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D-Tag numbers immediately precede the description of regulation.

Subpart A--General Provisions

§493.1 Basis and Scope.

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

§493.2 Definitions.

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

Accredited institution means a school or program which--

- (a) Admits as regular student only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate;
- (b) Is legally authorized within the State to provide a program of education beyond secondary education;
- (c) Provides an educational program for which it awards a bachelor's degree or provides not less than a 2-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master's or doctoral degree;
- (d) Is accredited by a nationally recognized accrediting agency or association.

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

Interpretive Guidelines §493.2(d)

HHS has determined that Foreign academic credential evaluation may be performed by any nationally recognized organization. Equivalency evaluations may be performed by these organizations and their affiliates. Such organizations may include the National Association Credential Evaluation Services, Inc. (NACES) (<http://www.naces.org>) and the Association of International Credential Evaluators, Inc. (AICE) (<http://www.aice-eval.org>) or telephone (310) 550-3305.. The Internet may also be searched for other such nationally recognized organizations and affiliates.

A nationally recognized accrediting agency or association, recognized by the Secretary means a school or program that is approved by:

- *The Council of Medical Education of the American Medical Association (AMA). AMA schools are listed in the Allied Medical Education Directory and may be obtained from the AMA Order Department at 515 North Dearborn Chicago, Illinois 60610;*
- *One of the eight Regional accreditation programs [commission] listed in the latest edition of Education Directory that can be obtained from the U.S. Department of Education at <http://www.ed.gov> or by telephone at 1-800-872-5327;*
- *New York Board of Regents (<http://www.nysed.gov>) or by telephone at (518) 474-5844;*
- *National Institutional and Specialized Accrediting Bodies includes the Accrediting Bureau of Health Education schools. The web address is: www.abhes.gov or by telephone at (703) 917-9503.*

Individuals qualify by obtaining the appropriate degree after completing the academic requirements and training in an accredited school at a time when the school is

accredited. If there is any question about the accreditation status of the school, contact the accrediting agency involved.

If there is an issue concerning the confirming of a particular degree by an institution, contact the school involved for a decision.

States have varying degrees of control over education. However, there are several associations of regional or national scope that provide assistance pertinent to identifying accredited institutions and educational programs.

Personnel that perform tests of moderate and/or high complexity in a CLIA certified laboratory must meet specific education, training, and experience requirements. Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States (US). The equivalency evaluations may be performed by a nationally recognized organization.

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

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

ALJ stands for Administrative Law Judge.

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

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

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

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

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

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

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

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

CLIA means the Clinical Laboratory Improvement Amendments of 1988.

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

(1) Certificate of compliance means a certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition level requirements, or reissued before the expiration date, pending an appeal, in accordance with §493.49, when an inspection has found the laboratory to be out of compliance with one or more condition level requirements.

(2) Certificate for provider-performed microscopy (PPM) procedures means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with §493.47, to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than PPM procedures and, if desired, waived tests listed in §493.15(c).

(3) Certificate of accreditation means a certificate issued on the basis of the laboratory’s accreditation by an accreditation organization approved by CMS (indicating that the laboratory is

deemed to meet applicable CLIA requirements) or reissued before the expiration date, pending an appeal, in accordance with §493.61, when a validation or complaint survey has found the laboratory to be noncompliant with one or more CLIA conditions.

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

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

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

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

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

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

Credible allegations of compliance means a statement or documentation that--

- (1) Is made by a representative of a laboratory that has a history of having maintained a commitment to compliance and of taking corrective action when required;
- (2) Is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and
- (3) Indicates that the problem has been resolved.

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

Equivalency means that an accreditation organization's or a State laboratory program's requirements, taken as a whole, are equal to or more stringent than the CLIA requirements established by CMS, taken as whole. It is acceptable for an accreditation organization's or State laboratory program's requirements to be organized differently or otherwise vary from the CLIA requirements, as long as (1) all of the requirements taken as a whole would provide at least the same protection as the CLIA requirements taken as a whole; and (2) a finding of noncompliance with respect to CLIA requirements taken as a whole would be matched by a finding of noncompliance with the accreditation or State requirements taken as a whole.

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

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

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

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

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

Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Interpretive Guideline

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

Tissue embedding, sectioning, and staining in Pathology are considered part of specimen preparation, not a laboratory test, and do not fall under CLIA. Macroscopic (gross) examinations of specimens must be performed by an individual qualified under §493.1449(l)(1). However, the laboratory that interprets histopathology preparations must ensure that a control slide is included with each slide or group of slides for differential or special stains as required under §4993.1273. Also, laboratories that screen or interpret cytopathology slides are responsible for ensuring that cytology slides are stained in compliance with the applicable requirements at §493.1274(b). In addition for laboratories that prepare cytology specimens using automated or semi-automated liquid-based preparatory techniques, they must comply with the manufacturer's instructions for the preanalytic, analytic, and postanalytic phases of testing.

