Alternative Sanctions/CLIA Fees/Histocompatibility/Personnel Final Rule

RED font= revised regulatory language/text.

	DEFINTIONS
Associated Current D-Tag	**Current Regulation**
N/A	**§ 493.2 Definitions.** 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.

(CMS-3326-F) Crosswalk
Orange font=deleted regulation

New/Revised Regulation
§ 493.2 Definitions. Continuing education (CE) credit hours means either continuing medical education (CME) or continuing education units (CEUs). The CE credit hours must cover the applicable laboratory director responsibilities and be obtained prior to qualifying as a laboratory director. Doctoral degree means an earned post-baccalaureate degree with at least 3 years of graduate level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science, medical laboratory science, or medical technology. For purposes of this part, doctoral degrees do not include doctors of medicine (MD), doctors of osteopathy (DO), doctors of podiatric medicine (DPM), doctors of veterinary medicine (DVM) degrees, or honorary degrees. Experience directing or supervising means that the director or supervisory experience must be obtained in a facility that meets the definition of a laboratory under this section and is not excepted under § 493.3(b). Laboratory training or experience means that the training or experience must be obtained in a facility that meets the definition of a laboratory under this section and is not excepted under § 493.3(b). Midlevel practitioner means a nurse midwife, nurse practitioner, nurse anesthetist, clinical nurse specialist, or physician assistant licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located. Replacement certificate means an active CLIA certificate that is reissued with no changes made. Revised certificate means an active CLIA certificate that is reissued with changes to one or more fields displayed on the certificate, such as the laboratory's name, address, laboratory director, or approved specialties/subspecialties. For purposes of this part, revised certificates do not include the issuance, renewal, change in certificate type, or reinstatement of a terminated certificate with a gap in service.

BLUE font= redesignated regulations; same language/text.

Comments	Current IG
Added 6 new definitions and revised the definition of “Midlevel practitioner”	No IG

New IG

Associated Current D-Tag

N/A

N/A

N/A

N/A

N/A

N/A

N/A

N/A

N/A

Alternative Sanctions/CLIA Fees/Histocompatibility/Personnel Final Rule (CMS-3326-F) Crosswalk

RED font= revised regulatory language/text.

CLIA FEES

Current Regulation

§ 493.557(b)(4)
Agree to pay the cost of the validation program administered in that State as specified in §§ 493.645(a) and 493.646(b). § 493.5
Failure to pay fees. CMS withdraws the approval of a State licensure program if the State fails to pay the applicable fees, as specified in §§ 493.645(a) 493.646(b).

§ 493.638 Certificate fees.
(a) Basic rule. Laboratories must pay a fee for the issuance of a registration certificate, certificate for PPM procedures, certificate of waiver, certificate of accreditation, c compliance, as applicable. Laboratories must also pay a fee to reapply for a certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certifica compliance. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification p section 353 of the PHS Act.

(1) For registration certificates and certificates of compliance, the costs include issuing the certificates, collecting the fees, evaluating and monitoring proficiency testing evaluating which procedures, tests or examinations meet the criteria for inclusion in the appropriate complexity category, and implementing section 353 of the PHS Act.

(2) For a certificate of waiver, the costs include issuing the certificate, collecting the fees, determining if a certificate of waiver should be issued, evaluating which tests q inclusion in the waived category, and other direct administrative costs.

(3) For a certificate for PPM procedures, the costs include issuing the certificate, collecting the fees, determining if a certificate for PPM procedures should be issued, ev procedures meet the criteria for inclusion in the subcategory of PPM procedures, and other direct administrative costs.

(4) For a certificate of accreditation, the costs include issuing the certificate, collecting the fees, evaluating the programs of accrediting bodies, and other direct administ

(b) Fee amount. The fee amount is set annually by HHS on a calendar year basis and is based on the category of test complexity, or on the category of test complexity an ranges of annual laboratory test volume (excluding waived tests and tests performed for quality control, quality assurance, and proficiency testing purposes) and special the amounts of the fees in each schedule being a function of the costs for all aspects of general administration of CLIA as set forth in § 493.649 (b) and

(c) . This fee is assessed and payable at least biennially. The methodology used to determine the amount of the fee is found in § 493.649. The amount of the fee applicab issuance of the registration certificate or the issuance or renewal of the certificate for PPM procedures, certificate of waiver, certificate of accreditation, or certificate of the amount in effect at the time the application is received. Upon receipt of an application for a certificate, HHS or its designee notifies the laboratory of the amount of for the requested certificate.

§ 493.639 Fee for revised certificate.
(a) If, after a laboratory is issued a registration certificate, it changes its name or location, the laboratory must pay a fee to cover the cost of issuing a revised registration
fee for the revised registration certificate is based on the cost to issue the revised certificate to the laboratory.

(b) A laboratory must pay a fee to cover the cost of issuing a revised certificate in any of the following circumstances:

(1) The fee for issuing an appropriate revised certificate is based on the cost to issue the revised certificate to the laboratory as follows:

(i) If a laboratory with a certificate of waiver wishes to perform tests in addition to those listed in § 493.15(c) as waived tests, it must, as set forth in § 493.638, pay an ad
the appropriate certificate to cover the additional testing.

(ii) If a laboratory with a certificate for PPM procedures wishes to perform tests in addition to those specified as PPM procedures or listed in § 493.15(c) as waived tests,
forth in § 493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(2) A laboratory must pay a fee to cover the cost of issuing a revised certificate when—

(i) A laboratory changes its name, location, or its director; or

(ii) A laboratory deletes services or wishes to add services and requests that its certificate be changed. (An additional fee is also required under § 493.643(d) if it is neces
determine compliance with additional requirements.)

§ 493.643 Fee for determination of program compliance.
(a) Fee requirement. In addition to the fee required under § 493.638, a laboratory subject to routine inspections must pay a fee to cover the cost of determining progra
Laboratories issued a certificate for PPM procedures, certificate of waiver, or a certificate of accreditation are not subject to this fee for routine inspections.

(b) Costs included in the fee. Included in the fee for determining program compliance is the cost of evaluating qualifications of personnel; monitoring proficiency testing
onsite inspections; documenting deficiencies; evaluating laboratories' plans to correct deficiencies; and necessary administrative costs. HHS sets the fee amounts annua
year basis. Laboratories are inspected biennially; therefore, fees are assessed and payable biennially. If additional expenses are incurred to conduct follow up visits to ve
of deficiencies, to impose sanctions, and/or for surveyor preparation for and attendance at ALJ hearings, HHS assesses an additional fee to include these costs. The addit
based on the actual resources and time necessary to perform the activities.

(c) Classification of laboratories that require inspection for purpose of determining amount of fee.

(1) There are ten classifications (schedules) of laboratories for the purpose of determining the fee amount a laboratory is assessed. Each laboratory is placed into one of
following schedules based on the laboratory's scope and volume of testing (excluding tests performed for quality control, quality assurance, and proficiency testing purp

(i)

(A) Schedule A Low Volume. The laboratory performs not more than 2,000 laboratory tests annually.

(B) Schedule A. The laboratory performs tests in no more than 3 specialties of service with a total annual volume of more than 2,000 but not more than 10,000 laborato

(ii) Schedule B. The laboratory performs tests in at least 4 specialties of service with a total annual volume of not more than 10,000 laboratory tests.

(iii) Schedule C. The laboratory performs tests in no more 3 specialties of service with a total annual volume of more than 10,000 but not more than 25,000 laboratory te

(iv) Schedule D. The laboratory performs tests in at least 4 specialties with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(v) Schedule E. The laboratory performs more than 25,000 but not more than 50,000 laboratory tests annually.

