the laboratory conducted a risk assessment with respect to:

- Multiple laboratory/testing locations within a single CLIA number
- Point-of -care devices throughout health care/laboratory systems
- Multiple identical devices or kits in a single location
- Differences in testing personnel

Has the laboratory's RA identified the sources of potential failures and sources of error contained in the most current version of the manufacturer's instructions?
Has the laboratory documented all activities completed for the risk assessment? Does the laboratory have documentation, including data, to support their risk assessment decisions? Use D5481.

SPECIMEN

Probe §493.1256(d)

Has the laboratory identified and evaluated the potential failures and sources of error in the preanalytic phase, as applicable, for:

- Patient preparation
- Specimen collection
- Specimen labeling
- Specimen storage, preservation and stability
- Specimen transportation
- Specimen processing
- Specimen acceptability and rejection
- Specimen referral

TEST SYSTEM

The risk assessment must include consideration of the manufacturer instructions for function checks and maintenance checks. In addition, the risk assessment should take

into consideration the laboratory's test volume, and intended use of the test results (i.e. screening or diagnostic).

Additional factors to consider in the risk assessment for analyte and test systems may include, but are not limited to potential failures and sources of error due to:

- Inadequate sampling
- Clot detection capabilities
- Capabilities for detection of interfering substances (e.g., hemolysis, lipemia, icterus, turbidity)
- Calibration associated issues
- Mechanical/electronic failure of test system
- Optics
- Pipettes or pipettors
- Barcode readers
- Failure of system controls and function checks
- Built-in procedural and electronic controls (internal controls)
- External or internal liquid quality control (assayed vs. unassayed)
- Temperature monitors and controllers
- Software/Hardware
- Transmission of data to Laboratory Information System
- Result reporting

REAGENT

Factors to consider in the risk assessment for reagents, quality control materials, calibrators, and similar materials may include, but are not limited to potential failures and sources of error related to:

- Shipping/Receiving
- Storage condition requirements
- Expiration Date (may vary based on storage requirements)
- Preparation

Probes §493.1256(d)

Has the laboratory assessed potential test system failures or sources of error, which may result from reagent, quality control material, and calibrator contamination or deterioration and reagent lot variation?

Has the laboratory assessed potential test system failures or sources of error due to the risk of inadvertently mixing reagents from different kits or lot numbers, if applicable?

ENVIRONMENT

Probes §493.1256(d)

Has the laboratory evaluated environmental conditions, which may affect test system performance including, but not limited to potential failures and sources of error due to:

- Temperature
- Airflow/ventilation
- Light intensity
- Noise and vibration
- Humidity
- Altitude
- Dust
- Water
- Utilities (e.g. Electrical failure/power supply variance or surge)
- Adequate space

Has the laboratory evaluated potential failures and sources of error due to the transport of instruments and reagents in a mobile laboratory?

TESTING PERSONNEL

Testing personnel must participate in the process of conducting the risk assessment. It is not necessary for all personnel to be involved.

Probe §493.1256(d)

Has the laboratory assessed the potential failures and sources of error due to testing personnel by evaluating the following:

- Training
- Competency
- Appropriate education and experience qualifications
- Adequate staffing

After the laboratory has identified the sources of potential failures and errors for a testing process and evaluated the frequency and impact of those failures and errors on test quality, the resulting risk assessment is then used to develop the Quality Control Plan (QCP).

Quality Control Plan

A QCP is a document that describes the practices, resources, and procedures to control the quality of a particular test process. The QCP must ensure accurate, reliable and timely test results, and that test result quality is appropriate for patient care. The QCP must be available to, and followed by, laboratory personnel. Use D5401.

The QCP must provide for the immediate detection of errors that occur due to test system failure, adverse environmental conditions, and operator performance. It must also monitor, over time, the accuracy and precision of test performance that may be influenced by changes in the test system, environmental conditions, or variance in operator performance. Use D5441.

The QCP must at least include the number, type, frequency of testing and criteria for acceptable result(s) of the quality control(s). Use D5441 or D5469, as appropriate.
If indicated by the evaluation of the risk assessment, the QCP may also include:

- Electronic controls
- Procedural controls
- Training and competency assessment
- Other specified quality control activities

Laboratories implementing IQCP for new tests are encouraged to perform control procedures at more frequent intervals during initial implementation, allowing the laboratory to identify performance issues that could indicate a need to adjust the QCP.

The task of development and implementation of QCPs may be delegated (in writing) to a qualified individual (§493.1407(e)(14) or §493.1445(e)(15)). However, the laboratory director has the ultimate responsibility for the proper development and implementation of a QCP. (§493.1407(b) or §493.1445(b)). There must be documented evidence that the laboratory director has approved, signed and dated the QCP (§493.1251(d)). Use D5407. Re-evaluation of the QCP must be considered by the director or his/her designee when changes occur in any of the following components: specimen, test system, reagent, environment and testing personnel.

Probes §493.1256(d)

Does the laboratory have a written QCP for each test system, as applicable? Use D5441 or D5445, as appropriate.

Does the QCP specify the number, type, and frequency of testing of the quality control material(s)? Does the QCP provide for immediate detection of errors? Use D5441.

Does the QCP contain criteria to determine acceptable quality control results? Use D5469.

Does the QCP require that the laboratory perform QC as specified by the manufacturer's instructions? Regardless, if the laboratory is performing QC less frequently than required by the manufacturer, use D5411 or D5445, as appropriate.

Is there documented evidence of laboratory director approval of the QCP before it was put into use? Use D5407.

Quality Assessment

All IQCP Quality Assessment monitoring must be part of the laboratory's overall Quality Assessment plan. The laboratory must establish and follow written policies and procedures for the ongoing monitoring of the effectiveness of their IQCP. The monitoring should include, but is not limited to, the following components: specimen, test system, reagent, environment and testing personnel. Re-evaluation of the RA and the QCP must be considered by the director or his/her designee when changes occur in any of the above components.

Laboratories implementing IQCP for new tests are encouraged to perform monitoring activities at more frequent intervals during initial implementation, allowing the laboratory to identify performance issues that could indicate a need to adjust the QCP.

Documents to consider for QA review may include, but are not limited to:

- QC review
- Proficiency testing records (e.g. scores, testing failures, trends)
- Patient results review
- Specimen rejection logs
- Turnaround time reports
- Records of preventive measures, corrective actions, & follow-up
- Personnel Competency Records

When the laboratory discovers a testing process failure, the laboratory must conduct an investigation to identify the cause of the failure, its impact on patient care, appropriate corrective action for affected patients and appropriate modifications to their QCP to prevent recurrence, as applicable. The investigation must include documentation of all corrections, corresponding corrective actions for all patients affected by the testing process failure, and evaluation of the effectiveness of the corrective action(s). The laboratory must implement the correction(s) and corresponding corrective action(s) necessary to resolve the failure and reduce the risk of recurrence of the failure in the future. If necessary, the laboratory must update the risk assessment with the new information and modify the QCP, as needed.

Probes §493.1256(d)

Has the laboratory established written policies and procedures for the ongoing monitoring of the QCP (use D5391, D5791 or D5891 as appropriate) and evaluation of its effectiveness? (Use D5393, D5793 or D5893 as appropriate)

In the event of a testing process failure, has the laboratory evaluated all patient test results since the last acceptable quality control? Use D5783.

D5449

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

§493.1256 Standard: Control procedures

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

Interpretive **Guidelines §493.1256(d)(3)(ii)**

Urinalysis

Photomicrographs or charts of all possible urine sediment components will meet the control requirement for manual microscopic urinalysis examinations. Use D5445.

D5451

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

§493.1256 Standard: Control procedures

(d)(3)(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively;

Interpretive Guidelines §493.1256(d)(3)(iii)

For tests in which patient results are reported in terms of graded reactivity (1+, 2+, 3+, etc.) control(s) of graded reactivity must be used. For tests in which patient results are reported as a titer, controls of known titer must be used.

EXCEPTIONS:

A negative control is not required for anti-streptolysin O titer, anti-hyaluronidase titer tests. A positive control is not required for the cold agglutination test. For radial immuno-diffusion, one control or calibration material is required on each plate.

D5455

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

§493.1256 Standard: Control procedures

(d)(3)(v) Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition.

Interpretive Guidelines §493.1256(d)(3)(iii)

The laboratory is also responsible for following the manufacturer's instructions concerning procedure limitations for detecting nucleic acid target amplification sequences, when provided by the manufacturer.

If the laboratory suspects the presence of interfering substances (inhibitors), the laboratory is responsible for using a control material (in addition to positive and negative control materials) capable of detecting interfering substances. Patient specimens may contain substances (inhibitors) that interfere with the enzymatic reaction of a molecular amplification procedure. These interfering substances could affect the assay's sensitivity causing a false negative result. Interfering substances may include, but are not limited to components within the patient specimen or exogenous substances introduced during the preanalytic and/or analytic phase of testing.

D5457

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

§493.1256 Standard: Control procedures

(d)(4) For thin layer chromatography--

(d)(4)(i) Spot each plate or card, as applicable, with a calibrator containing all known substances or drug groups, as appropriate, which are identified by thin layer chromatography and reported by the laboratory; and

(d)(4)(ii) Include at least one control material on each plate or card, as applicable, which must be processed through each step of patient testing, including extraction processes.

Interpretive Guidelines §493.1256(d)(4)

For qualitative urine drug screens performed by thin layer chromatography, a negative control is not required. However, a control containing one or more drugs representative of each drug group reported (e.g., tricyclic antidepressants, barbiturates) that goes through each test phase (including the extraction process) is required.

D5459

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§493.1256 Standard: Control procedures

(d)(5) For each electrophoretic procedure include, concurrent with patient specimens, at least one control material containing the substances being identified or measured.

D5461

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

§493.1256 Standard: Control procedures

(d)(6) Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced.

D5463

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

§493.1256 Standard: Control procedures

(d)(7) Over time, rotate control material testing among all operators who perform the test.

Interpretive Guidelines §493.1256(d)(7)

The laboratory may use this requirement to assist in competency assessment determinations specified in subpart M.

D5465

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§493.1256 Standard: Control procedures

(d)(8) Test control materials in the same manner as patient specimens.

Interpretive Guidelines §493.1256(d)(8)

Control materials of a similar matrix to that of patient specimens should be utilized, if available, and the control materials must be treated in the same manner as patient specimens and go through all analytic test phases.

Flow Cytometry

In cell surface phenotyping by flow cytometry or fluorescent microscopy, control samples must be analyzed within the same time period after staining as test specimens.

Probes §493.1256(d)(8)

Flow Cytometry

How did the laboratory establish the time period in which stained cells must be analyzed to avoid significant loss of any cell subpopulations or total cell numbers?

If analysis will be based on a population of cells selected by flow cytometry "gating" on size or density parameters, or selected by depletion or enrichment techniques, are controls tested with each patient to detect the presence of contaminating cells in the selected population? (e.g., Monocyte contamination of "lymphocytes" gated by forward angle or forward angle versus 90° light scatter must be detected with a monocyte-specific antibody.) Use D5465 or D5425 as appropriate.

D5467

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

§493.1256 Standard: Control procedures

(d)(9) When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system.

D5469

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

§493.1256 Standard: Control procedures

(d)(10) Establish or verify the criteria for acceptability of all control materials.

(d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.

(d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory.

(d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

Interpretive Guidelines §493.1256(d)(10)

Acceptable ranges must be verified (assayed) or established (unassayed) by the laboratory for control materials and any calibrators that are used in lieu of control materials.

For procedures in which a spiked sample is used as a control, an acceptable range must be established for the amount of recovery of the spiked sample, either in percentage or actual concentration.

If laboratories rely on commercial companies to establish statistical limits for controls, the laboratory must have documentation to verify that its control results correlate with the established limits.

When patient specimens are used to meet the control requirements, data must be evaluated in accordance with §493.1256(d)(10)(iii).

There are no specific guidelines for the number of times a material must be tested to establish statistical limits. In general, twenty replicate tests should be considered the minimum for determining a standard deviation.

Probes §493.1256(d)(10)

What statistics does the laboratory have to demonstrate the number of assays and the period of time in which the laboratory repetitively tested control materials to verify or establish control limits?

How does the laboratory evaluate control results to detect any outliers, shifts or trends in control values due to instrument malfunctions or changes in the analytical system?

If more than one test system is in use for a test procedure, did the laboratory evaluate the data for each test method in the establishment of control limits?

D5481

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

§493.1256 Standard: Control procedures

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results.

§493.1256(g) The laboratory must document all control procedures performed.

Interpretive Guidelines §493.1256(g)

The actual measurement(s) taken, reactions and/or observations must be recorded.

D5501
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1261 Standard: Bacteriology

(a)(1) Each day of use for beta-lactamase methods other than Cefinase™.

Interpretive Guidelines §493.1261(a)(1)

Beta-lactamase testing performed by acidometric, iodometric or chromogenic methodologies other than Cefinase™ must have positive and negative reactivity checked each day of use.

For Cefinase™, use D5471.

D5503
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1261 Standard: Bacteriology

(a)(2) Each week of use for Gram stains.

D5505
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1261 Standard: Bacteriology

(a)(3) When each batch (prepared in-house), lot number (commercially prepared), and shipment of antisera is prepared or opened, and once every 6 months thereafter.

Interpretive Guidelines §493.1261(a)(3)

In addition to Salmonella and Shigella antisera, antisera used for serotyping of homologous isolates, (i.e., streptococcal serotyping systems) must be checked for positive and negative reactivity. Polyvalent antisera should be tested with at least one organism from each polyvalent group.

Requirements for antisera QC apply to testing that has a direct impact on patient care.

D5507
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1261 Standard: Bacteriology

(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms.

(b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results.

Interpretive Guidelines §493.1261(b)(1-2)

"Approved control organism(s)" means either an appropriate control strain or an equivalent strain as defined below.

The laboratory must ensure proper standardization of the inoculum (e.g., use a 0.5 McFarland standard or its optical equivalent, or follow manufacturer's instructions for a commercially available system).