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

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

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

- (1) A director of the laboratory if he or she meets the stated criteria; and
- (2) The members of the board of directors and the officers of a laboratory that is a small corporation under subchapter S of the Internal Revenue Code.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Unsuccessful participation in proficiency testing means any of the following:

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

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

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

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

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

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

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

§493.3 Applicability.

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

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

(2) Is CLIA-exempt.

(b) **Exception.** These rules do not apply to components or functions of--

(1) Any facility or component of a facility that only performs testing for forensic purposes;

(2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or

(3) Laboratories certified by the Substance Abuse and Mental Health Service Administration (SAMSHA), in which drug testing is performed which meets SAMSHA guidelines and regulations. However, all other testing conducted by a SAMSA-certified laboratory is subject to this rule.

Interpretive Guidelines §493.3(b)

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

For blood donor screening, the FDA requirements are product-related, while CLIA requirements are donor/recipient-related. Tests such as hepatitis, HIV and syphilis serology, among others, are used in donor screening to assess the health of the person donating blood, one of the activities that come within the statutory definition of "laboratory". Therefore, the performance of these tests must meet CLIA requirements.

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

Individuals who self-administer a test in their own home with a device that has been cleared specifically for home use by the FDA are not regulated under CLIA. To the extent that a home health agency (HHA) or hospice that is providing care in an individual's home is engaged solely in assisting an individual in performing a test, by virtue of that activity, CLIA requirements for the HHA or hospice do not apply. However, an HHA or hospice that performs laboratory testing on individuals that meets the definition for laboratory testing in §493.2 is subject to CLIA requirements.

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

Interpretive Guidelines §493.3(c)

Refer to §§6002 and 6022 of the State Operations Manual (SOM) to assist in distinguishing which laboratories are under the jurisdiction of the Federal government for purposes of inspecting for CLIA.

§493.5 Categories of tests by complexity.

(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 test, only test 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.

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

(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.

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(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 CMS-2567 and solicit a Plan of Correction when a laboratory has failed to obtain a registration 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 "Specific List For Categorization of Laboratory Test Systems, Assays, and Examinations by Complexity" [www.fda.gov/cdrh/cli/index.html]. Test systems, assays, and examinations not yet classified are considered high complexity. Significant deficiencies cited under this condition may also indicate deficiencies under personnel responsibilities.

Notify the RO of a possible action by the OIG if the laboratory does not obtain the appropriate certificate or cease non-waived 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

(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:

- o To collect information regarding the appropriateness of waived tests;*
- o If a complaint is alleged; or*
- o You have information that the performance of such tests poses a situation of immediate jeopardy; and*

- o To determine if a laboratory is performing only tests categorized as waived. Refer to §§493.1773 and 493.1775 for additional guidelines for inspecting laboratories issued a certificate of waiver.
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§493.17 Test Categorization.

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

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

(1) Knowledge.

(i) **Score 1.** (A) Minimal scientific and technical knowledge is required to perform the test; and (B) Knowledge required to perform the test may be obtained through on-the-job instruction.

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

(2) Training and experience.

(i) **Score 1.** (A) Minimal training is required for preanalytic, analytic and postanalytic phases of the testing process; and (B) Limited experience is required to perform the test.

(ii) **Score 3.** (A) Specialized training is essential to perform the preanalytic, analytic or postanalytic testing process; or (B) Substantial experience may be necessary for analytic test performance.

(3) Reagents and materials preparation.

(i) **Score 1.** (A) Reagents and materials are generally stable and reliable; and (B) Reagents and materials are prepackaged, or premeasured, or require no special handling, precautions or storage conditions.

(ii) **Score 3.** (A) Reagents and materials may be labile and may require special handling to assure reliability; or (B) Reagents and materials preparation may include manual steps such as gravimetric or volumetric measurements.

(4) Characteristics of operational steps.

(i) **Score 1.** Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled.

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

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

(i) **Score 1.** (A) Calibration materials are stable and readily available; (B) Quality control materials are stable and readily available; and (C) External proficiency testing materials, when available, are stable.

(ii) **Score 3.** (A) Calibration materials, if available, may be labile; (B) Quality control materials may be labile, or not available; or (C) External proficiency testing materials, if available, may be labile.

(6) Test system troubleshooting and equipment maintenance.

(i) **Score 1.** (A) Test system troubleshooting is automatic or self-correcting, or clearly described or requires minimal judgment; and (B) Equipment maintenance is provided by the manufacturer, is seldom needed, or can easily be performed.

(ii) **Score 3.** (A) Troubleshooting is not automatic and requires decision-making and direct intervention to resolve most problems; or (B) Maintenance requires special knowledge, skills, and abilities.

(7) Interpretation and judgment.