(vi) Schedule F. The laboratory performs more than 50,000 but not more than 75,000 laboratory tests annually.

(vii) Schedule G. The laboratory performs more than 75,000 but not more than 100,000 laboratory tests annually.

(viii) Schedule H. The laboratory performs more than 100,000 but not more than 500,000 laboratory tests annually.

(ix) Schedule I. The laboratory performs more than 500,000 but not more than 1,000,000 laboratory tests annually.

(x) Schedule J. The laboratory performs more than 1,000,000 laboratory tests annually.

(2) For purposes of determining a laboratory's classification under this section, a test is a procedure or examination for a single analyte. (Tests performed for quality con
assurance, and proficiency testing are excluded from the laboratory's total annual volume). Each profile (that is, group of tests) is counted as the number of separate pro
examinations; for example, a chemistry profile consisting of 18 tests is counted as 18 separate procedures or tests.

(3) For purposes of determining a laboratory's classification under this section, the specialties and subspecialties of service for inclusion are:

(i) The specialty of Microbiology, which includes one or more of the following subspecialties:
(A) Bacteriology.
(B) Mycobacteriology.

§ 493.645 Additional fee(s) applicable to approved State laboratory programs and laboratories issued a certificate of accreditation, certificate of waiver, or certificate fo procedures.

(a) Approved State laboratory programs. State laboratory programs approved by HHS are assessed a fee for the following:

(1) Costs of Federal inspections of laboratories in that State (that is, CLIA-exempt laboratories) to verify that standards are being enforced in an appropriate manner.

(2) Costs incurred for investigations of complaints against the State's CLIA-exempt laboratories if the complaint is substantiated.

(3) Costs of the State's prorata share of general overhead to develop and implement CLIA.

(b) Accredited laboratories.

(1) In addition to the certificate fee, a laboratory that is issued a certificate of accreditation is also assessed a fee to cover the cost of evaluating individual laboratories to overall whether an accreditation organization's standards and inspection policies are equivalent to the Federal program. All accredited laboratories share in the cost of t inspections. These costs are the same as those that are incurred when inspecting nonaccredited laboratories.

(2) If a laboratory issued a certificate of accreditation has been inspected and followup visits are necessary because of identified deficiencies, HHS assesses the laborator the cost of these visits. The fee is based on the actual resources and time necessary to perform the followup visits. HHS revokes the laboratory's certificate of accreditati pay the assessed fee.

(c) If, in the case of a laboratory that has been issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures, it is necessary to conduct a co investigation, impose sanctions, or conduct a hearing, HHS assesses that laboratory a fee to cover the cost of these activities. Costs are based on the actual resources an necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the certificate for failure to pay the assessed costs. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the the administrative appeals process, the costs of these activities are not imposed upon the laboratory.

§ 493.646 Payment of fees.

(a) Except for CLIA-exempt laboratories, all laboratories are notified in writing by HHS or its designee of the appropriate fee(s) and instructions for submitting the fee(s), due date for payment and where to make payment. The appropriate certificate is not issued until the applicable fees have been paid.

(b) For State-exempt laboratories, HHS estimates the cost of conducting validation surveys within the State for a 2-year period. HHS or its designee notifies the State by appropriate fees, including the due date for payment and the address of the United States Department of Treasury designated commercial bank to which payment must addition, if complaint investigations are conducted in laboratories within these States and are substantiated, HHS bills the State(s) the costs of the complaint investigatio

§ 493.649 Methodology for determining fee amount.

(a) General rule. The amount of the fee in each schedule for compliance determination inspections is based on the average hourly rate (which includes the costs to perfo
required activities and necessary administration costs) multiplied by the average number of hours required or, if activities are performed by more than one of the entitie
paragraph (b) of this section, the sum of the products of the applicable hourly rates multiplied by the average number of hours required by the entity to perform the act
for issuance of the registration certificate or certificate of compliance is based on the laboratory's scope and volume of testing.

(b) Determining average hourly rates used in fee schedules. Three different entities perform activities related to the issuance or reissuance of any certificate. HHS deter
average hourly rates for the activities of each of these entities.

(1) State survey agencies. The following costs are included in determining an average hourly rate for the activities performed by State survey agencies:

(i) The costs incurred by the State survey agencies in evaluating personnel qualifications and monitoring each laboratory's participation in an approved proficiency testin
cost of onsite inspections and monitoring activities is the hourly rate derived as a result of an annual budget negotiation process with each State. The hourly rate encom
costs (as determined by each State's civil service pay scale) and fringe benefit costs to support the required number of State inspectors, management and direct support

(ii) Travel costs necessary to comply with each State's administrative requirements and other direct costs such as equipment, printing, and supplies. These costs are esta
on historical State requirements.

(iii) Indirect costs as negotiated by HHS.

(2) Federal agencies. The hourly rate for activities performed by Federal agencies is the most recent average hourly cost to HHS to staff and support a full time equivalen
Included in this cost are salary and fringe benefit costs, necessary administrative costs, such as printing, training, postage, express mail, supplies, equipment, computer s
building service charges associated with support services provided by organizational components such as a computer center, and any other oversight activities necessar
program.

(3) HHS contractors. The hourly rate for activities performed by HHS contractors is the average hourly rate established for contractor assistance based on an independen
cost estimate for the required workload. This rate includes the cost of contractor support to provide proficiency testing programs to laboratories that do not participate
proficiency testing program, provide specialized assistance in the evaluation of laboratory performance in an approved proficiency testing program, perform assessment
testing laboratories, conduct special studies, bill and collect fees, issue certificates, establish accounting, monitoring and reporting systems, and assist with necessary su

(c) Determining number of hours. The average number of hours used to determine the overall fee in each schedule is HHS's estimate, based on historical experience, of
time needed by each entity to perform the activities for which it is responsible.

N/A

N/A

Orange font=deleted regulation

New/Revised Regulation

§ 493.557(b)(4)
Agree to pay the cost of the validation program administered in that State as specified in §§ 493.649(a) and 493.655(b).
§ 493.575(i)
Failure to pay fees. CMS withdraws the approval of a State licensure program if the State fails to pay the applicable fees, as specified in §§ 493.649(a)

§ 493.638 Certificate fees.
(a) Basic rule. Laboratories must pay a fee that covers the costs incurred for the issuance, renewal, change in certificate type, or reinstatement of a terminated certificat
costs, as applicable. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certifi

(1) For registration certificates, the fee is a flat fee that includes the costs for issuing the certificates, collecting the fees, and evaluating whether the procedures, tests, o
testing allowed for the requested certificate.

(2) For a certificate of waiver, the fee includes the costs for issuing the certificate; collecting the fees; evaluating whether the procedures, tests, or examinations listed o
requested certificate; and determining whether a laboratory test meets the criteria for a waived test.

(3) For a certificate for PPM procedures, the fee includes the costs for issuing the certificate, collecting the fees; and evaluating whether the procedures, tests, or exami
inclusion in the subcategory of PPM procedures.

(4) For a certificate of accreditation, the fee includes the costs for issuing the certificate, collecting the fees, evaluating the programs of accrediting bodies, and evaluatir
the application fall within the testing appropriate for the requested certificate.

(5) For a certificate of compliance, the fee includes the costs for issuing the certificates, collecting the fees, evaluating and monitoring proficiency testing programs, and
listed on the application fall within the testing appropriate for the requested certificate.
(b) Fee amount. (1) The certificate fee amount is set biennially by HHS. CMS will publish a notice in the Federal Register biennially with any adjustments to the fee amou
accordance with § 493.680. For certificates of waiver and certificates of PPM, the certificate fee amount is based on the category of test complexity performed by the la
based on the category of test complexity performed by the laboratory and schedules or ranges of annual laboratory test volume (excluding waived tests and tests perfo
testing purposes) and specialties tested, with the amounts of the fees in each schedule being a function of the costs for all aspects of general administration of CLIA as s

(2) Certificate fees are assessed and payable at least biennially.