Antimicrobial Disk Diffusion Susceptibility
(Bauer, Kirby, Sherris and Turk Method)

Each new batch of medium and each new lot/shipment of antimicrobial disks must be checked as follows:

ANTIMICROBIAL DISK SUSCEPTIBILITY TEST

Appropriate Control Strain	Each New Batch of Media and Disks	Each Day If Isolates Are:
S. aureus ATCC 25923 or equivalent**	X	Staphylococcus spp.
E. coli ATCC 25922 or equivalent**	X	Enterobacteriaceae
P. aeruginosa ATCC 27853 and E. coli ATCC 25922 or equivalent**	X	Pseudomonas aeruginosa Acinetobacter spp.

The above table provides guidance to surveyors of the checks required for each new batch of medium and each new lot/shipment of antimicrobial disks. These must be checked as follows:

1. S.aureus ATCC 25923 or equivalent must be used to test each new batch of

media or disks and it must be used each day if the isolate is Staphylococcus ssp.

2. E. coli ATCC 25922 or equivalent must be used to test each new batch of media or disks and it must be used each day if the isolate is Enterobacteriaceae ssp.

3. P.aeruginosa ATCC 27853 and E.coli ATCC 25922 or equivalent must be used to test each new batch of media or disks and it must be used each day if the isolate is Pseudomonas aeruginosa and/or Acinetobacter spp.

Zone sizes must be recorded for each antimicrobial control and limits must be established.

**An equivalent strain is one which demonstrates reactivity similar to an ATCC strain and for which limits have been established. Organisms which manufacturers recommend or require for use in their systems are acceptable strains of control organisms.

Direct susceptibility testing is a modification of the standardized disk diffusion susceptibility testing method. Therefore, the laboratory must establish the interpretive zone diameters for patient specimens, as well as establish the zone diameters for quality control organisms.

MINIMUM INHIBITORY CONCENTRATION (MIC)

Each new batch of macrodilution tubes, microdilution trays, or agar dilution plates must be checked as follows:

MINIMUM INHIBITORY CONCENTRATION (MIC)

Appropriate Control Strain	**Each New Batch of Media**	**Each Day If Isolates are:**
S. aureus ATCC 29213 or equivalent**	X	Staphylococcus spp.
E. coli ATCC 25922 or equivalent**	X	Enterobacteriaceae
P. aeruginosa ATCC 27853 and E. coli ATCC 25922 or equivalent **	X	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.

§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.

D5519

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

§493.1263 Standard: Mycology

(b)For antifungal susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antifungal agent(s) before, or concurrent with, initial use, using an appropriate control organism(s).

(b)(1) The laboratory must establish limits for acceptable control results.

Probes §493.1263(b)(1)

Which control strains are used and how did the laboratory establish acceptable control limits for susceptibility tests?

(b)(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

Probes §493.1263(b)(2)

Are quality control samples tested at the same time specimens are tested?

(b)(3) The results for the control organism(s) must be within established limits before reporting patient results.

§493.1263(c) The laboratory must document all control procedures performed, as specified in this section.

Interpretive Guidelines §493.1263(c)

QC records should include lot numbers, date prepared/opened, expiration dates, the actual measurements, reactions, and/or observations and demonstrate that controls were tested when shipments of reagents, discs, stains, or antisera for identification systems were opened or when the laboratory prepared these materials.

D5525

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

§493.1264 Standard: Parasitology

(b) The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.

Interpretive Guidelines §493.1264(b)

Check for the following:

- Presence of an ocular micrometer for the microscope(s) used;

- Availability of a stage micrometer;
- Instructions for calibration. Use D5403;
- Records of the measurements and calculations used to show that each objective (high, oil, low) has been calibrated; and
- Criteria for the use of the micrometer for determining the size of ova and parasites. Use D5403.

Probes §493.1264(b)

How has the laboratory determined the accuracy of the ocular calibration and that the staff has the knowledge for proper use?

§493.1267 Standard: Routine chemistry

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

For blood gas analyses, the laboratory must perform the following: Interpretive Guidelines §493.1267(a)-(d)

When condition-level deficiencies in Routine Chemistry are identified in one or more phases of testing, use D5016.

Control materials generally are not available to verify the reportable range at the very high range of patient results. When necessary, the laboratory may verify the results by splitting patient samples and assaying them on two different blood gas analyzers.
Quality control records should include lot numbers, date prepared/opened, expiration dates, the actual measurements, reaction and/or observations and demonstrate that controls were tested as required.

Do not dictate the acceptable format for documentation.

Probes §493.1267(a)-(d)

For blood gas testing, do the records include barometric pressure and room temperature, as necessary?

Do the records of a laboratory that moves from testing site to testing site demonstrate the performance of control samples following transport of equipment when such activity affects test performance specifications and/or instrument calibration?

D5535

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

§493.1267 Standard: Routine chemistry

(a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer.

Interpretive Guidelines §493.1267(a)

For blood gas analysis, the laboratory must perform calibration and calibration verification in accordance with the manufacturer's instructions. If the laboratory meets the manufacturer's instructions, and the requirements at this section, the laboratory does not have to adhere to calibration and calibration verification requirements at §493.1255.

D5537

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

§493.1267 Standard: Routine chemistry

(b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing.

Interpretive Guideline§493.1267(b)

"Each 8 Hours of testing" is defined as each shift of 8 consecutive hours the laboratory is in operation, including "on-call" shifts. When documenting standards/controls results, the laboratory must identify the shifts in which controls are tested with patients.

For a laboratory that is only open 8 hours/day and the instrument autocalibrators, the laboratory must test both a low and high value in the eight hours to meet the requirement.

In addition to testing one control each eight hours, the combination of controls and calibrators used each day of testing must include a high and low value. Controls should be rotated to check normal, alkalosis and acidosis levels.

D5539

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

§493.1267 Standard: Routine chemistry

(c) Test one sample of control material each time specimens are tested unless automated instrumentation internally verifies calibration at least every 30 minutes.

Interpretive Guidelines §493.1267(c)

If blood gas analysis is performed with an instrument that does not internally verify the calibration at least every thirty minutes, then a calibrator or control must be tested each time patient specimens are tested. It is not the intent of this requirement to require the laboratory to maintain records of each auto-calibration.

§493.1267 Standard: Routine chemistry

(d) Document all control procedures performed, as specified in this section.

D5547

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

§493.1269 Standard: Hematology

(c) For manual coagulation tests--

(c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and

(c)(2) Patient specimens and control materials must be tested in duplicate.

§493.1269 Standard: Hematology

(d) The laboratory must document all control procedures performed, as specified in this section.

Interpretive Guidelines §493.1269(d)

Quality control records should include lot numbers, date prepared/opened, expiration dates, the actual measurement(s) taken, reactions and/or observations and demonstrate that controls were tested when shipments of reagents or stains were opened or when the laboratory prepared these materials. However, do not dictate the acceptable format for documentation.

D5557

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

§493.1271 Standard: Immunohematology

(d) Retention of Samples of Transfused Blood. According to the laboratory's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of transfusion reactions. The laboratory must promptly dispose of blood not retained for further testing that has passed its expiration date.

Interpretive Guidelines §493.1271(d

There is no specific timeframe for retaining donor and recipient blood samples. However, it is common practice to keep these samples for a minimum of seven days after each transfusion in case there is a need for retesting.

D5603

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

§493.1273 Standard: Histopathology

(b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in §493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under §§493.1449(b), (l), or (m).

D5605

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

§493.1273 Standard: Histopathology

(c) An individual who has successfully completed a training program in neuromuscular pathology approved by HHS may examine and provide reports for neuromuscular pathology.

Interpretive **Guidelines §493.1273(c)**

HHS approves the American Academy of Neurology Committee for Neuromuscular Pathology Training Program.

D5609

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

§493.1273 Standard: Histopathology

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results.

Interpretive **Guidelines §493.1273(e)**

“SNOMED®” - Systemized Nomenclature of Medicine is an example of a recognized system of disease nomenclature.

§493.1273(f) The laboratory must document all control procedures performed, as

specified in this section.

Interpretive **Guidelines §493.1273(f)**

QC records should include lot numbers, date prepared/opened, expiration dates, the actual measurements, reactions, and/or observations and demonstrate that controls were tested when shipments of reagents, stains, or kits were opened or when the laboratory prepared these materials.

D5613

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

§493.1274 Standard: Cytology

(a) Cytology slide examination site. **All cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.**

§493.1274 Standard: Cytology

(b) Staining. **The laboratory must have available and follow written policies and procedures for each of the following, if applicable:**

D5617

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

§493.1274 Standard: Cytology

(b)(2) Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used.

Interpretive **Guidelines §493.1274(b)(2)**

The laboratory must develop its own policies and procedures for the prevention of cross-contamination between gynecologic and nongynecologic specimens. The majority of gynecologic specimens are fixed prior to transport to the laboratory. Staining times may differ between gynecologic and nongynecologic specimens. Commonly used methods include separate staining dishes for various specimens (i.e., gynecologic specimens, CSF, sputa, other body fluids), or separate staining times (i.e., gynecologic specimens in the morning and nongynecologic specimens in the afternoon), with the staining dishes washed and stains filtered between staining times.

Probes §493.1274(b)(2)

What does the laboratory do to ensure that cross-contamination between gynecologic and nongynecologic specimens does not occur?

D5619

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

§493.1274 Standard: Cytology

(b)(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining.

Interpretive **Guidelines §493.1274(b)(3)**

A monochromatic stain such as toluidine blue may be used to determine the cellularity of nongynecologic specimens. Once a specimen has been concentrated, usually by centrifugation, a small drop of specimen is placed on a slide. A drop of stain is placed next to the specimen, allowed to mix, and coverslipped. Cellularity is evaluated microscopically. Highly cellular specimens have a high potential for cross-contamination. One option would be for the laboratory to stain these specimens after routine staining has been completed.

Laboratories which use automated staining methodologies must follow the manufacturer's instructions. Use D5411.

Probes §493.1274(b)(3)

How is the cellularity of nongynecologic specimens checked prior to cytopreparation (staining)?

What procedure does the laboratory use to determine which specimens must be stained separately?

§493.1274 Standard: Cytology

(c) Control Procedures**. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following:**

D5621

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

§493.1274 Standard: Cytology

(c)(1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under §§493.1469 or 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of

this section).

Interpretive Guidelines §493.1274(c)(1)

The 10 percent rescreen of negative cases is not required for a one-person laboratory consisting of a technical supervisor or a laboratory which only employs pathologists qualified as technical supervisors. However, these laboratories must establish and follow a program to detect errors. This program must include, but is not limited to, cytologic/histologic correlations, retrospective review of negative cases, documentation of initial and rescreening results, and statistics [(c)(2)-(5) of this section].

The laboratory must review all slides from each case selected for rescreen.

> **(c)(1)(i) The review must be performed by an individual who meets one of the following qualifications:**
>
> > **(c)(1)(i)(A) A technical supervisor qualified under §§493.1449(b) or (k).**
> >
> > **(c)(1)(i)(B) A cytology general supervisor qualified under §493.1469.**
> >
> > **(c)(1)(i)(C) A cytotechnologist qualified under §493.1483 who has the experience specified in §493.1469(b)(2).**

Interpretive **Guidelines §493.1274(c)(1)(i)**

The laboratory must document which individual(s) are qualified to conduct the 10 percent rescreen. Slides reviewed as part of the 10 percent rescreen must be included in the workload limit of the cytology general supervisor or the cytotechnologist performing the review. Use D5639.

> **(c)(1)(ii) Cases must be randomly selected from the total caseload and include negatives and those from patients or groups of patients that are identified as having a higher than average probability of developing cervical cancer based on available patient information.**

Interpretive **Guidelines §493.1274(c)(1)(ii)**

The laboratory must have a procedure to determine which slides are rescreened. This procedure should ensure that individuals screening the slides do not know which slides will be chosen for rescreen.

The laboratory must establish criteria to ensure that random negative gynecological cases selected for rescreening include, when possible, cases from patients that are identified as having a higher than average probability for developing cervical cancer.

> **(c)(1)(iii) The review of those cases selected must be completed before**

reporting patient results.

D5623

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

§493.1274 Standard: Cytology

(c)(2) Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies.

Interpretive **Guidelines §493.1274(c)(2)**

The laboratory must compare clinical information with cytology final reports. For example, an atrophic smear (usually characteristic of a post menopausal woman) from a 21-year-old female with an LMP (last menstrual period) of 2-weeks-ago constitutes inconsistent findings and must be resolved.

The laboratory must define criteria to determine a discrepancy between a final cytological diagnosis of High Grade Squamous Intraepithelial Lesion (HSIL) or squamous carcinoma, adenocarcinoma or other malignant neoplasias and the correlating histology report.

Cases considered HSIL include: moderate and severe dysplasia, carcinoma in-situ (CIS)/Cervical Intraepithelial Neoplasia (CIN) 2 and CIN 3 or with features suspicious for invasion.

Probes §493.1274(c)(2)

How does the laboratory identify and resolve discrepancies for:

- Clinical information vs. cytology report; and
- Gynecologic cytology report vs. histopathology report?

D5625

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

§493.1274 Standard: Cytology

(c)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient

care, the laboratory must notify the patient's physician and issue an amended report.

Probes §493.1274(c)(3)

How does the laboratory track previous cases on an individual patient?

What criteria does the laboratory use to determine discrepancies when reviewing normal or negative slides from the past five years? How does the laboratory document the review?

How does the laboratory use the retrospective review to assess the analytic system and communicate findings to the appropriate staff? Use D5793

D5627

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

§493.1274 Standard: Cytology

(c)(4) Records of initial examinations and all rescreening results must be documented.