(i) **Score 1.** (A) Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and (B) Resolution of problems requires limited independent interpretation and judgment; and

(ii) **Score 3.** (A) Extensive independent interpretation and judgment are required to perform the preanalytic, analytic or postanalytic processes; and (B) Resolution of problems requires extensive interpretation and judgment.

(b) Revisions to the criteria for categorization.

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

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

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

(A) When categorizing previously uncategorized new technology;

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

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

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

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

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

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

(5) PHS will publish revisions periodically to the list of moderate and high complexity tests in the FEDERAL REGISTER in a notice with opportunity for comment.

Interpretive Guidelines §493.17

To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity tests), refer to the "Specific List For Categorization of Laboratory Test Systems, Assays, and Examinations by Complexity" [www.fda.gov/cdrh/cli/index.html]. Test systems, assays, and examinations not yet classified are considered high complexity.

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

§493.19 Provider-performed microscopy (PPM) procedures.

- (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.

Interpretive Guidelines §493.20

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

(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.

Interpretive Guidelines §493.25

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

(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 subparts 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.

Subpart B--Certificate of Waiver

§493.35 Application for a certificate of waiver

(a) *Filing of application.* Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in §435.15(b) of this chapter must file a separate application for each laboratory location.

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

Interpretive Guidelines §493.35(b)(1)

A mobile unit is a laboratory located within a self-contained vehicle, such as a van. The vehicle moves from location to location to perform laboratory testing activities. All pre-analytic, analytic and post analytic activities are conducted within the confines of the vehicle.

Laboratories with multiple testing sites or mobile laboratories eligible for a single certificate should obtain a separate certificate for each State in which testing is performed.

If a mobile laboratory operates in more than one State and does not obtain a separate certificate from each State, contact the RO to determine which State conducts the inspection.

Each laboratory that moves from testing site to testing site, or has a temporary testing location, should provide the survey agency with the home base or central dispatch phone number so that an updated schedule of the location of testing and the hours of operation can be obtained upon request.

Mobile vans will be distinguished by the vehicle identification number (VIN #). See §6034 of the SOM for additional information on mobile laboratories.

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

Interpretive Guidelines §493.35(b)(2)

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

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

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

Interpretive Guidelines §493.35(b)(3)

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

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

(c) Application format and contents. The application must--

- (1) Be made to HHS or its designee on a form or forms prescribed by HHS;**
- (2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and**
- (3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including--**
 - (i) The name and the total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assessment or proficiency testing purposes;**
 - (ii) The methodologies for each laboratory test procedure or examination performed, or both; and**
 - (iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.**

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

Interpretive Guidelines §493.35(d)

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

- (1) Make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section and §493.15(e);**
- (2) Agree to permit announced and unannounced inspections by HHS in accordance with subpart Q of this part under the following circumstances:**
 - (i) When HHS has substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health.**

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

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

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

(ii) To evaluate complaints from the public.

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

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

See §§6136, 6220 and 6222 (along with the cross reference to Chapter 5) of the SOM for specific procedures regarding complaint investigations and §6174 through §6210 of the SOM for validation surveys.

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

(e) Denial of application. If HHS determines that the application for a certificate of waiver is to be denied, HHS will--

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

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

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

§493.37 Requirements for a certificate of waiver

(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.

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

§493.39 Notification requirements for laboratories issued a certificate of waiver.

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

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

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

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

Interpretive Guideline §493.39(a) and (b)

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

See the section of the SOM regarding The Survey Process beginning at §6100 for instructions on handling changes in ownership, name, location, or director.

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

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

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

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

Interpretive Guidelines §493.43(b)(1)

A mobile unit is a laboratory located within a self-contained vehicle, such as a van. The vehicle moves from location to location to perform laboratory testing activities. All pre-analytic, analytic and post analytic activities are conducted within the confines of the vehicle.

Laboratories with multiple testing sites or mobile laboratories eligible for a single certificate should obtain a separate certificate for each State in which testing is performed.

If a mobile laboratory operates in more than one State and does not obtain a separate certificate from each State, contact the RO to determine which State conducts the inspection.

Each laboratory that moves from testing site to testing site, or has a temporary testing location, should provide the survey agency with the home base or central dispatch phone number so that an updated schedule of the location of testing and the hours of operation can be obtained upon request.

Records may be maintained in the mobile laboratory or at the home base. Reports should reflect the home base address and indicate which mobile unit performed the test.

Mobile vans will be distinguished by the vehicle identification number (VIN #). See SOM §6034 for additional information on mobile laboratories.

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

Interpretive Guidelines §493.43(b)(2)

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

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

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

Interpretive Guidelines §493.43(b)(3)

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

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

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

(c) Application format and contents. The application must--(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

- (2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and
- (3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including--
- (i) The name and total number of test procedures and examinations performed annually (excluding waived tests or tests for quality control, quality assessment or proficiency testing purposes);
 - (ii) The methodologies for each laboratory test procedure or examination performed, or both;
 - (iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the examinations and test procedures.
- (d) **Access and reporting requirements.** All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.
-

§493.45 Requirements for a registration certificate.