(3) The amount of the fee payable by the laboratory is the amount listed in the most recent notice published in the Federal Register at the time the application, renewa
by HHS or its designee.

(4) After processing an application for an issuance, renewal, change in certificate type, or reinstatement of a terminated certificate with a gap in service, HHS or its desig

(c) Classification of laboratories for purposes of determining the fee amount for certificate types other than certificates of waiver or certificates of PPM. (1) For purposes
section, a test is a procedure or examination for a single analyte. (Tests performed for quality control, quality assessment, and proficiency testing are excluded from the
group of tests) is counted as the number of separate procedures or examinations; for example, a chemistry profile consisting of 18 tests is counted as 18 separate proce

(2) For purposes of determining a laboratory's classification under this section, the specialties and subspecialties of service for inclusion are:

(i) The specialty of Microbiology, which includes one or more of the following subspecialties:
(A) Bacteriology.
(B) Mycobacteriology.
(C) Mycology.
(D) Parasitology.
(E) Virology.
(ii) The specialty of Serology, which includes one or more of the following subspecialties:
(A) Syphilis Serology.
(B) General immunology.
(iii) The specialty of Chemistry, which includes one or more of the following subspecialties:
(A) Routine chemistry.
(B) Endocrinology.
(C) Toxicology.
(D) Urinalysis.
(iv) The specialty of Hematology.

§ 493.639 Fees for revised and replacement certificates.
(a) If, after a laboratory is issued a certificate, it requests a revised certificate, the laboratory must pay a fee to cover the cost of issuing a revised certificate. The fee for a certificate to the laboratory. The fee must be paid in full before the revised certificate will be issued.

(1) If laboratory services are added to a certificate of compliance, the laboratory must pay an additional fee if required under § 493.643(d)(2).

(2) [Reserved]

(b) If, after a laboratory is issued a certificate, it requests a replacement certificate, the laboratory must pay a fee to cover the cost of issuing a replacement certificate. T issuing the replacement certificate to the laboratory. The fee must be paid in full before issuing the replacement certificate.

§ 493.643 Additional fees applicable to laboratories issued a certificate of compliance.
(a) Fee requirement. In addition to the fee required under § 493.638, a laboratory subject to routine inspections must pay a fee to cover the cost of determining progra procedures, certificate of waiver, or a certificate of accreditation are not subject to this fee for routine inspections.

(b) Costs included in the fee. Included in the fee for determining program compliance are costs for evaluating qualifications of laboratory personnel; monitoring laborato laboratories including: documenting deficiencies, evaluating laboratories' plans to correct deficiencies, creating training programs, training surveyors, and necessary adm

(c) Fee amount. The amount of the fee for determining program compliance is set biennially by HHS.

(1) The fee is based on the category of test complexity and schedules or ranges of annual laboratory test volume and specialties tested, with the amounts of the fees in determining program compliance as set forth in § 493.638(c).

(2) The fee is assessed and payable biennially.

(3) The amount of the program compliance fee is the amount applicable to the laboratory listed in the most recent notice published in the Federal Register at the time t

(d) Additional fees. (1) If a laboratory issued a certificate of compliance has been inspected and follow-up visits are necessary because of identified deficiencies, HHS ass The fee is based on the actual resources and time necessary to perform the follow-up visits. HHS revokes the laboratory's certificate of compliance for failure to pay the

(2) If, after a certificate of compliance is issued, a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, to d necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing performance. The additional fee is based on the actual resources and time neces certificate for failure to pay the compliance determination fee.

(3) If it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses the laboratory holding a certificate of compliance a fee t investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the Govern laboratory. Costs for these activities are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory conce HHS. HHS revokes the laboratory's certificate of compliance for failure to pay the assessed costs.

(4) Laboratories with a certificate of compliance must pay a fee if the laboratory fails to perform successfully in proficiency testing for one or more specialties, subspecia it is necessary to conduct a desk review of the unsuccessful performance. The additional fee is based on the actual resources and time necessary to perform the desk re for failure to pay the assessed costs.

§ 493.645 Additional fees applicable to laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures.

(a) Accredited laboratories.

(1) A laboratory that is issued a certificate of accreditation is assessed an additional fee to cover the cost of performing validation inspections described at § 493.563. All inspections. These costs are 5 percent of the same costs as those that are incurred when inspecting nonaccredited laboratories of the same schedule (or range) and are accredited laboratory has a validation inspection or not. HHS revokes the laboratory's certificate of accreditation for failure to pay the fee.

(2) If a laboratory issued a certificate of accreditation has been inspected and follow-up visits are necessary because of identified deficiencies, HHS assesses the laborato is based on the actual resources and time necessary to perform the follow-up visits. HHS revokes the laboratory's certificate of accreditation for failure to pay the fee.

(b) Complaint surveys.

§ 493.646 [Removed]

§ 493.649 Additional fees applicable to approved State laboratory programs.

(a) Approved State laboratory programs. State laboratory programs approved by HHS are assessed a fee for the following:

(1) Costs of Federal inspections of laboratories in that State (that is, CLIA-exempt laboratories) to verify that standards are being enforced in an appropriate manner.

(2) Costs incurred for investigations of complaints against the State's CLIA-exempt laboratories if the complaint is substantiated.

(3) The State's pro rata share of general overhead to administer the laboratory certification program under section 353 of the PHS Act.

(b) [Reserved]

§ 493.655 Payment of fees.
(a) Except for laboratories covered by approved State laboratory programs, all laboratories are notified in writing by HHS or its designee of the appropriate fee(s) and ins
for payment and where to make payment. The appropriate certificate is not issued until the applicable fees have been paid.

(b) For approved State laboratory programs, HHS estimates the cost of conducting validation inspections as described at § 493.563 within the State on at least a biennia
appropriate fees, including the due date for payment and the address of the United States Department of Treasury designated commercial bank to which payment must
conducted in laboratories within these States and are substantiated, HHS bills the State(s) the costs of the complaint investigations.

§ 493.680 Methodology for determining the biennial fee increase.
(a) General rule. Except for fees assessed to State laboratory programs approved by HHS, the fee amounts described in this subpart are subject to a biennial increase bas
Urban (CPI-U) inflation adjustment and, if applicable, an additional increase as follows:

(1) CMS calculates the inflation rate using the compounded CPI-U over 2 years and, provided that the calculated rate is greater than zero, applies an increase to all fee a

(2) If the total fee amounts, including any increase applied under paragraph (a)(1) of this section, do not match or exceed actual program obligations based on a review o
additional across the board increase to each laboratory's fees by calculating the difference between the total fee amounts and actual program obligations.

(b) Baseline. Any increase applied under paragraph (a) of this section is incorporated into the baseline fee amounts for any subsequent biennial increase.

(c) Publication. Any increase applied under paragraph (a) of this section, including the calculation thereof, will be published as a notice in the Federal Register.

BLUE font= redesignated regulations; same language/text.

Comments	Current IG (no IG for fees reg. scetion)
Amend § 493.557 in paragraph (b)(4) by removing the reference “§§ 493.645(a) and 493.646(b)” and adding in its place the reference “§§ 493.649(a) and 493.655(b)”. Amend § 493.575 in paragraph (i) by removing the reference “§§ 493.645(a) and 493.646(b)” and adding in its place the reference “§§ 493.649(a) and 493.655(b)”. Updated the regulatory language/text for this section.	No IG

Updated the regulatory language/text for this section.