D5629

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

§493.1274 Standard: Cytology

(c)(5) An annual statistical laboratory evaluation of the number of--

(c)(5)(i) Cytology cases examined;

(c)(5)(ii) Specimens processed by specimen type;

(c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation);

(c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison;

(c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and

(c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

Interpretive **Guidelines §493.1274(c)(5)(vi)**

Low-grade Squamous Intraepithelial Lesions (LSIL) encompasses all lesions that demonstrate cellular changes consistent with human papillomavirus, mild dysplasia, or CIN 1.

D5633

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

§493.1274 Standard: Cytology

(d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

Interpretive **Guidelines §493.1274(d)(1)**

The maximum workload limit established by the technical supervisor must be based on each individual's capabilities. A generic workload limit for the laboratory as a whole does not meet this requirement.

Probes §493.1274(d)(1)

What criteria does the technical supervisor use to determine the slide limit for each person who examines slides?

D5635

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

§493.1274 Standard: Cytology

(d)(1)(i) The workload limit is based on the individual's performance using evaluations of the following:

Interpretive **Guidelines §493.1274(d)(1)(i)**

The technical supervisor maintains documentation of the slide performance and provides feedback.

Probes §493.1274(d)(1)(i)

What records are maintained to document the technical supervisor's evaluation of the slide performance of each individual?

> **(d)(1)(i)(A) Review of 10 percent of the cases interpreted as negative for the conditions defined in paragraph (e)(1) of this section.**

(d)(1)(i)(B) Comparison of the individual's interpretation with the technical supervisor's confirmation of patient smears specified in paragraphs (e)(1) and (e)(3) of this section.

Probes §493.1274(d)(1)(i)(B)

How does the technical supervisor ensure that feedback is provided on slide examination performance to each person evaluating slides?

What mechanism is used to allow individuals an opportunity to discuss instances of misdiagnosis?

D5637

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

§493.1274 Standard: Cytology

(d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

Probes §493.1274(d)(1)(ii)

What criteria does the technical supervisor use to determine when a workload adjustment is needed?

How are records maintained to document that workload records are reassessed at least every six months and adjusted when necessary?

D5641

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

§493.1274 Standard: Cytology

-(d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined.

The formula--

$$\frac{\text{Number of hours examining slides X 100}}{8}$$

is used to determine maximum slide volume to be examined;

D5643

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

§493.1274 Standard: Cytology

(d)(2)(iii) Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and

Interpretive **Guidelines §493.1274(d)(2)(iii)**

Nongynecologic slide preparations made using automated, semi-automated or other liquid-based slide preparatory techniques include specimens prepared by centrifugation, cytocentrifugation, filtering techniques or monolayering techniques. Any instrument used to assist in the adherence of cells to the slide is considered to meet this requirement. This requirement refers to slide preparatory techniques, not liquid based coverslips. Slides prepared by traditional methods (usually smears prepared by hand) are not included.

Maximum Workload Limits for Nongynecologic Specimens

Traditional Smear Technique	100 Slides
Automated, Semi-Automated, Liquid-Based	200 Slides
Combination of Techniques (Based on Prorated Time)	100 - 200 Slides

§493.1274(d)(2)(iv) Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100 slide workload limit.

D5645

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

§493.1274 Standard: Cytology

(d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

Interpretive **Guidelines §493.1274(d)(3)**

Verify that the laboratory monitors the number of slides examined by each individual and the number of hours spent examining slides.

D5647

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

§493.1274 Standard: Cytology

(d)(4) Records are available to document the workload limit for each individual.

Probes §493.1274(d)(4)
What records are maintained of each individual's workload limit when various types of slides are evaluated?

§493.1274 Standard: Cytology

(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following:

D5649
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1274 Standard: Cytology

(e)(1) A technical supervisor confirms each gynecologic slide preparation interpreted to exhibit reactive or reparative changes or any of the following epithelial cell abnormalities:

(e)(1)(i) Squamous Cell

***Interpretive* Guidelines §493.1274(e)(1)(i)**

NOTE: This requirement is in addition to the review and confirmation by a technical supervisor of all nongynecologic preparations as described under §493.1274(e)(3).

Probes §493.1274(e)(1)(i)

How does the laboratory ensure that the technical supervisor confirms every slide containing cells exhibiting reactive, reparative, atypical squamous/glandular cells, LSIL, HSIL, and all carcinomas?

(e)(1)(i)(A) Atypical squamous cells of undetermined significance (ASC-US) or cannot exclude HSIL (ASC-H).

(e)(1)(i)(B) LSIL-Human papillomavirus (HPV)/mild dysplasia/cervical intraepithelial neoplasia 1 (CIN 1).

(e)(1)(i)(C) HSIL-moderate and severe dysplasia, carcinoma in situ (CIS)/CIN 2 and CIN 3 or with features suspicious for invasion.

(e)(1)(i)(D) Squamous cell carcinoma.

(e)(1)(ii) Glandular Cell

(e)(1)(ii)(A) Atypical cells not otherwise specified (NOS) or specified in comments (endocervical, endometrial, or glandular).

(e)(1)(ii)(B) Atypical cells favor neoplastic (endocervical or glandular).

(e)(1)(ii)(C) Endocervical adenocarcinoma in situ.

(e)(1)(ii)(D) Adenocarcinoma endocervical, adenocarcinoma endometrial, adenocarcinoma extrauterine, and adenocarcinoma NOS.

(e)(1)(iii) Other malignant neoplasms.

D5655

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

§493.1274 Standard: Cytology

(e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

Interpretive **Guidelines §493.1274(e)(4)**

The report should clearly specify when the slide is unsatisfactory for evaluation. Unsatisfactory slide preparations should not be reported as negative or normal.
Use D5805.

Probes §493.1274(e)(4)

What criteria have been developed for categorizing a slide preparation as unsatisfactory (e.g., scant cellularity, obscuring blood, obscuring inflammation, or lack of endocervical component)?

D5657

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

§493.1274 Standard: Cytology

(e)(5) The report contains narrative descriptive nomenclature for all results.

Interpretive **Guidelines §493.1274(e)(5)**

In cytology, great variation exists among the systems and terms a laboratory may use to report patient results on cytology reports. The laboratory must specify the descriptive nomenclature used for reporting patient results. This nomenclature must define the

criteria used to classify patient results in a particular category in a clear and concise manner to ensure that all employees report patient results in a uniform, consistent manner. Use of the Papanicolaou numerical system without narrative description is not acceptable.

The Bethesda System is an example of a recognized system of narrative descriptive nomenclature for gynecologic cytology.

Probes §493.1274(e)(5)

When cytology evaluations are recorded on worksheets in "code" how does the laboratory ensure that the correct interpretation is used in reporting the results?
Use D5801.

D5661

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

§493.1274 Standard: Cytology

(f)(2) Slides may be loaned to proficiency testing programs in lieu of maintaining them for the required time period, provided the laboratory receives written acknowledgment of the receipt of slides by the proficiency testing program and maintains the acknowledgment to document the loan of these slides.

(f)(3) Documentation of slides loaned or referred for purposes other than proficiency testing must be maintained.

D5663

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

§493.1274 Standard: Cytology

(f)(4) All slides must be retrievable upon request.

Probes §493.1274(f)(4)

If the laboratory loans slides, what protocol has been established to ensure prompt return of slides, when necessary?

D5665

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

§493.1274 Standard: Cytology

(g) Automated and semi-automated screening devices. When performing evaluations

using automated and semi-automated screening devices, the laboratory must follow manufacturer's instructions for preanalytic, analytic, and postanalytic phases of testing, as applicable, and meet the applicable requirements of this subpart K.

Interpretive **Guidelines §493.1274(g)**

Some automated devices, such as instruments where only a portion of the slide is reviewed, may have a higher workload limit than 100 slides. This must be stated in the manufacturer's product insert to be applicable. However, the maximum workload limit for those slides which require 100% manual review (as a result of automated or semi-automated analysis OR in the routine workload) remains 100 slides.

Probes §493.1274(g)

When technology (automated/semi-automated devices) is introduced into the laboratory, how does the laboratory ensure its operation is within the specifications of previous methods used by the laboratory?

Some automated devices remove a percentage of the slides from the workload. How does the laboratory ensure that the correct slides are archived?

D5685

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

§493.1276 Standard: Clinical cytogenetics

(c) Determination of sex must be performed by full chromosome analysis.

D5687

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

§493.1276 Standard: Clinical cytogenetics

(d) The laboratory report must include a summary and interpretation of the observations, number of cells counted and analyzed, and use the International System for Human Cytogenetic Nomenclature.

Probes §493.1276(d)

Does the laboratory report include:

- Type of banding method used, if applicable;
- Stage of cell mitosis when banded;
- Number of cells counted and analyzed microscopically;

- Number of cells from which photographic or computerized karyotypes were prepared; and

- Estimate of the banding resolution achieved?

Does the laboratory, where appropriate, ensure that FISH clinical interpretations are made in conjunction with standard cytogenetic analyses and evaluated against patient medical history and other diagnostic test results?

Preliminary reports of karyotypes based on less than full analysis are acceptable if the diagnosis is clear.

For what types of cultures are preliminary reports issued? These may include, but are not limited to, the following:

- Bone marrow analysis (within 14 days);

- Unstimulated blood cultures (within 14 days); and

- Lymphocytes from newborns (within 7 days).

What is the **average** length of time for reporting (use D5801or D5815, as appropriate):

- Amniotic fluid cell cultures (90% of prenatal diagnosis cases should be signed out in 21 days);

- Routine lymphocyte cultures (approximately 4-5 weeks); and

- Fibroblast cultures (approximately 2-3 months)?

Do records document:

- Observations made concurrently with the performance of each step in the examination of specimens/cultures (use D5683); and

- The number of cases reviewed, signed out and/or the frequency of failed or sub-optimal cultures?

§493.1276 Standard: Clinical cytogenetics

(e) The laboratory must document all control procedures performed, as specified in this section.

Probes §493.1276(e)

Each day of use, does the laboratory test the positive and negative reactivity of staining

materials to ensure predictable staining characteristics? Use D5473.

Does the laboratory, concurrent with the initial use, check each batch of media for pH (amniotic cell cultures should be kept between pH 6.8 and 7.8), sterility, and ability to support growth? Use D5477.

Does the laboratory employ an alternative procedure for the immediate assessment and monitoring of all testing over time? For example: Control materials are not routinely available to demonstrate chromosome abnormalities for linkage, breakage or translocation, but the laboratory must demonstrate an alternative mechanism for detecting chromosome abnormalities to be analyzed. Use D5485.

An alternative procedure might include spit sample with another laboratory, repeat patient specimen, special stains, FISH assays, and/or molecular assays.

§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.

D5729

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

§493.1278 Standard: Histocompatibility

(a)(1) An audible alarm system must be used to monitor the storage temperature of specimens (donor and recipient) and reagents. The laboratory must have an emergency plan for alternate storage.

Interpretive **Guidelines §493.1278(a)(1)-(a)(2)**

Ultra low (-80ºC) freezers and liquid nitrogen (LN2) reservoirs are common in these laboratories. LN2 reservoirs should be monitored to ensure adequate supply of LN2 at all times.

Verify that the laboratory has an audible alarm system for freezers and refrigerators where critical patient specimens and test reagents are stored. The laboratory should have established the temperature at which the audible alarm will activate. Determine if the laboratory has an emergency power source for this alarm system in the event of an electrical failure. If emergency power is not available, the laboratory should have policies/procedures on how to ensure a prompt response to an activated alarm, 24 hours a

day, 7 days a week, including holidays.

An emergency plan for alternate storage of historic patient serum specimens necessary for pre-transplant crossmatching is critical. Verify that the laboratory has an emergency plan for alternate storage appropriate for its operational needs.

D5731

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

§493.1278 Standard: Histocompatibility

(a)(2) All patient specimens must be easily retrievable.

Interpretive **Guidelines §493.1278(2)**

Patient specimens needed for pre-transplant testing should be stored on-site.

D5733

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

§493.1278 Standard: Histocompatibility

(a)(3) Reagent typing sera inventory prepared in-house must indicate source, bleeding date and identification number, reagent specificity, and volume remaining.

D5735

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

§493.1278 Standard: Histocompatibility

(a)(4) If the laboratory uses immunologic reagents (for example, antibodies, antibody-coated particles, or complement) to facilitate or enhance the isolation of lymphocytes, or lymphocyte subsets, the efficacy of the methods must be monitored with appropriate quality control procedures.

Interpretive **Guidelines 493.1278(a)(4)**

Lymphocytes can be isolated from peripheral blood, lymph nodes and spleen. These cells can be further separated into subsets such as T cells and B cells. Examples of commonly used commercial immunologic reagents include immunomagnetic beads and monoclonal reagents. The laboratory should determine the quality (cell viability), the quantity (final yield), subset specificity (T cell, B cell, etc.), and purity (contaminating cells removed) of the final cell preparation. The laboratory should have policies and/or procedures for assessment of the efficacy of these reagents to include criteria for acceptability. For deficiencies related to the procedure, use D5403; for control material

acceptability, use D5469.

The subset specificity of each lot of immunomagnetic beads should be verified with antiserum specific for each cell type (e.g., T cell beads with anti-T-lymphocyte serum).

D5737

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

§493.1278 Standard: Histocompatibility

(a)(5) Participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

Interpretive **Guidelines §493.1278(a)(5)**

Programs offered by proficiency testing companies and cell exchanges for histocompatibility laboratories are readily available. An example of a regional exchange program is the Southeastern Organ Procurement Foundation (SEOPF). UCLA provides an international monthly exchange program with sera, cells and DNA. The College of American Pathologists (CAP) and the American Society for Histocompatibility and Immunogenetics (ASHI) each offer programs that assess the primary areas of testing in histocompatibility laboratories by test techniques (i.e., antibody screening and identification, HLA typing for Class I (HLA-A, B, C) and Class II (HLA-DR, DQ), lymphocyte crossmatching (T cell and B cell)).

Laboratories participating in a local exchange should record information concerning the frequency of exchange and the grading system.