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

(a) A registration certificate is required-- (1) Initially for all laboratories performing test procedures of moderate complexity (other than the subcategory of PPM procedures) or high complexity, or both; and

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

Interpretive Guidelines §493.45(a)

All facilities performing laboratory testing must have a registration certificate or certificate of waiver prior to performing patient testing.

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

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

(1) Complies with the requirements of §493.43;

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

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

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

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

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

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

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

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

(e) A registration certificate is--

- (1) Valid for a period of no more than two years or until such time as an inspection to determine program compliance can be conducted, whichever is shorter; and
 - (2) Not renewable; however, the registration certificate may be reissued if compliance has not been determined by HHS prior to the expiration date of the registration certificate.
- (f) In the event of a noncompliance determination resulting in an HHS denial of a laboratory's certificate of compliance application, HHS will provide the laboratory with a statement of grounds on which the noncompliance determination is based and offer an opportunity for appeal as provided in subpart R.

Interpretive Guidelines §493.45(f)

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

- (g) If the laboratory requests a hearing within the time specified by HHS, it retains its registration certificate or reissued registration certificate until a decision is made by an administrative law judge as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.
- (h) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the certificate application even if there has been no appeals decision issued.

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

- (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.

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.

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(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.

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.

Subpart D--Certificate of Accreditation

§493.55 Application for registration certificate and certificate of accreditation.

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

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

Interpretive Guidelines §493.55(a)(1)

When HHS approves accreditation organizations and State licensure programs, the ROs are notified and the approved organizations and programs are published as a notice in the Federal Register.

See the section of the SOM for special procedures for accredited laboratories and CLIA-exempt laboratories beginning at §§6152 and 6210.

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

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

Interpretive Guidelines §493.55(b)(1)

A mobile unit is a laboratory located within a self-contained vehicle, such as a van. The vehicle moves from location to location to perform laboratory testing activities. All pre-analytic, analytic and post analytic activities are conducted within the confines of the vehicle.

Laboratories with multiple testing sites or mobile laboratories eligible for a single certificate should obtain a separate certificate for each State in which testing is performed.

If a mobile laboratory operates in more than one State and does not obtain a separate certificate from each State, contact the RO to determine which State conducts the inspection.

Each laboratory that moves from testing site to testing site, or has a temporary testing location, should provide the survey agency with the home base or central dispatch phone number so that an updated schedule of the location of testing and the hours of operation can be obtained upon request.

Records may be maintained in the mobile laboratory or at the home base. Reports should reflect the home base address and indicate which mobile unit performed the test.

Mobile vans will be distinguished by the vehicle identification number (VIN #). See §6034 of the SOM for additional information on mobile laboratories.

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

Interpretive Guidelines §493.55(b)(2)

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

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

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

Interpretive Guidelines §493.55(b)(3)

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

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

(c) Application format and contents. The application must-- (1) Be made to HHS on a form or forms prescribed by HHS;
(2) Be signed by an owner or authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and
(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including--
(i) The name and total number of tests and examinations performed annually (excluding waived tests and tests for quality control, quality assurance or proficiency testing purposes);
(ii) The methodologies for each laboratory test procedure or examination performed, or both; and
(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.
(d) Access and reporting requirements. All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

§493.57 Requirements for a registration certificate.

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.

(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.

§493.61 Requirements for a certificate of accreditation.

- (a) HHS will issue a certificate of accreditation to a laboratory if the laboratory--
- (1) Meets the requirements of §493.57 or, if applicable, §493.49 of subpart C of this part; and
 - (2) Remits the certificate of accreditation fee specified in subpart F of this part.
- (b) Laboratories issued a certificate of accreditation must--
- (1) Treat proficiency testing samples in the same manner as patient samples;
 - (2) Meet the requirements of §493.63;
 - (3) Comply with the requirements of the approved accreditation program;
 - (4) Permit random sample validation and complaint inspections as required in subpart Q of this part;
 - (5) Permit HHS to monitor the correction of any deficiencies found through the inspections specified in paragraph (b)(4) of this section;

Interpretive Guidelines §493.61(b)(5)

See the section of the SOM regarding Special Procedures for Accredited and CLIA-exempt laboratories beginning at §§6152 and 6200 for procedures on follow-up of correction of deficiencies cited during validation inspections.

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

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

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

(1) Will no longer meet the requirements of this part by virtue of its accreditation in an approved accreditation program;

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

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

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

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

Interpretive Guidelines §493.61(d)

42 CFR §488.11 refers to State survey agency functions.

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

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

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

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

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

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

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

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

Interpretive Guidelines §493.61(g)

Accrediting organizations which lose deemed status are required to notify their participating laboratories. These laboratories must apply for a CLIA certificate.