Updated the regulatory language/text for this section.

Amend § 493.645--
a. By revising the section heading;
b. By removing paragraph (a);
c. By redesignating paragraphs (b) and (c) as paragraphs (a) and (b);
d. By revising newly redesignated paragraph (a); and
e. By adding a paragraph heading for newly redesignated paragraph (b).

Section 493.646 is removed.

Updated the regulatory language/text for this section.

Added new section.

Added new section.

Associated Current D-Tag;
(493.1278: D5729-D5773);
(subpart K: D5002-D5893)

D5729

D5731

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D5773

Alternative Sanctions/CLIA Fees/Histocompatibility/Personnel Final Rule (CMS-3326-F) Crosswalk

RED font= revised regulatory language/text.

HISTOCOMPATIBILITY

Current Regulation

§ 493.1278 Standard: Histocompatibility.

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

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

(2) All patient specimens must be easily retrievable.

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

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

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

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

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

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

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

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

(5) Have available and follow written criteria for the following:
(i) The preparation of cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the HLA typing technique(s) performed.

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

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

(iv) The assignment of HLA antigens.

(v) When antigen redefinition and retyping are required.

(6) Check each HLA typing by testing, at a minimum the following:
(i) A positive control material.
(ii) A negative control material in which, if applicable to the technique performed, cell viability at the end of incubation is sufficient to permit accurate interpretation of results. In assays in which cell viability is not required, the negative control result must be sufficiently different from the positive control result to permit accurate interpretation of results.
(iii) Positive control materials for specific cell types when applicable (that is, T cells, B cells, and monocytes).

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

(d) **Antibody Screening**. The laboratory must do the following:
(1) Use a technique(s) that detects HLA-specific antibody with a specificity equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay.
(2) Use a method that distinguishes antibodies to HLA Class II antigens from antibodies to Class I antigens to detect antibodies to HLA Class II antigens.
(3) Use a panel that contains all the major HLA specificities and common splits. If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding.

(4) Make a reasonable attempt to have available monthly serum specimens for all potential transplant beneficiaries for periodic antibody screening and crossmatch.
(5) Have available and follow a written policy consistent with clinical transplant protocols for the frequency of screening potential transplant beneficiary sera for preformed HLA-specific antibodies.

(6) Check each antibody screening by testing, at a minimum the following:
(i) A positive control material containing antibodies of the appropriate isotype for the assay.
(ii) A negative control material.

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

(e) **Crossmatching**. The laboratory must do the following:
(1) Use a technique(s) documented to have increased sensitivity in comparison with the basic complement-dependent microlymphocytotoxicity assay.

(2) Have available and follow written criteria for the following:
(i) Selecting appropriate patient serum samples for crossmatching.
(ii) The preparation of donor cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the crossmatch technique(s) performed.

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

(f) **Transplantation**. Laboratories performing histocompatibility testing for transfusion and transplantation purposes must do the following:
(1) Have available and follow written policies and protocols specifying the histocompatibility testing (that is, HLA typing, antibody screening, compatibility testing and crossmatching) to be performed for each type of cell, tissue or organ to be transfused or transplanted. The laboratory's policies must include, as applicable—
(i) Testing protocols for cadaver donor, living, living-related, and combined organ and tissue transplants;
(ii) Testing protocols for patients at high risk for allograft rejection; and
(iii) The level of testing required to support clinical transplant protocols (for example, antigen or allele level).

N/A

(2) For renal allotransplantation and combined organ and tissue transplants in which a kidney is to be transplanted, have available results of final crossmatches before the kidney is transplanted.

(3) For nonrenal transplantation, if HLA testing and final crossmatches were not performed prospectively because of an emergency situation, the laboratory must document the circumstances, if known, under which the emergency transplant was performed, and records of the transplant must reflect any information provided to the laboratory by the patient's physician.

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

Orange font=deleted regulation

New/Revised Regulation

§ 493.1278 Standard: Histocompatibility.
(a) **General**. The laboratory must meet the following requirements:
(a)(1) Use a continuous monitoring system and alert system to monitor the storage temperature of specimens (donor and recipient) and reagents and notify laboratory personnel when temperature limits are exceeded.

(a)(2) Establish and follow written policies and procedures for the storage and retention of specimens based on the specific type of specimen. All specimens must be easily retrievable. The laboratory must have an emergency plan for alternate storage.

N/A

(a)(3) If the laboratory uses immunologic reagents to facilitate or enhance the isolation or identification of lymphocytes or lymphocyte subsets, the efficacy of the methods must be monitored with appropriate quality control procedures.

(a)(4) Participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

N/A

N/A

N/A

(b) **Human leukocyte antigen (HLA) typing**. The laboratory must do the following:
(b)(1) Use HLA antigen terminology from the World Health Organization (WHO) Nomenclature Committee for Factors of the HLA System.

N/A

N/A

N/A

N/A

(b)(2) Have available and follow written criteria for determining when antigen and allele typing are required.

N/A

N/A

N/A

(c) **Antibody screening and identification**. The laboratory must make a reasonable effort to have available monthly serum specimens for all potential transplant recipients for periodic antibody screening, identification, and crossmatch.

N/A

N/A

(d) **Crossmatching**. For each type of crossmatch that a laboratory performs, the laboratory must do the following, as applicable:
(d)(1) Establish and follow written policies and procedures for performing a crossmatch.

(d)(2) Have available and follow written criteria for the following:
(d)(2)(i) Defining donor and recipient HLA antigens, alleles, and antibodies to be tested;
(d)(2)(ii) Defining the criteria necessary to assess a recipient's alloantibody status;
(d)(2)(iii) Assessing recipient antibody presence or absence on an ongoing basis;
(d)(2)(iv) Typing the donor, to include those HLA antigens to which antibodies have been identified in the potential recipient, as applicable;
(d)(2)(v) Describing the circumstances in which pre- and post-transplant confirmation testing of donor and recipient specimens is required;
(d)(2)(vi) Making available all applicable donor and recipient test results to the transplant team;
(d)(2)(vii) Ensuring immunologic assessments are based on test results obtained from a test report from a CLIA-certified laboratory; and
(d)(2)(viii) Defining time limits between recipient testing and the performance of a crossmatch.

(d)(3) The test report must specify the type of crossmatch performed.

(e) **Transplantation**. Laboratories performing histocompatibility testing for infusion and transplantation purposes must establish and follow written policies and procedures specifying the histocompatibility testing (that is, HLA typing, antibody screening and identification, and crossmatching) to be performed for each type of cell, tissue, or organ to be infused or transplanted. The laboratory's policies and procedures must include, as applicable—
(e)(1) Testing protocols that address:
(e)(1)(i) Transplant type (organ, tissue, cell);
(e)(1)(ii) Donor (living, deceased, or paired): and
(e)(1)(iii) Recipient (high risk vs. unsensitized);
(e)(2) Type and frequency of testing required to support clinical transplant protocols; and

(e)(3) Process to obtain a recipient specimen, if possible, for crossmatch that is collected on the day of the transplant. If the laboratory is unable to obtain a recipient specimen on the day of the transplant, the laboratory must have a process to document its efforts to obtain the specimen.

N/A

N/A

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

BLUE font= redesignated regulations; same language/text.