Cite a deficiency if the laboratory is not enrolled in a cell exchange program or is enrolled in a program, but fails to return the results. A laboratory's performance in a regional or national exchange program should be evaluated against a peer group performing the same technique.

D5739

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

§493.1278 Standard: Histocompatibility

(b) HLA typing. The laboratory must do the following:

Interpretive **Guidelines §493.1278(b)**

HLA (Human Leukocyte Antigens) typing is the identification of histocompatibility antigens and/or alleles. HLA typing is performed by serologic or molecular methods. Serologic typing is usually performed by incubating viable lymphocytes with antisera of

known HLA specificities. Antibodies will bind cells with the corresponding HLA antigen(s) on their surface. When complement is added to an immune complex, it binds to the complex causing cell death. The surface of the lymphocyte becomes permeable to stains and this positivity is determined microscopically.

HLA typing using nucleic acid (DNA) and primers and/or probes involves using the polymerase chain reaction (PCR) to amplify HLA sequences of interest which are detected by gel electrophoresis, ELISA or by fluorescence detection using flow cytometry.

(b)(1) Use a technique(s) that is established to optimally define, as applicable, HLA Class I and II specificities.

Interpretive **Guidelines §493.1278(b)(1)**

HLA CLASS I specificities include HLA-A, B, Cw.

HLA CLASS II specificities include HLA-DR, DQ, and DP.

Verify that the laboratory has validated the reagents and methods it uses. For deficiencies related to verification of methods, use D5421; for establishment of methods, use D5423.

(b)(2) HLA type all potential transplant recipients at a level appropriate to support clinical transplant protocol and donor selection.

Interpretive **Guidelines §493.1278(b)(2):**

The laboratory should be an active participant of the transplant center's clinical program. It should provide the technical assistance and pertinent data necessary to help establish transplant protocols for solid organ, tissue and cellular transplants and transfusions. Each protocol should specify what HLA specificities should be identified and at what level this testing needs to be performed. HLA Class I and Class II typing must be performed in accordance with the protocol.

(b)(3) HLA type cells from organ donors referred to the laboratory.

(b)(4) Use HLA antigen terminology that conforms to the latest report of the World Health Organization (W.H.O.) Committee on Nomenclature. Potential new antigens not yet approved by this committee must have a designation that cannot be confused with W.H.O. terminology.

(b)(5) Have available and follow written criteria for the following:

§493.1278 Standard: Histocompatibility

(b)(5)(i) The preparation of cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the HLA typing technique(s) performed.

Interpretive **Guidelines §493.1278(b)(5)(i):**

The laboratory's procedure manual should contain cell and /or DNA isolation procedures for each type of specimen it uses (e.g., peripheral blood, lymph nodes and spleen, cell cultures, filter paper blood spots, buccal swabs).

Laboratories should assess pretest viability of cells prior to dotting on typing trays. They may use trypan blue stain, wet preps, etc. Verify that the laboratory maintains records of this activity. For most techniques, viability should exceed 80%.

Determine if the laboratory has verified their extraction method. Use D5421.

D5743

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

§493.1278 Standard: Histocompatibility

(b)(5)(ii)Selecting typing reagents, whether prepared in-house or commercially.

Interpretive **Guidelines §493.1278(b)(5)(ii)**

For HLA complement dependent lymphocytotoxicity typing, each batch of complement must be tested to determine that it mediates cytotoxicity (cell death) in the presence of a specific HLA antibody, but is not cytotoxic in the absence of a specific antibody. The test should ensure that it is maximally active at least one dilution beyond that intended for use. The test should be carried out with at least two antibodies known to react with at least two different cells (positive control), and at least one cell which should not react (negative control). A strong and a weak antibody should be selected for the test. Serial dilutions of a single serum may also be used. Verify that the laboratory has performed complement quality control and that an optimum dilution has been selected and documented. Complement is temperature sensitive (labile) and should be retitered periodically to ensure its activity. Determine if the laboratory has complement retitering policies/procedures.

The results of each batch/lot of reagents (typing trays) whether commercially made or prepared in-house must be reviewed to determine which sera failed to react as expected (false negative reactions) and which sera had unexpected reactions (false positive reactions). Future tray preparation and interpretation of commercially purchased trays should be evaluated and revised based on the results of these reviews.

Probes §493.1278(b)(5)(ii)

What criteria were used to determine the acceptability of each batch of complement for HLA serologic assays?

How does the laboratory select the typing trays it uses for each patient?

D5745

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

§493.1278 Standard: Histocompatibility

(b)(5)(iii) Ensuring that reagents used for typing are adequate to define all HLA-A, B and DR specificities that are officially recognized by the most recent W.H.O. Committee on Nomenclature and for which reagents are readily available.

Interpretive **Guidelines §493.1278(b)(5)(iii)**

Antisera for less frequent and rare specificities may be unavailable to laboratories. It is good laboratory practice for each HLA antigen to be defined by at least two operationally monospecific sera. Typing for (HLA) class I or class II antigens must employ a sufficient number of anitsera or monoclonal antibodies to clearly define all the antigens for which the laboratory tests. For example: If multispecific sera must be used, at least three partially non-overlapping sera should be used to define each HLA-antigen. For each HLA-DR and HLA-DQ antigen to be defined, at least 3 operationally monospecific sera should be used. If multispecific sera must be used, at least 5 partially non-overlapping sera should be used.

The laboratory should demonstrate that typing sera reactions are recorded, reviewed and used to modify locally prepared typing trays and interpret commercial tray specificities.

Primer and/or probe sequence, specificity and sensitivity should be defined with reference material (previously typed DNA). For typing methods using probe technology, verify whether optimum hybridization temperatures have been verified or established for each probe.

The laboratory should demonstrate that reference material testing is recorded regularly, reviewed and used to modify locally prepared reagents, as well as interpret commercial primer and/or probe specificities.

Probes §493.1278(b)(5)(iii)

How are the specificities of new typing sera, primers and probes (whether local or commercial) verified, e.g., by parallel testing with known cells or DNA?

How does the laboratory report HLA typings performed by serology and DNA (i.e.,

follow the W.H.O. nomenclature list)? Are antigens and alleles reported appropriately?

D5747

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

§493.1278 Standard: Histocompatibility

(b)(5)(iv) The assignment of HLA antigens.

Interpretive **Guidelines §493.1278(b)(5)(iv)**

Criteria for antigen and/or allele assignment must take into account basic principles of genetic inheritance.

Examples

1. No more than 2 antigens or alleles per HLA-A, B, and DR locus can be assigned to any patient; e.g., antigens HLA-A2, A24; B46, B61; DR8, 14; alleles HLA-A*02XX, 24XX; B*4002, 4601; DRB1*0803, 1401. Public specificities may be observed; i.e. for HLA-B, additional specificities of Bw4 and/or Bw6 are reported, for Class II antigens, additional gene products of DR51, DR52 and/or DR53 are reported.

2. When family studies are performed, typing interpretations should be in accordance with genetic relationships (i.e., haplotype assignments, determination of homozygosity at a particular locus).

Verify that the laboratory has established acceptability criteria for assignment of HLA antigens and/or alleles. Examples for alleles include signal intensity, band clarity and migration, specificity, and procedures to resolve ambiguous alternative combinations.

Determine if testing personnel follow the scoring and reporting system defined in the procedure manual. Two independent interpretations are recommended for each DNA analysis. Determine if the laboratory has validated computer software for the analysis of antigens and/or alleles.

D5749

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

§493.1278 Standard: Histocompatibility

(b)(5)(v) When antigen redefinition and retyping are required.

Interpretive **Guidelines §493.1278(b)(5)(v)**

Verify that the laboratory has policies and procedures for antigen and/or allele

redefinition and retyping. Records should indicate that results from redefinition and retyping are evaluated and that patient typings are updated accordingly. Discrepancies identified as the result of this activity should be documented and resolved. Use D5775.

D5751

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

§493.1278 Standard: Histocompatibility

(b)(6) Check each HLA typing by testing, at a minimum the following:

(b)(6)(i) A positive control material.

(b)(6)(ii) A negative control material in which, if applicable to the technique performed, cell viability at the end of incubation is sufficient to permit accurate interpretation of results. In assays in which cell viability is not required, the negative control result must be sufficiently different from the positive control result to permit accurate interpretation of results.

(b)(6)(iii) Positive control materials for specific cell types when applicable (that is, T cells, B cells, and monocytes).

Interpretive **Guidelines §493.1278(b)(6)**

Each HLA-A, B, C or supplemental Class I typing tray must include at least one positive control serum, previously shown to react with all lymphocytes, and one negative control serum which has been demonstrated to be non-cytotoxic. HLA-DR and DQ typing trays must include a positive control serum, previously shown to react with only B cells, and one negative control serum which has been demonstrated to be non-cytotoxic.

Cell controls must be tested with each batch/lot/shipment of typing trays. Typing results are invalid if controls fail to react as expected. The negative control should either be one previously shown to lack antibody or should be from a healthy male with no history of blood transfusion. Cell viability in the negative control well at the end of the incubation must be sufficient to permit accurate interpretation of results. For most techniques, viability should exceed 80%. However, when less than optimal specimens, such as cadaver and mailed specimens, this threshold may not be met.

For DNA typing, negative control wells or wells with no DNA should not give a positive result (the presence of a band), however, internal controls should give a positive result. DNA reference material must be tested with each lot of typing reagents. Primers and/or probes must be tested for allele specificity with reference material.

D5755

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

§493.1278 Standard: Histocompatibility

(d) Antibody Screening. The laboratory must do the following:

(d)(1) Use a technique(s) that detects HLA-specific antibody with a specificity equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay.

(d)(2) Use a method that distinguishes antibodies to HLA Class II antigens from antibodies to Class I antigens to detect antibodies to HLA Class II antigens.

(d)(3) Use a panel that contains all the major HLA specificities and common splits. If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding.

Interpretive **Guidelines §493.1278(d)(1)-(d)(3)**

An antibody screen is performed to identify whether a patient's serum contains antibodies to one or more HLA antigens. This is accomplished by screening the serum against target antigens from a suitable panel appropriate for the population served, i.e., a variety of ethnic groups. Results are expressed as percent reactive antibodies (PRA).

The panel of antigens used must include all of the HLA antigens to which the most common HLA antibodies are formed. Cell panels of known HLA type must be available to prove the specificity of new antibodies. The serum cell panel should be consistent from month to month and from lot to lot. Verify that the frequency of each antigen represented does not vary significantly.

An example of PRA differences from panel to panel:

If a patient demonstrates a HLA-A2 antibody and the cell panel contains 15 A2 positive cells out of 100, the patient's PRA on this tray will be 15%. If the same patient is tested against a panel where there are 37 A2 positive cells out of 100, the patient's PRA will increase to 37%. The number of A2 positive cells on this laboratory's cell panel should reflect the frequency observed in the population it serves; e.g., 15-20% of the local population possess the HLA-A2 antigen.

If the laboratory tests for antibodies to Class II antigens, the laboratory should have a procedure for removing Class I antibodies or should use purified Class II antigens. Class II antigens (HLA-DR, DQ) are found only on the B cell subset of lymphocytes. B cells also have a high density of Class I antigens (HLA-A, B, C), which are found on all nucleated cells. If a patient has a significant titer of Class I antibodies, it may result in a false positive Class II antibody test result. Platelet absorption is one method of removing the Class I antibodies.

Verify that the laboratory's antibody screening technique is as sensitive as the crossmatch method it uses to ensure optimum compatibility.

D5757

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

§493.1278 Standard: Histocompatibility

(d)(4) Make a reasonable attempt to have available monthly serum specimens for all potential transplant recipients for periodic antibody screening and crossmatch.

(d)(5) Have available and follow a written policy consistent with clinical transplant protocols for the frequency of screening potential transplant recipient sera for preformed HLA-specific antibodies.

Interpretive **Guidelines §493.1278(d)(4)-(d)(5)**

A recipient's antibody profile should be evaluated when the individual is entered on the transplant waiting list. Determine whether the laboratory obtains specimens at initial typing for antibody screening and for pre-transplantation auto crossmatches.

The laboratory should have clearly defined and appropriate screening protocols for potentially sensitizing events such as transfusion, transplant loss, pregnancy or infection. Verify that the laboratory obtains and tests patient specimens to determine if there have been changes in the antibody profiles as defined by the transplant center's protocols. Determine when the laboratory verifies that the antibodies in the serum have been characterized against HLA antigens.

Probes §493.1278(d)(4)-(d)(5)

What policies and procedures has the laboratory implemented in an effort to procure monthly serum specimens for potential transplant recipients?

What is the laboratory's frequency for screening potential transplant recipient sera for preformed HLA-specific antibodies?

D5759

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

§493.1278 Standard: Histocompatibility

(d)(6) Check each antibody screening by testing, at a minimum the following:

> **(d)(6)(i) A positive control material containing antibodies of the appropriate isotype for the assay.**

(d)(6)(ii) A negative control material.

Interpretive **Guidelines §493.1278(d)(6)**

For serologic antibody screening, each tray must include at least one positive control serum previously shown to react with all lymphocytes and one negative control serum which has been demonstrated to be non-cytotoxic or lack antibody. Results are invalid if controls fail to react as expected. Cell viability in the negative control well at the time of reading must be sufficient to permit accurate interpretation of results. Viability should exceed 80%. The positive control must contain antibodies of the appropriate isotype (e.g., IgG and/or IgM). If the frozen cell tray is specific for Class II (HLA-DR or DQ) antibody testing, the laboratory must ensure B cells are being tested and have a mechanism to distinguish Class II antibodies from antibodies to Class I antigens that are also found on B cells.

Laboratories using ELISA and/or flow cytometric techniques must include one positive control serum and one negative control serum. Reagent controls for non-specific binding of antibody should be included with all ELISA testing. The negative control for flow cytometers should demonstrate non-reactivity and the positive control should be specific for HLA antigens. Again, the positive control for both techniques must contain antibodies of the appropriate isotype (i.e., IgG and/or IgM).