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

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

(2) Meet the requirements of this subpart; and

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

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

(1) The basis for denial of the application;

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

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

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

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

Laboratories issued a certificate of accreditation must:

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

- (1) Ownership;**
- (2) Name;**
- (3) Location; or**
- (4) Director.**

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

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

Interpretive Guidelines §493.63(c)

See the section of the SOM beginning at §6016 and §6032 for handling changes in ownership, name, location, personnel and test methodology, or additions or deletions of specialties or subspecialties that may result in changes in complexity levels for the laboratory.

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

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

Subpart H - Guidelines - General

By law, proficiency testing (PT) programs are evaluated initially for CMS approval and annually thereafter for re-approval. After review, Central Office (CO) will issue PT program approvals and/or re-approvals. A listing of these programs with the specialties, subspecialties, and analytes for which they are approved will be provided to ROs. The RO is responsible for disseminating the approved program listing to the States within their region on an annual basis. Address questions related to the currently approved PT programs to the RO.

An approved PT program is a program that has been evaluated and found to be in compliance with the requirements of Subpart I and the applicable sections of Subpart H. When a laboratory experiences problems with PT, it resolves them with the PT program. If a PT program fails to meet the requirements of Subpart I, report all available information to the RO, which discusses the findings with CO. CO renders a decision on the termination or continued approval of the PT program, as appropriate. The Centers for Disease Control and Prevention may be requested by CO to provide technical advise.

D2000

§493.801 Condition: Enrollment and testing of samples

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

Interpretive Guidelines §493.801

Each laboratory must determine the extent of patient testing it performs. The laboratory must review the specialty, subspecialties and analytes listed in Subpart I and determine which specialty, subspecialties and analytes they must enroll in to meet this requirement. Enrollment must be in a CMS approved PT program. The surveyor should verify that the laboratory is properly enrolled in an approved PT program.

Note: *If a laboratory has not enrolled for any or all tests that it perform that are listed in Subpart I, cite ONLY D2000, Enrollment and testing of samples; do not cite D2016, Successful Participation.*

PT requirements apply to the non-waived tests listed in Subpart I. PT is not required for waived tests. If a laboratory enrolls and participates in PT for any waived tests, do not review these PT results and do not determine compliance with any other PT requirements. Do not take enforcement action for referral of PT specimens for waived tests.

PT enrollment and participation is required, as applicable, for each certificate other than a Certificate of Waiver. A facility offering testing at more than one site, but the testing is all included under one certificate, must enroll in an approved PT program(s) for the collective tests covered under that certificate, not for each site. A general rule is "PT enrollment per certificate".

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

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

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

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

revoked for cholesterol, the laboratory would be precluded from performing cholesterol by any test method.

- A laboratory with a single certificate performing testing at multiple sites under that certificate must participate in PT for each analyte listed in Subpart I that is under that certificate. The performance of PT testing events may be alternated between different sites, provided the primary method at the time of the PT event is used to perform the PT. Should the facility not perform successfully for an analyte, that analyte may not be tested at any location under that certificate.
- A multiple site laboratory, which is covered by a single certificate and participates in one PT program per analyte, must be aware that a failure in PT could lead to the revocation of its certificate for all sites, not just the one participating in PT.

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

D2001

§493.801 Standard: Enrollment and testing of samples

(a) Standard: Enrollment. The laboratory must--

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

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

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

Note: These requirements are met when the CMS approved PT program transmits the laboratory enrollment to the CMS PT monitoring system.

D2003

§493.801 Standard: Enrollment and testing of samples

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

Interpretive Guidelines §493.801(a)

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

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

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

D2004

§493.801 Standard: Enrollment and testing of samples

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

Interpretive Guidelines §493.801(a)(3)

When a laboratory initially applies for CLIA certification or adds a specialty or subspecialty in the middle of the calendar year, it may change PT programs at the next PT enrollment period.

D2005

§493.801 Standard: Enrollment and testing of samples

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

Interpretive Guidelines §493.801(a)(4)

Provide laboratories with the appropriate Federal or State Agency address to which PT results must be sent. Laboratories that are accredited by a CMS approved accreditation organization must release all PT data to its accreditation organization.

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

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

Probes §493.801(a)-(b)

What procedure or test method was used? Is this a routine test method used in the laboratory? Did routine personnel perform the PT? How often were PT samples tested? How are deviations (if any) justified?

Do the PT results documented in the laboratory work records (worksheet) correlate with the results reported to the PT program?

What is the laboratory's policy for testing patient samples when PT specimens are tested more than once?

Do reports submitted to the PT program provider accurately reflect the procedure (i.e., instrument, method) used in the laboratory?

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

D2006

§493.801 Standard: Enrollment and testing of samples

(b) Standard: Testing of proficiency testing samples.

The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.