Comments	Current IG (see Histocomp IG excel worksheet.)
Changed “an audible alarms system” to “a continuous monitoring and alert system”.	
Expanded the regulatory language to include that the laboratory must establish and follow written policies and procedures for the storage and retention of patient specimens based on the specific type of specimen because the type and duration of specimen storage are equally important as ease of retrieval.	
Deleted the labeling requirement for in-house prepared typing sera reagent.	
Revised this requirement by removing the examples (that is, antibodies, antibody-coated particles, or complement) to clarify that these technologies, as well as current and future technologies, are allowed for the isolation of lymphocytes or lymphocyte subsets. Clarified the requirement by adding “identification” of lymphocytes, or lymphocyte subsets. Redesignated § 493.1278(a)(4) as revised to § 493.1278(a)(3).	
Redesignated § 493.1278(a)(5) as § 493.1278(a)(4). This requirement remains unchanged.	
Deleted requirements at § 493.1278(b)(1) through (3) pertaining to establishing HLA typing procedures. The requirement that the laboratory must establish and have written procedures that ensure quality test results are already addressed by the general requirements for all test systems under current § 493.1445(e)(1) and (e)(3)(i) and revision at § 493.1278(f), respectively, and therefore, are duplicative.	

Deleted requirements at § 493.1278(b)(1) through (3) pertaining to establishing HLA typing procedures. The requirement that the laboratory must establish and have written procedures that ensure quality test results are already addressed by the general requirements for all test systems under current § 493.1445(e)(1) and (e)(3)(i) and revision at § 493.1278(f), respectively, and therefore, are duplicative.

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Redesignated and revised language the provisions at paragraph (b)(4) to paragraph (b)(1). At newly redesignated paragraph (b)(1), we proposed deleting the language that states potential new antigens not yet approved by this committee must have a designation that cannot be confused with WHO terminology because new alleles are approved monthly, which makes this requirement obsolete.

At § 493.1278(b)(5)(i) through (iv), deleted the requirements for preparation of cells or cellular extracts, selecting typing reagents, ensuring that reagents used for typing are adequate, and assignment of HLA antigens as they are already addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, and 493.1252, and therefore, are duplicative.ated regulatory language/text.

At § 493.1278(b)(5)(i) through (iv), deleted the requirements for preparation of cells or cellular extracts, selecting typing reagents, ensuring that reagents used for typing are adequate, and assignment of HLA antigens as they are already addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, and 493.1252, and therefore, are duplicative.ated regulatory language/text.

At § 493.1278(b)(5)(i) through (iv), deleted the requirements for preparation of cells or cellular extracts, selecting typing reagents, ensuring that reagents used for typing are adequate, and assignment of HLA antigens as they are already addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, and 493.1252, and therefore, are duplicative.ated regulatory language/text.

At § 493.1278(b)(5)(i) through (iv), deleted the requirements for preparation of cells or cellular extracts, selecting typing reagents, ensuring that reagents used for typing are adequate, and assignment of HLA antigens as they are already addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, and 493.1252, and therefore, are duplicative.ated regulatory language/text.

Updated regulatory language. Modified the requirement to add “allele” and delete the “re” prefix in the word “retyping” in this paragraph and to redesignate the provisions at paragraph (b)(5)(v) to paragraph (b)(2).

Deleted requirements for HLA typing control materials procedures as they are addressed by the general requirements regarding quality control materials and procedures for all test systems under § 493.1256(a) through (d) and (f) through (h), and therefore, are duplicative.

Deleted this requirement for control procedures and materials regarding disease related studies because this is addressed by the general requirements for all test systems under §§ 493.1256(d) and 493.1451(b)(4), and therefore, is duplicative.

Changed the name of this section from “Antibody Screening” to “Antibody Screening and Identification” for clarification as both processes apply to histocompatibility testing. The provisions covered under this section apply to both screening and identification. Moved § 493.1278(d) as revised to § 493.1278(c).

At § 493.1278(d)(1) through (3) and (5) through (7), deleted these requirements for antibody screening laboratory procedures as they are addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, 493.1252, and 493.1256, and therefore, are duplicative.

Changed the name of this section from “Antibody Screening” to “Antibody Screening and Identification” for clarification as both processes apply to histocompatibility testing. The provisions covered under this section apply to both screening and identification. Moved § 493.1278(d) as revised to § 493.1278(c).

At § 493.1278(d)(1) through (3) and (5) through (7), deleted these requirements for antibody screening laboratory procedures as they are addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, 493.1252, and 493.1256, and therefore, are duplicative.

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At § 493.1278(d)(1) through (3) and (5) through (7), deleted these requirements for antibody screening laboratory procedures as they are addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, 493.1252, and 493.1256, and therefore, are duplicative.

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At § 493.1278(d)(1) through (3) and (5) through (7), deleted these requirements for antibody screening laboratory procedures as they are addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, 493.1252, and 493.1256, and therefore, are duplicative.

At § 493.1278(e)(1) through (3), removed/deleted these three requirements regarding the laboratory having crossmatch procedures and controls as we believe the provisions to be removed are addressed by the general requirements for all test systems under §§ 493.1445(e)(1), 493.1251, 493.1256, and 493.1451(b)(4), and therefore, are duplicative.

Added the requirements summarized below, at § 493.1278(d), to increase flexibility in the regulations and remove perceived barriers. These requirements include:

- Defining donor and recipient HLA antigens, alleles, and antibodies to be tested;
- Defining the criteria necessary to assess a recipient's alloantibody status;
- Assessing recipient antibody presence or absence on an ongoing basis;
- Typing the donor at the serological level, to include those HLA antigens to which antibodies have been identified in the potential recipient, as applicable;
- Describing the circumstances in which a pre- and post-transplant confirmation testing of donor and recipient specimens is required;
- Making available all applicable donor and recipient test results to transplant team;
- Ensuring immunologic assessments are based on the test report results obtained from a test report from CLIA certified testing laboratory(ies);
- Defining time limits between recipient testing and the performance of crossmatch; and
- Requiring that the test report must specify what type of crossmatch was performed.

At § 493.1278(e)(1) through (3), removed/deleted these three requirements regarding the laboratory having crossmatch procedures and controls as we believe the provisions to be removed are addressed by the general requirements for all test systems under §§ 493.1445(e)(1), 493.1251, 493.1256, and 493.1451(b)(4), and therefore, are duplicative.

Added the requirements summarized below, at § 493.1278(d), to increase flexibility in the regulations and remove perceived barriers. These requirements include:

- Defining donor and recipient HLA antigens, alleles, and antibodies to be tested;
- Defining the criteria necessary to assess a recipient's alloantibody status;
- Assessing recipient antibody presence or absence on an ongoing basis;
- Typing the donor at the serological level, to include those HLA antigens to which antibodies have been identified in the potential recipient, as applicable;
- Describing the circumstances in which a pre- and post-transplant confirmation testing of donor and recipient specimens is required;
- Making available all applicable donor and recipient test results to transplant team;
- Ensuring immunologic assessments are based on the test report results obtained from a test report from CLIA certified testing laboratory(ies);
- Defining time limits between recipient testing and the performance of crossmatch; and
- Requiring that the test report must specify what type of crossmatch was performed.

At § 493.1278(e)(1) through (3), removed/deleted these three requirements regarding the laboratory having crossmatch procedures and controls as we believe the provisions to be removed are addressed by the general requirements for all test systems under §§ 493.1445(e)(1), 493.1251, 493.1256, and 493.1451(b)(4), and therefore, are duplicative.