Verify that the laboratory uses a negative control and the appropriate isotype for its positive control.

Verify that the laboratory has established acceptability criteria for each control and for each method it uses.

D5763

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

§493.1278 Standard: Histocompatibility

(e) Crossmatching. The laboratory must do the following:

(e)(1) Use a technique(s) documented to have increased sensitivity in comparison with the basic complement-dependent microlymphocytotoxicity assay.

Interpretive **Guidelines §493.1278(e)(1)**

The minimum technique for crossmatching for transplantation must be more sensitive than the basic lymphocytotoxicity test (standard complement dependent or NIH procedure). A technique that enhances sensitivity must be used (e.g., increased incubation time, additional wash steps, antihumanglobulin (AHG) augmentation, ELISA testing, flow cytometry testing).

D5765
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1278 Standard: Histocompatibility

(e)(2) Have available and follow written criteria for the following:

(e)(2)(i) Selecting appropriate patient serum samples for crossmatching.

Interpretive **Guidelines §493.1278(e)(2)(i)**

The laboratory must have clearly defined protocols for selection of serum for crossmatch testing. There are numerous acceptable protocols for the selection of crossmatch samples which vary from transplant center to center. However, every effort should be made to procure a specimen at the time of transplant or unless the laboratory can clearly establish that the patient did not receive a blood transfusion or other alloimmunizing event between the times of specimen collection and transplant date.

Review patient transplant records for lymphocyte crossmatch results. Verify serum selected for crossmatching against antibody screening/identification records. Verify if the serum is tested at an optimal dilution. Crossmatches are performed with donor T cells (T lymphocytes) or unseparated lymphocytes. Crossmatches with donor B cells (B lymphocytes) may be performed.

Probes §493.1278(e)(2)(i)

Does the laboratory's policies and procedures specify which patient serum samples are to be used for crossmatching (e.g., renal, pancreas, heart, lung, small intestine or liver transplants)?

(e)(2)(ii) The preparation of donor cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the crossmatch technique(s) performed.

Interpretive **Guidelines §493.1278(e)(2)(ii)**

There are various techniques for the isolation of donor cells for use in crossmatching e.g., immunomagnetic beads, monoclonal antibody preparations, density gradient (ficoll hypaque). Crossmatching techniques utilizing cellular extracts (solubilized antigens and nucleic acid) are not well documented in the clinical setting.

Determine if the laboratory follows manufacturer's product insert procedures.
Use D5479.

Verify that the laboratory has established procedures and criteria for cell preparation viability, purity and quantity (i.e. peripheral blood, lymph node, spleen).

D5767

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

§493.1278 Standard: Histocompatibility

(e)(3) Check each crossmatch and compatibility test for HLA Class II antigenic differences using control materials to monitor the test components and each phase of the test system to ensure acceptable performance.

Interpretive **Guidelines §493.1278(e)(3)**

The mixed leukocyte (lymphocyte) culture (MLC) is used by a small number of laboratories and it may be used in conjunction with other cellular assays such as cell mediated lympholysis (CML), primed lymphocyte typing (PLT) or homozygous typing cell (HTC) to determine donor recipient pair compatibility in renal or tissue transplants.

The MLC method may vary from micro, macro, one way or both one way, and two way. Data expressed in counts per minute of tritiated thymidine (H3) are used to calculate the stimulation index (SI) or the relative response (RR). Controls include: a negative control (responder cells stimulated with autologous cells), positive controls (responder cells stimulated with cells from unrelated individuals with known Class II antigen differences or fresh or frozen cell pool). If the laboratory performs MLCs, review their criteria for accepting or rejecting a run and a narrative report on donor recipient compatibility. Confirm that all combinations of any given stimulator is tested against any given responder.

Verify that the laboratory has established criteria for defining positive and negative crossmatches.

Example1:

Basic crossmatch technique: (includes increased incubation time testing or wash(es))

1. Each crossmatch tray must include one positive control serum previously shown to react with all cells and one negative control serum which demonstrates non-cytotoxic activity. Additional controls may include antisera against specific cell lines and reagent controls.

2. Each serum is tested undiluted and at one or more dilutions.

Example 2:
Anti-human globulin augmentation:

1. Each crossmatch tray must include one positive control serum previously shown to react with all cells and one negative control serum which demonstrates non-cytotoxic activity. Additional controls may include antisera against specific cell

lines and reagent controls.

2. Each serum is tested undiluted and at one or more dilutions.

3. Verify that AHG has been titered for optimum test performance.

Example 3:

Flow cytometry:

1. Each crossmatch must include one positive control serum and one negative control serum. The positive control should be human serum of the appropriate isotype and specific for HLA antigens shown to react with all cells. The negative control should demonstrate non-reactivity against lymphocytes.

2. Verify that the laboratory has established a threshold for determining a positive reaction (e.g., mean channel shifts, quantitative fluorescence measurements).

3. The laboratory should be running an optical standard (lens focusing and alignment) and fluorescent standard (adequate signal amplification) with each use of the instrument.

4. Verify that the laboratory has established an optimum serum/cell ratio (standard number of cells to a fixed volume of serum).

5. A multi color technique should be used to ensure the purity of the cell population being tested.

Probes §493.1278(e)(3):

What is the laboratory's control acceptance criteria for MLC testing?

D5769

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

§493.1278 Standard: Histocompatibility

(f) Transplantation. Laboratories performing histocompatibility testing for transfusion and transplantation purposes must do the following:

(f)(1) Have available and follow written policies and protocols specifying the histocompatibility testing (that is, HLA typing, antibody screening, compatibility testing and crossmatching) to be performed for each type of cell, tissue or organ to be transfused or transplanted. The laboratory's policies must include, as applicable--

(f)(1)(i) Testing protocols for cadaver donor, living, living-related, and combined organ and tissue transplants;

(f)(1)(ii) Testing protocols for patients at high risk for allograft rejection; and

(f)(1)(iii)The level of testing required to support clinical transplant protocols (for example, antigen or allele level).

Interpretive **Guidelines §493.1278(f)**

In conjunction with the transplantation center the laboratory establishes written policies on the testing protocols it performs in support of the clinical transplant program. Policies should address when HLA testing and final crossmatches are required for patients that have demonstrated presensitization. For organs such as liver and heart (non-renal), it is not uncommon for laboratories to perform retrospective crossmatches if the patient demonstrates the absence of preformed antibodies by prior screening. Failure to perform a crossmatch prior to transplant **is not** a deficiency provided emergency transplant circumstances are documented.

For solid organ transplants (renal, heart, liver, lung, small intestine):

1. Determine what tests are performed for potential kidney and pancreas recipients.

2. Determine what tests are performed on living-related or unrelated donors and cadaver donors referred to the laboratory.

3. Determine if the laboratory performs HLA typing using complement dependent lymphocytotoxicity testing (antigen level) and/or DNA testing (allele level);

4. Compare policies for pre-sensitized patients with laboratory antibody screening and identification protocols for consistency;

5. Verify that the laboratory is using a crossmatch technique with increased sensitivity; and

6. Deviations from the established protocols should be documented by the laboratory, indicating the reason for the deviation, e.g., transplant physician request, emergency transplant.

For transfusions (platelet support of refractory patients):

1. Determine what tests are performed on recipients and donors. Recipients are usually HLA-A and HLA-B typed, e.g., platelets do not have Class II (HLA-DR, DQ) antigens on their surface. Donors may be typed by the laboratory, a blood center or a donor program laboratory. HLA typing may be performed using complement dependent lymphocytotoxicity testing (antigen level) and/or DNA

testing (allele level).

2. Determine if the laboratory performs antibody screening/identification on the recipient. Compare with the laboratory protocol for antibody screening and identification.

3. Determine if the laboratory performs Class I crossmatch testing.

For tissue transplant (bone marrow/stem cells, etc.)

1. Determine what level of HLA typing is performed on recipients and donors. For bone marrow/stem cell transplantation, recipients are at a minimum HLA-A and HLA-B typed by complement dependent lymphocytotoxicity and/or DNA testing. Recipients should be HLA-DR typed by high resolution DNA typing (allele level). Donors may be typed by the laboratory or a donor program laboratory.

2. Determine if the laboratory performs crossmatch testing, when a selected potential donor has an HLA mismatch. Determine if the laboratory performs Class II compatibility to evaluate Class II identity by either MLC testing, high resolution DNA typing, or a family study.

Probes §493.1278(f)

What is the laboratory's policy/protocol on referring patient specimens for testing at another laboratory?

What is the laboratory's policy/protocol on accepting HLA typing results obtained at another laboratory (i.e., does the laboratory reconfirm (repeat) testing)?

D5771

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

§493.1278 Standard: Histocompatibility

(f)(2) For renal allotransplantation and combined organ and tissue transplants in which a kidney is to be transplanted, have available results of final crossmatches before the kidney is transplanted.

Probes §493.1278(f)(2)

If the laboratory performs cadaveric renal transplant testing, what are the staffing policies and how do they ensure 24-hour coverage of qualified testing personnel and supervision for technical review?

D5773

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

§493.1278 Standard: Histocompatibility

(f)(3) For nonrenal transplantation, if HLA testing and final crossmatches were not performed prospectively because of an emergency situation, the laboratory must document the circumstances, if known, under which the emergency transplant was performed, and records of the transplant must reflect any information provided to the laboratory by the patient's physician.

§493.1278 Standard: Histocompatibility

(g) Documentation. The laboratory must document all control procedures performed, as specified in this section.

§493.1278(g) Guidelines

All QC records must be maintained for two years including instrument charts, graphs, printouts, transcribed data, manufacturer's assay information sheet for control and calibration materials and reagents to include typing trays, primers and/or probes. Do not dictate the acceptable format for documentation.

D5775

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

§493.1281 Standard: Comparison of test results

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

Interpretive Guidelines §493.1281(a)-(c)

The laboratory must have a system to monitor and evaluate all testing it performs. Examples of materials that may be used to evaluate the same test performed by different methodologies, at multiple locations, and/or on multiple instruments in the same laboratory are proficiency testing samples, split samples or "blind" testing of materials with known values.

A laboratory that performs the same test at multiple locations or on more than one instrument must have written criteria for acceptable differences in test values (e.g., between different or identical models of an instrument from the same manufacturer, between instruments from different manufacturers).

If the laboratory performs calibration verification as specified in §493.1255(b), it may use the calibration verification to meet the requirements at §493.1281(a), provided the 3 levels of materials used for calibration verification meet the laboratory's criteria for

acceptable differences in test values.

D5777

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

§493.1281 Standard: Comparison of test results

(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available:

(b)(1) Patient age.

(b)(2) Sex.

(b)(3) Diagnosis or pertinent clinical data.

(b)(4) Distribution of patient test results.

(b)(5) Relationship with other test parameters.

Interpretive Guidelines §493.1281(b)

Verify that the laboratory has a system in place to monitor and evaluate test results for inconsistencies with patient information, and for correlation between test results. For example, a laboratory could multiply the hemoglobin result by a factor of 3, to see if the result is equal to the hematocrit. If the laboratory has auto-validation in it's Laboratory Information System (LIS), verify that the laboratory is taking steps to reduce the likelihood of sample-switching errors, for example, when the creatinine result is significantly different from the patient's previous creatinine test results, or if the MCV is significantly different from the patient's previous test results and the patient did not receive a blood transfusion.

For automated laboratories, inconsistent patient results may be evaluated through the use of verified LIS supported logic, patient distribution test results, verified automated test comparison logic programs and individual test repeat criteria.

Probes §493.1281(b)

How does the laboratory obtain sufficient information to enable an evaluation of test results with clinically relevant patient information?

Does the laboratory have procedures to assess and evaluate patient test results for inconsistencies?

For example:

- Hemoglobin and Hematocrit (MCHC value exceeds reference range);
- BUN and Creatinine comparison;
- Albumin and Total Protein;
- Correlation of urine culture with urine microscopic; and
- Alkaline phosphatase with orthopedic surgical patients and/or pediatric patients; and
- Correlation of microscopic sediment findings with macroscopic results, such as, the presence of protein with casts, positive occults blood with red cells, and positive leukocyte esterase with white cells.

§493.1281 Standard: Comparison of test results

(c) The laboratory must document all test result comparison activities

Interpretive Guidelines §493.1281(c)

The actual measurement(s) of test results and comparison activities must be recorded. Acceptable formats for documentation may vary. Cite documentation deficiencies at §493.1281(a) or §493.1281(b). Use D5775 or D5777, as appropriate.

D5783

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

§493.1282 Standard: Corrective actions

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

Interpretive Guidelines §493.1282(b)(2)

When an internal control fails to fall within the defined limits of acceptability, the laboratory must identify the reason for the failure and correct the problem before resuming testing of patients. The laboratory must evaluate all patients test results since the last acceptable external control.

Probes §493.1282(b)(2)

When suboptimal staining or improper coverslipping are identified through quality control procedures, what corrective actions does the laboratory take?

What actions does the laboratory take when controls reflect an unusual trend or are outside of the acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem?

D5787

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

§493.1283 Standard: Test records

(a) The laboratory must maintain an information or record system that includes the following:

(a)(1) The positive identification of the specimen.

(a)(2) The date and time of specimen receipt into the laboratory.

(a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability.

(a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

Interpretive Guidelines §493.1283(a)

The regulations provide laboratories the flexibility to establish a system that ensures positive patient identification through specimen accessioning and storage, testing and reporting of test results. This may include a system that involves labeling the specimen container and request slip or the patient's medical record or chart with a unique patient identification number, but does not preclude the use of other mechanisms to assist in patient identification and tracking of specimens throughout the testing and reporting processes. The patient's name may be used as part of the identification system.

Ensure that work records reflect all the tests and dates of performance of in-house patient testing. For example, in bacteriology, each step from media inoculation to organism isolation and identification must be documented on worksheet records either manually or in a computer system.
Corrections of laboratory results include the corrected result, incorrect result (noted as such), the date of the correction, and the initials of the person making the correction. Laboratory records should not be documented in pencil and the use of whiteout is not acceptable for making corrections.