Interpretive Guidelines §493.801(b)

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

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

D2007

§493.801 Standard: Enrollment and testing of samples

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

D2009

§493.801 Standard: Enrollment and testing of samples

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

Interpretive Guidelines §493.801(b)(1)

Review records to assure that the analyst performing the testing and the director have signed the attestation statement certifying that PT samples were tested in the same manner as patient specimens. For moderate complexity testing, in accordance with §493.1407(e)((4)(i), the director may delegate the responsibility for signing the attestation statement to a technical consultant meeting the qualifications of §493.1409. For high complexity testing, in accordance with §493.1445(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical supervisor meeting the qualifications of §493.1447.

D2010

§493.801 Standard: Enrollment and testing of samples

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

D2011

§493.801 Standard: Enrollment and testing of samples

(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

D2013

§493.801 Standard: Enrollment and testing of samples

(b)(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples.

Interpretive Guidelines §493.801(b)(4)

The regulation refers to intentional referral of PT specimens by a laboratory for purposes of using another laboratory's results as its own. A laboratory that routinely performs only presumptive testing or screening methods and refers patient samples to another laboratory for definitive or confirmatory testing or comparison of test results must not refer PT samples to another laboratory for confirmatory testing. A laboratory must only test and report PT specimens to the degree those tests or examinations are performed for in-house patient testing.

Handle allegations of inter-laboratory communications or referral of proficiency testing specimens as a complaint and investigate using the complaint investigation procedures outlined in §6136 of the SOM.

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

D2015

§493.801 Standard: Enrollment and testing of samples

(b)(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

Interpretive Guidelines §493.801(b)(5)

Review records to assure that the analyst performing the testing and the director have signed the attestation statement certifying that PT samples were tested in the same manner as patient specimens. For moderate complexity testing, in accordance with §493.1407(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical consultant meeting the qualifications of §493.1409. For high complexity testing, in accordance with §493.1445(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical supervisor meeting the qualifications of §493.1447. The signature of the director or technical consultant/supervisor need not be obtained prior to reporting PT results to the PT provider.

(b)(6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

Interpretive Guidelines §493.801(b)(6)

"Primary" means the test system(s), assay(s) or examination(s) routinely used for patient testing at the time of the PT testing event; however, the primary method is determined after the laboratory has chosen the analyte(s) it performs for enrollment.

D2016

§493.803 Condition: Successful participation.

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

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

(c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:

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

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

(3) The laboratory has a poor compliance history.

Interpretive Guidelines §493.803

Only the PT program has the capability to correct scores. These corrections will be noted in the PT monitoring system as "non-routine" scores.

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

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

Absent any special circumstances (which must be documented in the case file), consider verified unsuccessful PT performance to represent unsuccessful PT participation and cite as a condition-level deficiency (use D2016 on the CMS-2567).

NOTE: The CMS PT monitoring system may NOT be used alone to determine unsuccessful participation. Surveyors must verify any unsuccessful participation

indicated in the PT monitoring system. This may be done by reviewing PT results supplied by the approved PT program (they will send copies to the surveyor if requested) or from results sent to the laboratory by the PT program.

If the unsuccessful PT participation is the first occurrence for the laboratory, and there is no immediate jeopardy to patient health or safety, notify the laboratory and require that it seek training of its personnel, obtain the necessary technical assistance to correct the problem causing the unsuccessful participation, or both. SAs may initiate training and/or technical assistance after first obtaining RO concurrence. No onsite review is required to initiate this action.

The laboratory will submit an acceptable plan of remedial action, listing projected completion dates and other pertinent information, for its training and/or technical assistance efforts. Follow-up is necessary to verify that the laboratory has carried out its plan. Satisfactory participation in the next PT event would provide verification that the laboratory's remedial action, training and/or technical assistance were successful. The remedial action plan should demonstrate that the laboratory will correct its problems within 3 months, although special circumstances may be considered. When a laboratory refuses to take acceptable training and/or technical assistance actions (including failure to submit an acceptable plan of remedial action, or failure to complete its plan), sanction action will be initiated.

When the unsuccessful PT participation is not the first such occurrence for the laboratory, and there is no issue of immediate jeopardy, cite as a condition-level deficiency and take appropriate enforcement action. For immediate jeopardy cases the procedures in Subpart R apply. For non-immediate jeopardy situations, enforcement procedures should be completed within 90 days from the date that the unsuccessful PT was first identified. In immediate jeopardy situations, enforcement procedures should be completed within 23 days from the date unsuccessful participation of PT is first identified.

Example:

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

Example:

A laboratory scores 60% on uric acid PT samples. On the next testing event, the laboratory scores 40% on the same analyte. The citations are §§493.841(a), 493.841(f), and 493.803. When recommending to the RO that a laboratory be subject to sanctions, submit copies of the laboratory's testing event or analyte score(s) that were unsatisfactory and the correct responses provided by the PT program. Also, enclose copies of any correspondence sent to or received by the laboratory concerning its PT performance.