Added the requirements summarized below, at § 493.1278(d), to increase flexibility in the regulations and remove perceived barriers. These requirements include:

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- Defining the criteria necessary to assess a recipient's alloantibody status;
- Assessing recipient antibody presence or absence on an ongoing basis;
- Typing the donor at the serological level, to include those HLA antigens to which antibodies have been identified in the potential recipient, as applicable;
- Describing the circumstances in which a pre- and post-transplant confirmation testing of donor and recipient specimens is required;
- Making available all applicable donor and recipient test results to transplant team;
- Ensuring immunologic assessments are based on the test report results obtained from a test report from CLIA certified testing laboratory(ies);
- Defining time limits between recipient testing and the performance of crossmatch; and
- Requiring that the test report must specify what type of crossmatch was performed.

Changed the words “transfusion” and “transfused” to “infusion” and “infused”, respectively.
Moved § 493.1278(f) as revised to § 493.1278(e).

At § 493.1278(f)(1), revised this requirement to state that laboratories performing histocompatibility testing must establish and have written policies and procedures specifying the types of histocompatibility testing. Moved this language to § 493.1278(e). In addition, added “identification” after “antibody screening” in the revised § 493.1278(c), as identification is an important part of the process for crossmatching. Removed “compatibility testing” at § 493.1278(f)(1) because this activity is specific to immunohematology, and crossmatching is a more appropriate description of what we understand is the current histocompatibility procedure used by laboratories. Moved § 493.1278(f)(1) as revised to § 493.1278(e).
At § 493.1278(f)(1), modified the current general requirement to specify that the laboratory must establish and follow written policies and procedures that address the transplant type (organ, tissue, cell) donor type (living, deceased, or paired) and recipient type (high risk vs. non-sensitized).
Moved § 493.1278(f)(1) as revised to § 493.1278(e)(1).
At § 493.1278(f)(1)(ii), modified this requirement for laboratory policies and procedures as it would be included in the amended protocol requirements under the proposed regulation at § 493.1278(e)(1)(i) and (iii), and therefore, would be duplicative.
At § 493.1278(f)(1)(iii), replaced “the level of” with “type and frequency” to clarify this revised requirement refers to the type and frequency of testing practice to support the clinical transplant protocols. Removed the examples of antigen and allele level in the regulation as these examples may not be all-inclusive and generally are reflected in guidance rather than regulatory text. Redesignated § 493.1278(f)(1)(iii) as § 493.1278(e)(2).

Added a new requirement for pre-transplant recipient specimens under § 493.1278(e)(3).

At § 493.1278(f)(2) through (3), removed/deleted these requirements for renal and nonrenal transplantation crossmatch procedures.

At § 493.1278(f)(2) through (3), removed/deleted these requirements for renal and nonrenal transplantation crossmatch procedures.

The requirement at § 493.1278(g) is redesignated as § 493.1278(f). This requirement remains unchanged.

New IG (see Histocomp IG excel worksheet.)

Associated Current D-Tag; (subpart M: D5980-D6183)
D5987

N/A

N/A

D6003

D6003

D6005

D6035

D6057

D6065

D6066

D6067

N/A

N/A

D6078

D6080

D6111

D6129

D6135

D6143

D6143? or N/A?

D6151

D6155

D6164

D6171

D6171

Alternative Sanctions/CLIA Fees/Histocompatibility/Personnel Final Rule (CMS-3326-F) Crosswalk
RED font= revised regulatory language/text.

PERSONNEL

Current Regulation

§ 493.1359 Standard; PPM laboratory director responsibilities.
(b)(2) Is performed in accordance with applicable requirements in subparts H, J, K, and M of this part.

N/A

N/A

§ 493.1405 Standard; Laboratory director qualifications.
(b) The laboratory director must—
(1)
(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or
(2)
(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and
(ii) Have had laboratory training or experience consisting of:
(A) At least one year directing or supervising non-waived laboratory testing; or
(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in § 493.1407; or
(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or
(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and
(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or
(ii) Have had at least one year experience directing or supervising non-waived laboratory testing;
(4)
(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution;
(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and
(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or
(5)
(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution;
(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and
(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing;
(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under § 493.1406; or
(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which

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

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

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

(b) The laboratory director must:

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

(2) Be a physician who:

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

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

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

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

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

(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and

(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or

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

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

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

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

(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological

§ 493.1407 Standard; Laboratory director responsibilities.

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

§ 493.1411 Standard; Technical consultant qualifications.
(b) The technical consultant must—
(1)
(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or
(2)
(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and
(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or
(3)
(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and
(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or
(4)
(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and
(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.
Note:
The technical consultant requirements for “laboratory training or experience, or both” in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

§ 493.1417 Standard; Clinical consultant qualifications.
(a) Be qualified as a laboratory director under § 493.1405(b) (1), (2), or (3)(i); or

§ 493.1423 Standard; Testing personnel qualifications.
(b) Meet one of the following requirements:
(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or
(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or
(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or
(4)
(i) Have earned a high school diploma or equivalent; and

(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

Such training must ensure that the individual has—
(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;
(B) The skills required for implementing all standard laboratory procedures;
(C) The skills required for performing each test method and for proper instrument use;
(D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;
(E) A working knowledge of reagent stability and storage;
(F) The skills required to implement the quality control policies and procedures of the laboratory;
(G) An awareness of the factors that influence test results; and
(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

N/A

N/A

§ 493.1443 Standard; Laboratory director qualifications.
(b) The laboratory director must—
(1)
(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or
(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and
(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or
(ii) Have at least 2 years of experience directing or supervising high complexity testing; or
(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution and—
(i) Be certified and continue to be certified by a board approved by HHS; or
(ii)Before February 24, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least—
(A) Two years of laboratory training or experience, or both; and
(B) Two years of laboratory experience directing or supervising high complexity testing.
(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or
(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or
(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

§ 493.1445 Standard; Laboratory director responsibilities.
(c)The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

(e) The laboratory director must-
(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under § 493.1489(b)(4);

§ 493.1449 Standard; Technical supervisor qualifications.
(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor—
(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification.
(c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must—
(1)
(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or
(2)
(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and
(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or
(3)
(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and
(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or
(4)
(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and
(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or
(5)
(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology
§ 493.1451 Standard: Technical supervisor responsibilities .
(c) In cytology, the technical supervisor or the individual qualified under § 493.1449(k)(2)-

§ 493.1455 Standard: Clinical consultant qualifications.
(a) Be qualified as a laboratory director under § 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, § 493.1443(b)(6);

§ 493.1461 Standard: General supervisor qualifications.
(c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must—
(1)
(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and
(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or
(2)
(i) Qualify as testing personnel under § 493.1489(b)(2); and
(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or
(3)
(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under § 493.1462 on or before February 28, 1992.
(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of § 493.1462 on or before January 1, 1994."
(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995—
(i) Meet one of the following requirements:
(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS.
(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).
(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or
(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and —
(i) Be a high school graduate or equivalent; and
(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992.
(d) For blood gas analysis, the individual providing general supervision must—
(3)
(i) Have earned an associate degree related to pulmonary function from an accredited institution; and

§ 493.1462 General supervisor qualifications on or before February 28, 1992.
To qualify as a general supervisor under § 493.1461(c)(3), an individual must have met or could have met the following qualifications as they were in effect on or before February 28, 1992.
(a) Each supervisor possesses a current license as a laboratory supervisor issued by the State, if such licensing exists; and
(b) The laboratory supervisor—
(1) Who qualifies as a laboratory director under § 493.1406(b)(1), (2), (4), or (5) is also qualified as a general supervisor; therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor; or
(2)
(i) Is a physician or has earned a doctoral degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and
(ii) Subsequent to graduation, has had at least 2 years of experience in one of the laboratory specialties in a laboratory; or
(3)
(i) Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and
(ii) Subsequent to graduation has had at least 4 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated specialty in a laboratory; or
(4)
(i) Is qualified as a laboratory technologist under § 493.1491; and
(ii) After qualifying as a laboratory technologist, has had at least 6 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated laboratory specialty in a laboratory; or
(5) With respect to individuals first qualifying before July 1, 1971, has had at least 15 years of pertinent full-time laboratory experience before January 1, 1968; this required experience may be met by the substitution of education for experience.