Probes §493.1283(a)

Do the records reflect all patient testing and the dates of their performance?

If handwritten values were reported, can the laboratory demonstrate the analytic source of those results?

If the laboratory has not retained the appropriate test records, cite D3031, D3033, or D3035.

D5789

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

§493.1283 Standard: Test records

(b) Records of patient testing including, if applicable, instrument printouts, must be retained.

Interpretive **Guidelines §493.1283(b)**

The regulations do not require that instrument printouts be posted directly in the patient's medical record or chart. However, these printouts must be maintained as part of the laboratory's record retention requirements specified throughout the regulations.

Probes §493.1283(b)

Are the original analytic work records complete (e.g., in a randomly chosen sample, is there an instrument printout for every day of the month on which testing was performed)? Are the original, as opposed to transcribed and/or edited work records, being retained? If the laboratory fails to retain the records for the appropriate amount of time, use D3031.

D5791

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

§493.1289 Standard: Analytic systems quality assessment

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in §§493.1251 through 493.1283.

Interpretive **Guidelines §493.1289(a)-(c)**

Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions at all location/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the non-laboratory areas or 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 Analytic System includes assessing:

- Test procedures;
- Accurate and reliable test systems, equipment, instruments, reagents, materials, and supplies;
- Specimen and reagent storage condition;
- Equipment/instrument/test/system maintenance and function checks;
- Establishment and verification of method performance specifications;
- Calibration and calibration verification;
- Control procedures;
- Comparison of test results;
- Corrective actions; and
- Test records.

For Clinical Cytogenetics, cases, the laboratory should identify increases in or excessive culture failure rates, determine the contributing factors, document efforts to reduce or eliminate these factors and assess the effectiveness of actions taken (i.e., a decrease in the culture failure rate).

Review assessment policies, procedures and reports to verify that the laboratory has a system in place to ensure continuous improvement. Corrective action reports are one indication that the laboratory is monitoring and evaluating laboratory performance and the quality of services.

Select a sample of abnormal cytology patient reports and determine that, when available, the histopathology and cytology comparison was performed and the cytology 5-year retrospective review was performed. Ensure the laboratory documents any discrepancies

and performs corrective action.

Review quality control records to determine if the laboratory's monitoring efforts are detecting control failures, shifts, and trends. If the surveyor identifies previously undetected quality control failures or omission, then the laboratory's system for monitoring and evaluating quality control may not be adequate.

For International Normalized Ratio (INR) calculation, ensure the laboratory:

- Periodically verifies, for each thromboplastin lot number in use, the correct normal prothrombin time mean and (the International Sensitivity Index (ISI) value are being used for calculating the INR value.

- Periodically verifies the accuracy of the INR calculation (manual, instrument or LIS).

To verify Prothrombin time testing with INR calculations:

- Check the accuracy of normal Prothrombin time mean calculation (manual, instrument or LIS).

- Verify the ISI used in the calculation correlates with the ISI specified in the reagent package insert. Select an abnormal low or abnormal high prothrombin time result and verify the calculation.

Probes §493.1289(a)

For clinical cytogenetics cases, does the laboratory monitor the frequency of culture failures and sub-optimal analyses?

Does the laboratory add additional maintenance procedures and/or function checks, when needed, to ensure accurate and reliable test results?

What is the laboratory's system for monitoring and evaluating test results for inconsistencies with patient information?

D5793

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

§493.1289 Standard: Analytic systems quality assessment

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff.

Interpretive **Guidelines §493.1289(b)**

Verify that the laboratory has a system in place to monitor and evaluate test results for inconsistencies with patient information, and for correlation between test results. For example, a laboratory could multiply the hemoglobin result by a factor of 3, to see if the result is equal to the hematocrit. If the laboratory has auto-validation in it's Laboratory Information System (LIS), verify that the laboratory is taking steps to reduce the likelihood of sample-switching errors, for example, when the creatinine result is significantly different from the patient's previous creatinine test results, or if the MCV is significantly different from the patient's previous test results and the patient did not receive a blood transfusion.

Probes §493.1289(b)

How does the laboratory address multiple failed or sub-optimal cultures that have been submitted from one client?

How does the laboratory use the review of all normal or negative gynecologic specimens received within the previous 5 years to assess the analytic system and communicate findings to the staff?

-(c) The laboratory must document all analytic systems assessment activities.

Interpretive Guidelines §493.1289(c)

The steps taken by the laboratory to identify and correct problems and prevent their recurrence must be documented. All laboratory policies amended due to its QA activities must also be noted.

POSTANALYTIC SYSTEMS

D5800

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

§493.1290 Condition: Postanalytic Systems

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in §493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in §493.1299 for each specialty and subspecialty of testing performed.

Interpretive Guidelines §493.1290

Significant deficiencies cited under this condition may indicate deficiencies under personnel responsibilities. Use D5800 when deficiencies are identified that are: significant and have the potential to, or adversely affect, patient testing, are systemic and pervasive throughout the laboratory, and are not limited to any one specialty or subspecialty.

D5803

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

§493.1291 Standard: Test report

(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

Interpretive Guidelines §493.1291(b)

The test report information should be legible, understandable, and complete.

D5805

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

§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)

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.

D5807

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

§493.1291 Standard: Test report

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

Interpretive Guidelines §493.1291(d)

The laboratory must ensure the "reference intervals" or "normal" values it provides to its clients are accurate, include appropriate units of measurement, and reflect the method performed and the patient population (if applicable).

D5815

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

§493.1291 Standard: Test report

(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

Interpretive Guidelines §493.1291(h)

If a delay in reporting patient test results may negatively impact patient care, the

laboratory should have an alternative method for reporting patient results when the LIS or test system is down.

Cite deficiencies only when the laboratory has failed to notify its client(s) when delays in testing patient specimens have the potential for or are adversely affecting patient care.

Probes §493.1291(h)

What criteria has the laboratory established for notifying the appropriate individual of the delay in testing? Use D5403.

How will the laboratory report patient test results if the LIS or test system is down?

D5823

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

§493.1291 Standard: Test report

(l) Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient.

Interpretive 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

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

§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 (https://www.fda.gov/medwatch/getforms.htm) or an electronic equivalent as soon as practical, but no later than 10 days from the time personnel become aware of the event. For more information on reporting requirements, contact the FDA: Office of In

Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health, Food and Drug Administration, HFZ-440, 2098 Gaither Road, Rockville, MD 20850, Phone: 240-276-0450, Fax: 240-276-0652.

D5893

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

§493.1299 Standard: Postanalytic system quality assessment

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff.

Interpretive Guidelines §493.1299(b)

Review assessment policies, procedures and reports to verify that the laboratory has a system in place to ensure continuous improvement. Corrective action reports are one indication that the laboratory is monitoring and evaluating laboratory performance and the quality of services.

§493.1299(c) The laboratory must document all postanalytic systems quality assessment activities.

Interpretive Guidelines §493.1299(c)

The steps taken by the laboratory to identify and correct problems, and prevent their recurrence must be documented. All laboratory policies amended due to its QA activities must be noted.

Probes §493.1299(a)-(c)

What mechanism does the laboratory use to update and correlate the information to clients (e.g., client reference manuals), procedure manuals, reporting systems (e.g., LIS) when the laboratory introduces a new test system with different normal/reference range?

Subpart M--Personnel for Nonwaived Testing

LABORATORIES PERFORMING PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES

§493.1353 Scope

In accordance with §493.19(b), the moderate complexity procedures specified as PPM procedures are considered such only when personally performed by a health care provider during a patient visit in the context of a physical examination. PPM procedures are subject to the personnel requirements in §§493.1355 through 493.1365.

Interpretive Guidelines §493.1353

PPM procedures are exempt from routine inspections only when performed under the auspices of a Certificate of Provider Performed Microscopy Procedures.

D5980

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

§493.1355 Condition: Laboratories performing PPM procedures; laboratory director

The laboratory must have a director who meets the qualification requirements of §493.1357 and provides overall management and direction in accordance with §493.1359.

D5983

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

§493.1359 Standard; PPM laboratory director responsibilities

The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. The laboratory director must--

D5985

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

§493.1359 Standard; PPM laboratory director responsibilities

(a) Direct no more than five laboratories; and

D5987
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1359 Standard; PPM laboratory director responsibilities

(b) Ensure that any procedure listed under §493.19(c)--

(b)(1) Is personally performed by an individual who meets the qualification requirements in §493.1363; and

(b)(2) Is performed in accordance with applicable requirements in subparts H, J, K, and M of this part.

D5990
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1361 Condition: Laboratories performing PPM procedures; testing personnel

The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1363 to perform the functions specified in §493.1365 for the volume and complexity of testing performed.

D5991
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1363 Standard; PPM testing personnel qualifications

Each individual performing PPM procedures must--

(a) Possess a current license issued by the State in which the laboratory is located if the licensing is required; and

(b) Meet one of the following requirements:

(b)(1) Be a physician, as defined in §493.2.

(b)(2) Be a midlevel practitioner, as defined in §493.2, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located.

(b)(3) Be a dentist as defined in §493.2 of this part.

D5993
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1365 Standard; PPM testing personnel responsibilities

The testing personnel are responsible for specimen processing, test performance, and for reporting test results. Any PPM procedure must be--

(a) Personally performed by one of the following practitioners:

> **(a)(1) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.**
>
> **(a)(2) A midlevel practitioner, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located, during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider, in which the midlevel practitioner is a member or an employee.**
>
> **(a)(3) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee; and**

D5995
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1365 Standard; PPM testing personnel responsibilities

(b) Performed using a microscope limited to a brightfield or a phase/contrast microscope.

LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING

D6000
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director

The laboratory must have a director who meets the qualification requirements of §493.1405 of this subpart and provides overall management and direction in accordance with §493.1407 of this subpart.

Interpretive **Guidelines §493.1403:**

The Condition: laboratory director is not met when the laboratory director:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the laboratory director's responsibilities.

An individual qualified as laboratory director may not qualify as a technical consultant in a particular specialty or subspecialty unless he or she has the required testing experience.

D6004

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

§493.1407 Standard; Laboratory director responsibilities

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.

Interpretive **Guidelines §493.1407**

If the laboratory has more than one person qualifying as director, the laboratory is required to designate one individual who has ultimate responsibility for overall operation and administration of the laboratory.

The requirement that a laboratory must be under the direction of a qualified person is not automatically met simply because the director meets the education and experience requirements. It must be demonstrated that the individual is, in fact, providing effective direction over the operation of the laboratory.

In determining whether the director responsibilities are met, consider deficiencies found in other conditions, e.g., facility administration, general laboratory systems, preanalytic systems, analytic systems, postanalytic systems, and proficiency testing.

(a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of §§493.1409, 493.1415, and 493.1421, respectively.

Interpretive **Guidelines §493.1407(a)**

If the laboratory director is not qualified as a technical consultant or clinical consultant,

he or she must employ individuals meeting the appropriate qualifications.

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

D6005

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

§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

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

§493.1407 Standard; Laboratory director responsibilities

(d) Each individual may direct no more than five laboratories.

Interpretive Guidelines §493.1407(d)

An individual may serve as a director of 5 nonwaived certified laboratories. An individual may serve as a technical consultant or clinical consultant for any number of laboratories.

D6007

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

§493.1407 Standard; Laboratory director responsibilities

(e) The laboratory director must--

> **(e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;**

D6011
(Rev.)

§493.1407 Standard; Laboratory director responsibilities

(e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

D6012
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1407 Standard; Laboratory director responsibilities

(e)(3) Ensure that—

(3)(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

D6013
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1407 Standard; Laboratory director responsibilities

(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

D6014
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1407 Standard; Laboratory director responsibilities

(3)(i) Laboratory personnel are performing the test methods as required for accurate and reliable results;

D6015
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1407 Standard; Laboratory director responsibilities

(e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that--

D6016
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1407 Standard; Laboratory director responsibilities

(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;

D6017
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1407 Standard; Laboratory director responsibilities

(e)(4)(ii) The results are returned within the timeframes established by the proficiency testing program;

D6018
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1407 Standard; Laboratory director responsibilities

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

D6019
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1407 Standard; Laboratory director responsibilities

(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;

D6020
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1407 Standard; Laboratory director responsibilities

(e)(5) Ensure that the quality control

D6021

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

§493.1407 Standard; Laboratory director responsibilities

and quality assessment programs are established and maintained to assure the quality of laboratory services provided and

D6022

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

§493.1407 Standard; Laboratory director responsibilities

to identify failures in quality as they occur;

D6023

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

§493.1407 Standard; Laboratory director responsibilities

(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

D6024

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

§493.1407 Standard; Laboratory director responsibilities

(e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and

D6025

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

§493.1407 Standard; Laboratory director responsibilities

that patient test results are reported only when the system is functioning properly;

D6026
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1407 Standard; Laboratory director responsibilities

(e)(8) Ensure that reports of test results include pertinent information required for interpretation;

D6027
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1407 Standard; Laboratory director responsibilities

(e)(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

D6028
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1407 Standard; Laboratory director responsibilities

(e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

D6029
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1407 Standard; Laboratory director responsibilities

(e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

D6032
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1407 Standard; Laboratory director responsibilities

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and

postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

Interpretive **Guidelines §493.1407(e)(14)**

The director must assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process. The list of assigned duties must be current.

D6033

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

§493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant

The laboratory must have a technical consultant who meets the qualification requirements of §493.1411 of this subpart and provides technical oversight in accordance with §493.1413 of this subpart.

Interpretive **Guidelines §493.1409**

The Condition of technical consultant is not met when the technical consultant:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the technical consultant's responsibilities.

D6034

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

§493.1411 Standard; Technical consultant qualifications

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

Interpretive **Guidelines §493.1411**

The type of experience required under this regulation is **clinical** in nature. This means,

examination and test performance on human specimens for purposes of obtaining information for the diagnosis, treatment, and monitoring of patients, or for providing information to others who will do the diagnosing and treating of the patient's condition. Patient or medically-oriented experience, which is defined as the ordering of tests and interpreting and applying the results of these tests in diagnosing and treating a patient's illness is **unacceptable** to meet the requirement for laboratory training or experience.