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

D2017

§493.807 Condition: Reinstatement of laboratories performing nonwaived testing after failure to participate

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

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

Proficiency Testing by Specialty and Subspecialty for Laboratories Performing Non-Waived Tests

§493.821 Condition: Microbiology.

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

D2020

§493.823 Standard; Bacteriology.

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

D2021

§493.823 Standard; Bacteriology.

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

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

- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
 - (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
 - (3) The laboratory participated in the previous two proficiency testing events.
-

D2025

§493.823 Standard; Bacteriology.

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

D2026

§493.823 Standard; Bacteriology.

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

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

D2028

§493.823 Standard; Bacteriology.

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

D2029

§493.825 Standard; Mycobacteriology.

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

D2030

§493.825 Standard; Mycobacteriology.

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

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

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

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

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

D2034

§493.825 Standard; Mycobacteriology.

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

D2035

§493.825 Standard; Mycobacteriology.

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

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

D2037

§493.825 Standard; Mycobacteriology.

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

D2038

§493.827 Standard; Mycology.

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

D2039

§493.827 Standard; Mycology.

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

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

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

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

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

D2043

§493.827 Standard; Mycology.

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

D2044

§493.827 Standard; Mycology.

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

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

D2046

§493.827 Standard; Mycology.

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

D2047

§493.829 Standard; Parasitology.

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

D2048

§493.829 Standard; Parasitology.

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

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

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

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

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

D2052

§493.829 Standard; Parasitology.

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

D2053

§493.829 Standard; Parasitology.

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

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

D2055

§493.829 Standard; Parasitology.

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

D2056

§493.831 Standard; Virology.

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

D2057

§493.831 Standard; Virology.

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

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

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

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

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

D2061

§493.831 Standard; Virology.

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

D2062

§493.831 Standard; Virology.

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

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

D2064

§493.831 Standard; Virology.

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

§493.833 Condition: Diagnostic immunology.

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

D2066

§493.835 Standard; Syphilis serology.

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

D2067

§493.835 Standard; Syphilis serology.

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

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

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

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

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

D2071

§493.835 Standard; Syphilis serology.

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

D2072

§493.835 Standard; Syphilis serology.

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

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

D2074

§493.835 Standard; Syphilis serology.

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

D2075

§493.837 Standard; General immunology.

Interpretive Guidelines: §493.837

Analytes or tests for which laboratory PT performance is to be evaluated:

Alpha-1 antitrypsin
Alpha-fetoprotein (tumor marker)
Antinuclear antibody
Antistreptolysin O – quantitative
Anti-human immunodeficiency virus (HIV)
Complement C3
Complement C4
Hepatitis markers (HBsAg, anti-HBc, HBeAg)
IgA
IgG
IgE
IgM
Infectious mononucleosis
Rheumatoid factor
Rubella

Note: If a laboratory performs both a quantitative and a qualitative procedure of a test or analyte, it may choose which to enroll in to fulfill the enrollment requirement. It need not enroll in both quantitative and qualitative PT for the same analyte.

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

D2076

§493.837 Standard; General immunology.

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

D2077

§493.837 Standard; General immunology.

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

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

- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
- (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
- (3) The laboratory participated in the previous two proficiency testing events.

D2081

§493.837 Standard; General immunology.

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

D2082

§493.837 Standard; General immunology

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

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

D2084

§493.837 Standard; General immunology

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

D2085

§493.837 Standard; General immunology

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

§493.839 Condition: Chemistry.

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

Analytes or tests for which laboratory PT performance is to be evaluated which include serum, plasma or blood samples:

Alanine aminotransferase (ALT/SGPT)
Albumin
Alkaline phosphatase
Amylase
Aspartate aminotransferase (AST/SGOT)
Bilirubin, total
Blood gas (pH, pO₂, and pCO₂)
Calcium, total
Chloride
Cholesterol, total
Cholesterol, high density lipoprotein
Creatine kinase
Creatine kinase isoenzymes
Creatinine
Glucose (Excluding measurements on devices cleared by FDA specifically for home use)
Iron, total
Lactate dehydrogenase (LDH)
LDH isoenzymes
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen
Uric Acid

D2087

§493.841 Standard; Routine chemistry.

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

D2088

§493.841 Standard; Routine chemistry.

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

D2089

§493.841 Standard; Routine chemistry.

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

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

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

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

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

D2093

§493.841 Standard; Routine chemistry.

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

D2094

§493.841 Standard; Routine chemistry.

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

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

D2096

§493.841 Standard; Routine chemistry.

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

D2097

§493.841 Standard; Routine chemistry.

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

D2098

§493.843 Standard; Endocrinology.

Analytes or tests for which laboratory PT performance is to be evaluated which include serum, plasma, blood, or urine:

Cortisol
Free Thyroxine
Human Chorionic Gonadotropin (Excluding color comparison tests for urine specimens)
T₃ Uptake
Triiodothyronine
Thyroid-stimulating hormone
Thyroxine

Note: If the laboratory performs the same analyte on different specimen types, it may choose which specimen type to enroll in PT. The laboratory need not enroll for each specimen type of the same analyte.