§ 493.1463 Standard: General supervisor responsibilities.
(b)(4) Annually evaluating and documenting the performance of all testing personnel.

§ 493.1469 Standard: Cytology General supervisor qualifications.
(a) Be qualified as a technical supervisor under § 493.1449 (b) or (k); or

§ 493.1483 Standard: Cytotechnologist qualifications.
(b) Meet one of the following requirements:
(1) Have graduated from a school of cytotechnology accredited by the Committee on Allied Health Education and Accreditation or other organization approved by HHS; or
(2) Be certified in cytotechnology by a certifying agency approved by HHS; or
(3) Before September 1, 1992—
(i) Have successfully completed 2 years in an accredited institution with at least 12 semester hours in science, 8 hours of which are in biology; and
(A) Have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by HHS; or
(B) Have received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by HHS and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal 6 months of training; or
(ii) Have achieved a satisfactory grade to qualify as a cytotechnologist in a proficiency examination approved by HHS and designed to qualify persons as cytotechnologists; or
(4) Before September 1, 1994, have full-time experience of at least 2 years or equivalent within the preceding 5 years examining slide preparations under the supervision of a physician qualified under § 493.1449(b) or (k)(1), and before January 1, 1969, must have—
(i) Graduated from high school;
(ii) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician providing cytology services; and
(iii) Completed 2 years of full-time supervised experience in cytotechnology; or
(5)
(i) On or before September 1, 1994, have full-time experience of at least 2 years or equivalent examining cytology slide preparations within the preceding 5 years in the United States under the supervision of a physician qualified under § 493.1449(b) or (k)(1); and
(ii) On or before September 1, 1995, have met the requirements in either paragraph (b)(1) or (2) of this section.

§ 493.1489 Standard; Testing personnel qualifications.
(b) Meet one of the following requirements:
(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;
(2)
(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or—
(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—
(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either—
(1) 24 semester hours of medical laboratory technology courses; or
(2) 24 semester hours of science courses that include—
(i) Six semester hours of chemistry;
(ii) Six semester hours of biology; and
(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and
(B) Have laboratory training that includes either of the following:
(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)
(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.
(3) Have previously qualified or could have qualified as a technologist under § 493.1491 on or before February 28, 1992;
(4) On or before April 24, 1995 be a high school graduate or equivalent and have either—
(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or
(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);
(5)
(i) Until September 1, 1997—
(A) Have earned a high school diploma or equivalent; and
(B) Have documentation of training appropriate for the testing performed before analyzing patient

§ 493.1491 Technologist qualifications on or before February 28, 1992.

In order to qualify as high complexity testing personnel under § 493.1489(b)(3), the individual must have met or could have met the following qualifications for technologist as they were in effect on or before February 28, 1992. Each technologist must—

(a) Possess a current license as a laboratory technologist issued by the State, if such licensing exists; and

(b)

(1) Have earned a bachelor's degree in medical technology from an accredited university; or

(2) Have successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the Secretary, and has successfully completed a course of training of at least 12 months in such a school; or

(3) Have earned a bachelor's degree in one of the chemical, physical, or biological sciences and, in addition, has at least 1 year of pertinent full-time laboratory experience or training, or both, in the specialty or subspecialty in which the individual performs tests; or

(4)

(i) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses—

(A) For those whose training was completed before September 15, 1963. At least 24 semester hours in chemistry and biology courses of which—

(1) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and

(2) At least 12 semester hours in biology courses pertinent to the medical sciences; or

(B) For those whose training was completed after September 14, 1963. (1) 16 semester hours in chemistry courses that included at least 6 semester hours in inorganic chemistry and that are acceptable toward a major in chemistry;

(2) 16 semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and

(3) 3 semester hours of mathematics; and

(ii) Has experience, training, or both, covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him or her with education and training in medical technology equivalent to that described in paragraphs (b)(1) and (2) of this section; or

(5) With respect to individuals first qualifying before July 1, 1971, the technologist—

(i) Was performing the duties of a laboratory technologist at any time between July 1, 1961, and January 1, 1968, and

(ii) Has had at least 10 years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience); or

(6) Achieves a satisfactory grade in a proficiency examination approved by HHS.

Orange font=deleted regulation

New/Revised Regulation

§ 493.1359 Standard; PPM laboratory director responsibilities.
(b)(2) Is performed in accordance with applicable requirements in this subpart and subparts H, J, and K of this part;

(c) Evaluate the competency of all testing personnel and ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—
(1) Direct observations of routine patient test performance, including, if applicable, specimen handling, processing, and testing;
(2) Monitoring the recording and reporting of test results;
(3) Review of test results or worksheets;
(4) Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and
(5) Assessment of problem solving skills; and

(d) Evaluate and document the performance of individuals responsible for PPM testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations and documentation must be performed at least annually.

§ 493.1405 Standard; Laboratory director qualifications.
(b) The laboratory director must—
(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or
(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and
(ii) Have had laboratory training or experience consisting of:
(A) At least 1 year directing or supervising nonwaived laboratory testing; and
(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407; or
(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or
(B) Hold an earned doctoral degree; and
(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or
(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and
(ii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407; and
(A) Be certified and continue to be certified by a board approved by HHS; and
(B) Have had at least 1 year of experience directing or supervising nonwaived laboratory testing; or
(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or
(B)(1) Meet bachelor’s degree equivalency; and
(2) Have at least 16 semester hours of additional graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science; or
(C)(1) Meet bachelor’s degree equivalency; and
(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and
(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; and
(iii) Have at least 1 year of supervisory laboratory experience in nonwaived testing; and
(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in §

N/A

§ 493.1407 Standard; Laboratory director responsibilities.
(c) The laboratory director must:
(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and
(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

§ 493.1411 Standard; Technical consultant qualifications.
(b) The technical consultant must—
(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or
(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and
(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or
(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or
(B) Meet either requirements in § 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (b)(4)(i)(C); and
(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or
(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or
(B) Meet § 493.1405(b)(5)(i)(B); and
(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or
(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and
(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.
(6) For blood gas analysis, the individual must—
(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or
(ii)(A) Have earned a bachelor’s degree in respiratory therapy or cardiovascular technology from an accredited institution; and
(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or
(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024 and have done so continuously since December 28, 2024.
Note 1 to paragraph (b): The technical consultant requirements for “laboratory training or experience, or both” in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or
§ 493.1417 Standard; Clinical consultant qualifications.
(a) Be qualified as a laboratory director under § 493.1405(b) (1), (2), or (3); or

§ 493.1423 Standard; Testing personnel qualifications.
(b) Meet one of the following requirements:
(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or
(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or
(3) Meet the requirements in § 493.1405(b)(3)(i)(B), (b)(4)(i)(B) , (b)(4)(i)(C) or (b)(5)(i)(B); or
(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or
(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or
(6)(i) Have earned a high school diploma or equivalent; and

(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has—

(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens;
(6)(ii)(B) The skills required for implementing all standard laboratory procedures;
(6)(ii)(C) The skills required for performing each test method and for proper instrument use;
(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;
(6)(ii)(E) A working knowledge of reagent stability and storage;
(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory;
(6)(ii)(G) An awareness of the factors that influence test results; and
(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

(7) For blood gas analysis, the individual must—
(i) Be qualified under paragraph (b)(1), (2), (3), (4), (5), or (6) of this section; or
(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and
(B) Have at least 1 year of laboratory training or experience, or both, in blood gas analysis; or
(iii)(A) Have earned an associate degree related to pulmonary function from an accredited institution; and
(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis.