The term "laboratory training or experience" means that the individual qualifying has the training and experience in the specialties and subspecialties in which the individual is providing technical consultation.

Technical consultants should have documentation of hands-on testing experience. This documentation may consist of, but is not limited to, the individual's initials on worksheets or work cards, attestation of the laboratory director to the experience the individual has, or formal laboratory rotation through a medical residency program or laboratory internship program.

Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is considered acceptable experience. Research experience is also acceptable experience if it is obtained while performing tests on human specimens.

D6035

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

§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.

D6036

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

§493.1413 Standard; Technical consultant responsibilities

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

Interpretive **Guidelines §493.1413**

In a specialty in which neither the director nor testing personnel can qualify to provide **technical** consultation, the laboratory may engage the services of a qualified person either on a part-time or full-time basis for this service. Under these circumstances, the qualified person is not required to be on the premises full-time or at all times tests are being performed in his/her specialty(ies). However, the technical consultant must be available to provide consultation and should spend time in the laboratory sufficient to supervise the technical performance of the staff in his/her specialty(ies).

D6037

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

§493.1413 Standard; Technical consultant responsibilities

The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.

D6038

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

§493.1413 Standard; Technical consultant responsibilities

(a) The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and
Interpretive Guidelines §493.1413(a)

Since the testing personnel usually will not have experience and training in all specialties, technical consultation is essential in identifying training needs and ensuring that each individual performing testing receives regular in-service training and education. There should be documentation, such as a log book or training/discussion reports, to indicate the services provided or activities performed by the technical consultant. These activities should correlate with the responsibilities delegated to the technical consultant by the laboratory director. The technical consultant is responsible for evaluating the capabilities of the technical personnel and advising the director on proper test performance in the specialty.

D6039

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

§493.1413 Standard; Technical consultant responsibilities

(b) The technical consultant is responsible for--

> **(b)(1) Selection of test methodology appropriate for the clinical use of the test results;**

D6040

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

§493.1413 Standard; Technical consultant responsibilities

(b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

D6041

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

§493.1413 Standard; Technical consultant responsibilities

(b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

D6042

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

§493.1413 Standard; Technical consultant responsibilities

(b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

D6043

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

§493.1413 Standard; Technical consultant responsibilities

(b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

D6044

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

§493.1413 Standard; Technical consultant responsibilities

(b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

D6045

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

§493.1413 Standard; Technical consultant responsibilities

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

Interpretive **Guidelines §493.1413(b)(7)**

In some instances, in-service training may be specifically related to an instrument or test, or may be very general in nature. The laboratory may establish its own format, content, and schedule or provide training on an as-needed basis. This is acceptable provided the laboratory does not have deficiencies related to test performance.

D6046

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

§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.

D6047

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

§493.1413 Standard; Technical consultant responsibilities

(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

D6048

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

§493.1413 Standard; Technical consultant responsibilities

(b)(8)(ii) Monitoring the recording and reporting of test results;

D6049

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

§493.1413 Standard; Technical consultant responsibilities

(b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

D6050

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

§493.1413 Standard; Technical consultant responsibilities

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

D6051

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

§493.1413 Standard; Technical consultant responsibilities

(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

D6052

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

§493.1413 Standard; Technical consultant responsibilities

(b)(8)(vi) Assessment of problem solving skills; and

D6053

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

§493.1413 Standard; Technical consultant responsibilities

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

D6054

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

§493.1413 Standard; Technical consultant responsibilities

(b)(9) Thereafter, evaluations must be performed at least annually

D6055

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

§493.1413 Standard; Technical consultant responsibilities

(b)(9) unless test methodology or instrumentation changes, in which case, prior to

reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

D6056

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

§493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant

The laboratory must have a clinical consultant who meets the qualification requirements of §493.1417 of this part and provides clinical consultation in accordance with §493.1419 of this part.

Interpretive **Guidelines §493.1415**

The Condition of clinical consultant is not met when the clinical consultant:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the clinical consultant's responsibilities.

D6057

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

§493.1417 Standard; Clinical consultant qualifications

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must--

(a) Be qualified as a laboratory director under §493.1405(b)(1), (2), or (3)(i); or

(b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

D6058

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

§493.1419 Standard; Clinical consultant responsibilities

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.

D6059

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

§493.1419 Standard; Clinical consultant responsibilities

The clinical consultant must--

(a) Be available to provide clinical consultation to the laboratory's clients;

D6060

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

§493.1419 Standard; Clinical consultant responsibilities

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

D6061

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

§493.1419 Standard; Clinical consultant responsibilities

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

Probes §493.1419(c)

Has the clinical consultant reviewed the reports to ensure that test results include patient information required for specific patient interpretations?

D6062

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

§493.1419 Standard; Clinical consultant responsibilities

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

D6066

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

§493.1423 Standard; Testing personnel qualifications

(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

D6067
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1423 Standard; Testing personnel qualifications

Such training must ensure that the individual has--

> **(b)(4)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;**
>
> **(b)(4)(ii)(B) The skills required for implementing all standard laboratory procedures;**
>
> **(b)(4)(ii)(C) The skills required for performing each test method and for proper instrument use;**
>
> **(b)(4)(ii)(D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;**
>
> **(b)(4)(ii)(E) A working knowledge of reagent stability and storage;**
>
> **(b)(4)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory;**
>
> **(b)(4)(ii)(G) An awareness of the factors that influence test results; and**
>
> **(b)(4)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.**

D6068
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1425 Standard; Testing personnel responsibilities

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

D6069
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1425 Standard; Testing personnel responsibilities

(a) Each individual performs only those moderate complexity tests that are

authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

D6070

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

§493.1425 Standard; Testing personnel responsibilities

(b) Each individual performing moderate complexity testing must--

> **(b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;**

D6071

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

§493.1425 Standard; Testing personnel responsibilities

(b)(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples;

D6072

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

§493.1425 Standard; Testing personnel responsibilities

(b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

D6073

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

§493.1425 Standard; Testing personnel responsibilities

(4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

D6074

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

§493.1425 Standard; Testing personnel responsibilities

(5) Be capable of identifying problems that may adversely affect test performance or

reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and

Interpretive **Guidelines §493.1425(b)(5)**

If, during the survey, testing personnel demonstrate an inability to identify a problem that adversely affects a patient test result, cite D6029 under director responsibilities.

Some examples of problems that may adversely affect patient test results may include, but are not limited to:

- A pleural fluid that is mislabeled and, therefore, is processed as a urine culture;
- Performing a potassium on a hemolyzed sample; or
- Tests are incubated at 37°C when the manufacturer's instructions require 25°C incubation.

D6075

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

§493.1425 Standard; Testing personnel responsibilities

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

LABORATORIES PERFORMING HIGH COMPLEXITY TESTING

D6076

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

§493.1441 Condition: Laboratories performing high complexity testing; laboratory director

The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart.

Interpretive **Guidelines §493.1441**

The Condition of laboratory director is not met when the laboratory director:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the laboratory director responsibilities.

D6078

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

§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,

ABMGG - American Board of Medical Genetics and Genomics (formerly ABMG - American Board of Medical Genetics),

ABMLI - American Board of Medical Laboratory Immunology,

ABMM - American Board of Medical Microbiology,

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*

Veterinary Medicine – D.V.M., 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.

D6079

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

§493.1445 Standard; Laboratory director responsibilities

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

Interpretive **Guidelines §493.1445**

The requirement that a laboratory must be under the direction of a qualified person is not automatically met simply because the director meets the education and experience requirements. It must be demonstrated that the individual is, in fact, providing effective direction over the operation of the laboratory.

In determining whether the director responsibilities are met, consider deficiencies found in other conditions, e.g., facility administration, general laboratory systems, preanalytic systems, analytic systems, postanalytic systems, and proficiency testing.

If the laboratory has more than one person qualifying as a director, one individual must be designated as accepting ultimate responsibility for the overall operation and administration of the laboratory.

(a) The laboratory director, if qualified, may perform the duties of the technical

supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under §§493.1447, 493.1453, 493.1459, and 493.1487, respectively.

Interpretive **Guidelines §493.1445(a)**

An individual qualified as laboratory director under §493.1443 may not qualify as technical supervisor in a particular specialty or subspecialty unless he or she has the required training or experience. If the director of high complexity testing is not qualified to perform the duties of the technical supervisor or clinical consultant, he or she must employ individual(s) meeting the respective qualifications.

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

D6081

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

§493.1445 Standard; Laboratory director responsibilities

(d) Each individual may direct no more than five laboratories.

Interpretive **Guidelines §493.1445(d)**

An individual may serve as a director of 5 nonwaived certified laboratories. However, an individual may serve as technical consultant, clinical consultant or technical supervisor for any number of laboratories.

D6082

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

§493.1445 Standard; Laboratory director responsibilities

(e) The laboratory director must--

> **(e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;**

D6083

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

§493.1445 Standard; Laboratory director responsibilities

(e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and

D6085

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

§493.1445 Standard; Laboratory director responsibilities

(e)(3) Ensure that--

> **(e)(3)(i) The test methodologies selected have the capability of providing the quality of results required for patient care;**

D6086

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

§493.1445 Standard; Laboratory director responsibilities

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

D6087

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

§493.1445 Standard; Laboratory director responsibilities

(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

D6088

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

§493.1445 Standard; Laboratory director responsibilities

(e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that--

D6089

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

§493.1445 Standard; Laboratory director responsibilities

(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;

D6090
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1445 Standard; Laboratory director responsibilities

(e)(4)(ii) The results are returned within the timeframes established by the proficiency testing program;

D6091
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1445 Standard; Laboratory director responsibilities

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

D6092
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1445 Standard; Laboratory director responsibilities

(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

D6093
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1445 Standard; Laboratory director responsibilities

(e)(5) Ensure that the quality control and

D6094
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1445 Standard; Laboratory director responsibilities

(e)(5) quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

D6095
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1445 Standard; Laboratory director responsibilities

(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

D6096

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

§493.1445 Standard; Laboratory director responsibilities

(e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and

D6097

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

§493.1445 Standard; Laboratory director responsibilities

(e)(7) that patient test results are reported only when the system is functioning properly;

D6098

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

§493.1445 Standard; Laboratory director responsibilities

(e)(8) Ensure that reports of test results include pertinent information required for interpretation;

D6099

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

§493.1445 Standard; Laboratory director responsibilities

(e)(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

D6100

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

§493.1445 Standard; Laboratory director responsibilities

(e)(10) Ensure that a general supervisor provides on-site supervision of high

complexity test performance by testing personnel qualified under §493.1489(b)(4);

D6101

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

§493.1445 Standard; Laboratory director responsibilities

(e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

D6102

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

§493.1445 Standard; Laboratory director responsibilities

(e)(12) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

D6107

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

§493.1445 Standard; Laboratory director responsibilities

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

Interpretive **Guidelines §493.1445(e)(15)**

The director must assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process. The list of assigned duties must be current.

D6108

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

§493.1447 Condition: Laboratories performing high complexity testing; technical supervisor

The laboratory must have a technical supervisor who meets the qualification requirements of §493.1449 of this subpart and provides technical supervision in accordance with §493.1451 of this subpart.

Guidelines §493.1447

The Condition of technical supervisor is not met when the technical supervisor:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the technical supervisor responsibilities

D6109

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

§493.1449 Standard; Technical supervisor qualifications

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

Interpretive **Guidelines §493.1449**

The type of experience required under this regulation is **clinical** in nature. This means examination and test performance on human specimens for purposes of obtaining information for the diagnosis, treatment, and monitoring of patients, or for providing information to others who will do the diagnosing and treating of the patient's condition. Patient or medically-oriented experience, which is defined as the ordering of tests and interpreting and applying the results of these tests in diagnosing and treating a patient's illness is **unacceptable** to meet the requirement for laboratory training or experience.

The term "laboratory training or experience" means that the individual qualifying has the training in and the experience with the specialties and subspecialties in which the individual is performing technical supervision. For technical supervisor, the requirement for training or experience can be met through any combination of training and/or experience in high complexity testing. This can be acquired subsequent to, concurrent with, or prior to obtaining academic requirements.

Be flexible in evaluating laboratory training and experience. The specified training or experience may be acquired simultaneously in more than one specialty/subspecialty. Although it is unreasonable in §§493.1449(c)(5) and (j)(5) to expect four full-time years

devoted only to high complexity microbiology testing and then four full-time years performing high complexity tests only in hematology, etc., to qualify under each specialty/subspecialty, it is necessary for the individual to have had continuous responsibilities in the specialty for the designated number of years and it would be more than simply performing an occasional test. Technical supervisors should have documentation of hands-on testing experience. This documentation may consist of, but is not limited to, the individual's initials on worksheets or work cards, attestation of the laboratory director to the experience the individual has, or formal laboratory rotation through a medical residency program or laboratory internship program.

Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is considered acceptable experience. Research experience is also acceptable experience if it is obtained while performing tests on human specimens.

A year of laboratory training or experience is equivalent to 2080 hours and could extend over more than one 12 calendar-month period.

D6111

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

§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)

Certification in dermatology by the American Osteopathic Board of Dermatology is equivalent to board certification by the American Board of Dermatology.

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.**

D6112

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

§493.1451 Standard: Technical supervisor responsibilities

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times

testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

Interpretive **Guidelines §493.1451**

In a specialty in which neither the director nor the general supervisor can qualify to provide **technical** supervision, the laboratory may engage the services of a qualified person either on a part-time or full-time basis for this service. The technical supervisor is not required to be on the premises full-time or at all times tests are being performed in his/her specialty(ies). However, the technical supervisor must be available to provide consultation and is required to spend an amount of time in the laboratory sufficient to supervise the technical performance of the staff in his/her specialty(ies). There should be documentation, such as a log book or notes from training which indicate the technical supervisor performs his/her assigned duties. The technical supervisor is responsible for evaluating the capabilities of the testing personnel and the general supervisor's testing performance.