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

D2099

§493.843 Standard; Endocrinology.

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

D2100

§493.843 Standard; Endocrinology.

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

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

- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;**
- (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and**
- (3) The laboratory participated in the previous two proficiency testing events.**

D2104

§493.843 Standard; Endocrinology.

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

D2105

§493.843 Standard; Endocrinology.

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

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

D2107

§493.843 Standard; Endocrinology.

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

D2108

§493.843 Standard; Endocrinology.

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

D2109

§493.845 Standard; Toxicology.

Analytes or tests for which laboratory PT performance is to be evaluated which include serum, plasma, or blood:

Alcohol (blood)
Blood lead
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium
Phenobarbital
Phenytoin
Primidone
Procinamide (and metabolite)
Quinidine
Theophylline
Tobramycin
Valproic Acid

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

D2110

§493.845 Standard; Toxicology.

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

D2111

§493.845 Standard; Toxicology.

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

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

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

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

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

D2115

§493.845 Standard; Toxicology.

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

D2116

§493.845 Standard; Toxicology.

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

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

D2118

§493.845 Standard; Toxicology.

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

D2119

§493.845 Standard; Toxicology.

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

§493.849 Condition: Hematology.

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

Analytes or tests for which laboratory PT performance is to be evaluated:

Cell identification or white blood cell differential (chosen by the laboratory)
Erythrocyte count
Hematocrit (excluding spun microhematocrit)
Hemoglobin
Leukocyte count
Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time

D2121

§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

§493.851 Standard; Hematology.

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

D2123

§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

§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

§493.851 Standard; Hematology.

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

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

D2130

§493.851 Standard; Hematology.

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

D2131

§493.851 Standard; Hematology.

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

§493.853 Condition: Pathology.

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

D2132

§493.855 Standard; Cytology: gynecologic examinations.

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

D2133

§493.855 Standard; Cytology: gynecologic examinations.

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

D2134

§493.855 Standard; Cytology: gynecologic examinations.

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

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

D2136

§493.855 Standard; Cytology: gynecologic examinations.

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

D2137

§493.855 Standard; Cytology: gynecologic examinations.

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

D2138

§493.855 Standard; Cytology: gynecologic examinations.

Individuals who fail this second test are subsequently retested with a 20-slide test set as described in paragraphs (b)(2) and (b)(3) of this section. Individuals are given not more than 2 hours to complete a 10-slide test and not more than 4 hours to complete a 20-slide test.

D2141

§493.855 Standard; Cytology: gynecologic examinations.

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

D2142

§493.855 Standard; Cytology: gynecologic examinations.

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

D2143

§493.855 Standard; Cytology: gynecologic examinations.

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

D2144

§493.855 Standard; Cytology: gynecologic examinations.

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

D2145

§493.855 Standard; Cytology: gynecologic examinations.

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

D2146

§493.855 Standard; Cytology: gynecologic examinations.

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

D2147

§493.855 Standard; Cytology: gynecologic examinations.

Reexamination of slides must be documented.

D2148

§493.855 Standard; Cytology: gynecologic examinations.

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

D2149

§493.855 Standard; Cytology: gynecologic examinations.

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

D2150

§493.855 Standard; Cytology: gynecologic examinations.

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

§493.855 Standard; Cytology: gynecologic examinations.

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

§493.857 Condition: Immunohematology.

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

Analytes or tests for which laboratory PT performance is to be evaluated:

ABO group (excluding subgroups)

D(Rho) typing

Unexpected antibody detection

Compatibility testing

Antibody identification

D2153

§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

§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.

D2155

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

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

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

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

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

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

D2159

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

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

D2160

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

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

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

D2162

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

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

D2163

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

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

D2164

§493.861 Standard; Unexpected antibody detection.

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

D2165

§493.861 Standard; Unexpected antibody detection.

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

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

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

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

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

D2169

§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

§493.861 Standard; Unexpected antibody detection.

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

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

D2172

§493.861 Standard; Unexpected antibody detection.

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

D2173

§493.863 Standard; Compatibility testing.

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

D2174

§493.863 Standard; Compatibility testing.

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

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

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

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

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

D2178

§493.863 Standard; Compatibility testing.

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

D2179

§493.863 Standard; Compatibility testing.

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

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

D2181

§493.863 Standard; Compatibility testing.

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

D2182

§493.865 Standard; Antibody identification.

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

D2183

§493.865 Standard; Antibody identification.

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

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

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

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

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

D2187

§493.865 Standard; Antibody identification.

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

D2188

§493.865 Standard; Antibody identification.

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

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

D2190

§493.865 Standard; Antibody identification.

(e) Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.

D2191

§493.865 Standard; Antibody identification.

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