D6113

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

§493.1451 Standard: Technical supervisor responsibilities

(a) The technical supervisor must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and

D6114

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

§493.1451 Standard: Technical supervisor responsibilities

(b) The technical supervisor is responsible for--

(b)(1) Selection of the test methodology that is appropriate for the clinical use of the test results;

D6115

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

§493.1451 Standard: Technical supervisor responsibilities

(b)(2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

D6117
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1451 Standard: Technical supervisor responsibilities

(b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

D6118
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1451 Standard: Technical supervisor responsibilities

(b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

D6119
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1451 Standard: Technical supervisor responsibilities

(b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

D6121
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1451 Standard: Technical supervisor responsibilities

The procedures for evaluation of the competency of the staff must include, but are not limited to--

(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

D6122
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1451 Standard: Technical supervisor responsibilities

(b)(8)(ii) Monitoring the recording and reporting of test results;

D6123
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1451 Standard: Technical supervisor responsibilities

(b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

D6124
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1451 Standard: Technical supervisor responsibilities

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

D6125
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1451 Standard: Technical supervisor responsibilities

(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

D6126
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1451 Standard: Technical supervisor responsibilities

(b)(8)(vi) Assessment of problem solving skills; and

D6127
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1451 Standard: Technical supervisor responsibilities

(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

D6128
(Rev. 166, Issued: 02-03-17, Effective: 02-03-17, Implementation: 02-03-17)

§493.1451 Standard: Technical supervisor responsibilities

(b)(9) Thereafter, evaluations must be performed at least annually *unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.*

D6129

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

§493.1451 Standard: Technical supervisor responsibilities

(c) In cytology, the technical supervisor or the individual qualified under §493.1449(k)(2)--

(c)(1) May perform the duties of the cytology general supervisor and the cytotechnologist, as specified in §§493.1471 and 493.1485, respectively;

D6130

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

§493.1451 Standard: Technical supervisor responsibilities

(c)(2) Must establish the workload limit for each individual examining slides;

§493.1451(c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary;

D6131

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

§493.1451 Standard: Technical supervisor responsibilities

(c)(4) Must perform the functions specified in §493.1274(d) and (e);

D6132

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

§493.1451 Standard: Technical supervisor responsibilities

(c)(5) Must ensure that each individual examining gynecologic preparations participates in an HHS approved cytology proficiency testing program, as specified in §493.945 and achieves a passing score, as specified in §493.855; and

D6133

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

§493.1451 Standard: Technical supervisor responsibilities

(c)(6) If responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.

D6134

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

§493.1453 Condition: Laboratories performing high complexity testing; clinical consultant

The laboratory must have a clinical consultant who meets the requirements of §493.1455 of this subpart and provides clinical consultation in accordance with §493.1457 of this subpart.

Interpretive **Guidelines §493.1453**

The Condition of clinical consultant is not met when the clinical consultant:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the clinical consultant responsibilities.

D6135

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

§493.1455 Standard; Clinical consultant qualifications

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must--

(a) Be qualified as a laboratory director under §493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, §493.1443(b)(6); or

(b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

D6136
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1457 Standard; Clinical consultant responsibilities

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.

D6137
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1457 Standard; Clinical consultant responsibilities

The clinical consultant must--

(a) Be available to provide consultation to the laboratory's clients;

D6138
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1457 Standard; Clinical consultant responsibilities

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

D6140
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1457 Standard; Clinical consultant responsibilities

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

D6141
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1459 Condition: Laboratories performing high complexity testing; general supervisor

The laboratory must have one or more general supervisors who are qualified under §493.1461 of this subpart to provide general supervision in accordance with §493.1463 of this subpart.

Interpretive **Guidelines §493.1459**

The Condition of general supervisor is not met when the general supervisor:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the general supervisor responsibilities.

D6142

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

§493.1461 Standard; General supervisor qualifications

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

Interpretive Guidelines §493.1461

The type of experience required under this regulation is **clinical** in nature. This means examination and test performance on human specimens for purposes of obtaining information for the diagnosis, treatment, and monitoring of patients, or for providing information to others who will do the diagnosing and treating of the patient's condition.

Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is considered acceptable experience. Research experience is also acceptable experience if it is obtained while performing tests on human specimens. A year of laboratory training and experience is equivalent to 2080 hours and could extend over more than one 12 calendar-month period.

If all testing personnel have associate degrees, but none meet the training or experience requirement for general supervisor, the duties of the general supervisor must be fulfilled by an appropriately qualified individual. This individual need not be on-site at all times.

D6144

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

§493.1463 Standard; General supervisor responsibilities

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

Interpretive **Guidelines §493.1463**

Interview several testing personnel to elicit information about the duties they perform and the degree of supervision they receive.

D6145

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

§493.1463 Standard; General supervisor responsibilities

(a) The general supervisor--

(a)(1) Must be accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor;

D6146

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

§493.1463 Standard; General supervisor responsibilities

(a)(2) Is responsible for providing day-to-day supervision of high complexity test performance by a testing personnel qualified under §493.1489;

D6147

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

§493.1463 Standard; General supervisor responsibilities

(a)(3) Except as specified in paragraph (c) of this section, must be onsite to provide direct supervision when high complexity testing is performed by any individuals qualified under §493.1489(b)(5); and

D6148

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

§493.1463 Standard; General supervisor responsibilities

(a)(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

D6149

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

§493.1463 Standard; General supervisor responsibilities

(b) The director or technical supervisor may delegate to the general supervisor the responsibility for--

(b)(1) Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

D6150

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

§493.1463 Standard; General supervisor responsibilities

(b)(2) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;

D6151

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

§493.1463 Standard; General supervisor responsibilities

(b)(3) Providing orientation to all testing personnel; and

(b)(4) Annually evaluating and documenting the performance of all testing personnel.

D6152

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

§493.1463 Standard; General supervisor responsibilities

(c) Exception. For individuals qualified under §493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (a)(3) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.

D6153

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

§493.1467 Condition: Laboratories performing high complexity testing; cytology general supervisor

For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of §493.1469 of this subpart, and provides supervision in accordance with §493.1471 of this subpart.

Interpretive **Guideline §493.1467**

The Condition of cytology general supervisor is not met when the cytology general supervisor:

- Position is not filled;
- Is not qualified; or
- Does not fulfill the cytology general supervisor responsibilities.

D6155

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

§493.1469 Standard; Cytology general supervisor qualifications

The cytology general supervisor must be qualified to supervise cytology services. The general supervisor in cytology must possess a current license issued by the State in which the laboratory is located, if such licensing is required, and must--

(a) Be qualified as a technical supervisor under §493.1449 (b) or (k); or

(b)(1) Be qualified as a cytotechnologist under §493.1483; and

(b)(2) Have at least 3 years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.

Interpretive **Guidelines §493.1469(b)(2)**

In addition to screening slides in a laboratory, the 3 years of full-time experience as a cytotechnologist can be fulfilled if the individual has been:

- Teaching in schools of cytotechnology;
- Teaching cytotechnology for residency programs in academic institutions; or
- Participating in research directly related to cytotechnology, which includes screening slides, library research, and documentation.

D6157

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

§493.1471 Standard; Cytology general supervisor responsibilities

(a) The cytology general supervisor is responsible for the day-to-day supervision or

oversight of the laboratory operation and personnel performing testing and reporting test results.

D6158

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

§493.1471 Standard; Cytology general supervisor responsibilities

(b) The cytology general supervisor must--

(b)(1) Be accessible to provide on-site, telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of cytology;

D6159

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

§493.1471 Standard; Cytology general supervisor responsibilities

(b)(2) Document the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified under §493.1274(c));

D6160

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

§493.1471 Standard; Cytology general supervisor responsibilities

(b)(3) For each 24-hour period, document the total number of slides he or she examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

D6161

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

§493.1471 Standard; Cytology general supervisor responsibilities

(b)(4) Document the number of hours spent examining slides in each 24-hour period.

D6162

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

§493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist

For the subspecialty of cytology, the laboratory must have a sufficient number of cytotechnologists who meet the qualifications specified in §493.1483 to perform the functions specified in §493.1485.

D6163

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

§493.1483 Standard; Cytotechnologist qualifications

Each person examining cytology slide preparations must meet the qualifications of §493.1449 (b) or (k), or--

D6166

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

§493.1485 Standard; Cytotechnologist responsibilities

(b) For each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

D6167

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

§493.1485 Standard; Cytotechnologist responsibilities

(c) The number of hours spent examining slides in each 24-hour period.
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

D6168

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

§493.1487 Condition: Laboratories performing high complexity testing; testing personnel

The laboratory has a sufficient number of individuals who meet the qualification requirements of §493.1489 of this subpart to perform the functions specified in §493.1495 of this subpart for the volume and complexity of testing performed.

Interpretive Guidelines §493.1487

The Condition of Testing Personnel is not met when the testing personnel:

- *Are not qualified; or*

- *Do not fulfill the testing personnel responsibilities.*

The criteria used to determine the adequacy of the testing personnel involves evaluating testing personnel responsibilities, ensuring that these responsibilities are specified by the director in writing and are appropriate to ensure compliance with the reporting and recordkeeping requirements, quality control monitoring, quality assessment activities, and proficiency testing participation. Cite this deficiency only when problems are found in areas that can be directly related to insufficient numbers of testing personnel. (Use D6101 to relate the finding regarding insufficient personnel to director responsibilities.)

D6170

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

§493.1489 Standard; Testing personnel qualifications

Each individual performing high complexity testing must--

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

D6174

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

§493.1495 Standard; Testing personnel responsibilities

(a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

D6175

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

§493.1495 Standard; Testing personnel responsibilities

(b) Each individual performing high complexity testing must--

(b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

D6176

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

§493.1495 Standard; Testing personnel responsibilities

(b)(2) Maintain records that demonstrate that proficiency testing samples are tested

in the same manner as patient specimens;

D6177

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

§493.1495 Standard; Testing personnel responsibilities

(b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

D6178

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

§493.1495 Standard; Testing personnel responsibilities

(b)(4) Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

D6179

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

§493.1495 Standard; Testing personnel responsibilities

(b)(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;

Interpretive **Guidelines §493.1495(b)(5):**

If, during the survey, testing personnel demonstrate an inability to identify a problem that adversely affects a patient test result, cite §493.1445(e)(12) under the director responsibilities.

Some examples of problems that may adversely affect patient test results may include:

- A pleural fluid that is mislabeled as a urine specimen and, therefore, is cultured as a urine culture;
- Performing a potassium on a hemolyzed sample; or
- Tests are incubated at 37°C when the manufacturer's instructions require 25°C incubation.

D6181
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1495 Standard; Testing personnel responsibilities

(b)(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications; and

D6182
(Rev.)

§493.1495 Standard; Testing personnel responsibilities

(b)(7) Except as specified in paragraph (c) of this section, if qualified under §493.1489(b)(5), perform high complexity testing only under the onsite, direct supervision of a general supervisor qualified under §493.1461.

D6183
(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

§493.1495 Standard; Testing personnel responsibilities

(c) Exception. For individuals qualified under §493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (b)(7) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.

Subpart Q--Inspection

D8100

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

§493.1771 Condition: Inspection requirements applicable to All CLIA-certified and CLIA-exempt laboratories

(a) Each laboratory issued a CLIA certificate must meet the requirements in §493.1773 and the specific requirements for its certificate type, as specified in §§493.1775 through 493.1780.

(b) All CLIA-exempt laboratories must comply with the inspection requirements in §§493.1773 and 493.1780, when applicable.

D8103

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

§493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories

(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following:

Interpretive **Guidelines §493.1773(b)-(c)**

The regulations **do not** require a laboratory to maintain records on-site. During the survey, the laboratory must be able to retrieve copies of all records and necessary information upon request. Determine what constitutes a reasonable timeframe based on the information requested.

(b)(1) Test samples, including proficiency testing samples, or perform procedures.

(b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part.

(b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process (preanalytic, analytic, and postanalytic).

(b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following:

(b)(4)(i) Specimen procurement and processing areas.

(b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports.

(b)(4)(iii) Testing and reporting areas.

(b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires.

(c) Accessible Records and Data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.

(d) Requirement to Provide Information and Data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

D8401

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

§493.1780 Standard: Inspection of CLIA-exempt laboratories or laboratories requesting or issued a certificate of accreditation

(a) Validation inspection. CMS or a CMS agent may conduct a validation inspection of any accredited or CLIA-exempt laboratory at any time during its hours of operation.

***Interpretive* Guidelines §493.1780**

Validation surveys of accredited laboratories will be conducted by the State survey agencies. Refer to special procedures for accredited laboratories in the SOM. The RO is responsible for conducting validations of CLIA-exempt laboratories.

(b) Complaint inspection. CMS or a CMS agent may conduct a complaint inspection of a CLIA-exempt laboratory or a laboratory requesting or issued a certificate of accreditation at any time during its hours of operation upon receiving a complaint applicable to the requirements of this part.

***Interpretive* Guidelines §493.1780(b)**

In **any** laboratory holding a CLIA certificate, tests listed on the waived list **are not** subject to routine surveys. A survey for waived tests may be conducted **only** when authorized by 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.

(c) Noncompliance determination. If a validation or complaint inspection results in a finding that the laboratory is not in compliance with one or more condition-level requirements, the following actions occur:

> **(c)(1) A laboratory issued a certificate of accreditation is subject to a full review by CMS, in accordance with subpart E of this part and §488.11 of this chapter.**
>
> **(c)(2) A CLIA-exempt laboratory is subject to appropriate enforcement actions under the approved State licensure program.**

(d) Compliance with basic inspection requirements. CLIA-exempt laboratories and laboratories requesting or issued a certificate of accreditation must comply with the basic inspection requirements in §493.1773.