(8) Notwithstanding any other provision of this section, an individual is considered qualified as a testing personnel under this section if they were qualified and serving as a testing personnel for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024 and have done so continuously since December 28, 2024.

§ 493.1443 Standard; Laboratory director qualifications.
(b) The laboratory director must—
(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or
(2)(i) Be a doctor of medicine, a doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and
(ii) Have at least 2 years of experience directing or supervising high complexity testing; and
(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1445; or
(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or
(B) Hold an earned doctoral degree; and
(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or
(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and
(ii) Be certified and continue to be certified by a board approved by HHS; and
(iii) Have at least 2 years of:
(A) Laboratory training or experience, or both: and
(B) Laboratory experience directing or supervising high complexity testing; and
(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1445; or
(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.
(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology.

§ 493.1445 Standard; Laboratory director responsibilities.
(c) The laboratory director must:
(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and

(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

(e) The laboratory director must-
(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under § 493.1489(b)(5);

§ 493.1449 Standard; Technical supervisor qualifications.
The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor—
(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(c) Bacteriology, Mycobacteriology, Mycology, Parasitology or Virology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, mycobacteriology, mycology, parasitology, or virology, the individual functioning as the technical supervisor must—
(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty; or

(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or
§ 493.1451 Standard: Technical supervisor responsibilities .
(c) In cytology, the technical supervisor or the individual qualified under § 493.1449(e)(2)-

§ 493.1455 Standard: Clinical consultant qualifications.
(a) Be qualified as a laboratory director under § 493.1443(b)(1), (2), or (3) or, for the subspecialty of oral pathology, § 493.1443(b)(5);

§ 493.1461 Standard: General supervisor qualifications.
(c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor must—
(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; and
(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or
(2)(i) Qualify as testing personnel under § 493.1489(b)(3); and
(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or
(3) Meet the requirements at § 493.1443(b)(3) or § 493.1449(c)(4) or (5); or
(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.
(d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and
(e)(1) In histopathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or (f)(1);
(e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or § 493.1449(f)(2);
(e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or § 493.1449(f)(3); and
(e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under § 493.1449(b) or (g).

N/A

§ 493.1463 Standard: General supervisor responsibilities.
(b)(4) Evaluating and documenting the competency of all testing personnel.

§ 493.1469 Standard: Cytology General supervisor qualifications.
(a) Be qualified as a technical supervisor under § 493.1449 (b) or (e); or

§ 493.1483 Standard: Cytotechnologist qualifications.

Each person examining cytology slide preparations must meet the qualifications of § 493.1449 (b) or (e), or—

(b) Meet one of the following requirements:

(1) Have graduated from a school of cytotechnology accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP); or

(2) Be certified in cytotechnology by a certifying agency approved by HHS; or

(3) Notwithstanding any other provision of this section, an individual is considered qualified as a cytotechnologist under this section if they were qualified and serving as a cytotechnologist in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously sinceDecember 28, 2024.

§ 493.1489 Standard; Testing personnel qualifications.
(b) Meet one of the following requirements:
(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or
(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or
(ii) Be qualified under the requirements of § 493.1443(b)(3) or § 493.1449(c)(4) or (5); or
(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or—
(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes —
(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—
(1) 24 semester hours of medical laboratory technology courses; or
(2) 24 semester hours of science courses that include—
(i) 6 semester hours of chemistry;
(ii) 6 semester hours of biology; and
(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and
(B) Have laboratory training that includes:
(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or
(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or
(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or
(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.
(6) For blood gas analysis—
(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or
(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or
(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or
(7) For histopathology, meet the qualifications of § 493.1449(b) or (f) to perform tissue examinations.

N/A

BLUE font= redesignated regulations; same language/text.

Comments

Revised; slight edit made at (b)(2) by removing reference to subpart M.

New reg. Clarified the competency assessment (CA) requirements for PPM laboratories in the Standard for PPM LD responsibilities, as this testing is moderate complexity per § 493.19(b)(2) and subject to CA.

New reg. Proposed at § 493.1359(d) the same CA intervals as in §§ 493.1413(b)(8) and 493.1451(b)(8) apply to mid level practitioners for consistency.

Revised this section; allowed alternative educational pathway for nontraditional degrees.

Section 493.1406 is removed/deleted.

At § 493.1407(c), revised the requirements so that the LD must be on site at the laboratory at least once every 6 months, with at least a 4-month interval between the two on site visits. However, LDs may elect to be on-site more frequently. The laboratory must provide documentation of these visits, including evidence of performing activities that are part of the LD responsibilities.

Revised this section; allowed alternative educational pathway for nontraditional degrees.

Updated cross-reference from (3)(i) to (3).

Revised this section; allowed alternative educational pathway for nontraditional degrees.

Revised this section; allowed alternative educational pathway for nontraditional degrees.

Revised this section; allowed alternative educational pathway for nontraditional degrees.

New for blood gas TP MC.

New.

Revised this section; allowed alternative educational pathway for nontraditional degrees.

At §§ 493.1445(c), revised the requirements so that the LD must be on site at the laboratory at least once every 6 months, with at least a 4-month interval between the two on site visits. However, LDs may elect to be on-site more frequently. The laboratory must provide documentation of these visits, including evidence of performing activities that are part of the LD responsibilities.

Revised this section; allowed alternative educational pathway for nontraditional degrees.

Updated cross reference from (k) to (e).

Updated cross references,
(3)(i) to (3) and from (b)(6) to (b)(5).

At § 493.1461(c)(1)(i), removed an earned doctoral, master's, or bachelor's degree in "physical science" as a means to qualify.
At § 493.1461(c)(3) through (5), deleted the grandfather provisions as these requirements had to have been met by February 28, 1992, April 24, 1995, and September 1, 1992, respectively, and individuals can no longer qualify under these provisions.
Added new paragraph (c)(4) to specify a new grandfather provision for those individuals who had qualified prior to the publication of the final rule.

Section 493.1462 is removed/deleted.

At § 493.1463(b)(4), revised the language stating the need to annually evaluate and document the performance of all testing personnel to now require the evaluation and documentation of the competency of all testing personnel.

Updated cross-reference from (k) to (e).

At §§ 493.1483(b)(2) and 493.1489(b)(2)(ii)(B)(1), replaced "CAHEA" with CAAHEP (Commission on Accreditation of Allied Health Education Programs) and removed, "or other organization approved by HHS."

At § 493.1483(b)(3) through (5), removed the grandfather provisions as these requirements had to have been met by September 1, 1992, or September 1, 1994, as individuals can no longer qualify under these provisions. We stated that we plan to grandfather all individuals qualified under this provision prior to the date of the final rule. These individuals would be included in the new grandfather provision at § 493.1483(b)(3).

Removed paragraph (b)(3) as the February 28, 1992 grandfather provision must have been met by February 28, 1992.

Redesignated paragraphs (b)(2)(i) and (ii) to paragraphs (b)(3)(i) and (ii), respectively.
At § 493.1489(b)(2)(ii)(B)(1), replaced "CAHEA" with "CAAHEP" and removing "or other organization approved by HHS."
Revised paragraph (b)(1) to separate the provisions into two paragraphs (that is, paragraph (b)(1) and new paragraph (b)(2)(i)).
Removed an earned doctoral, master's, or bachelor's degree in "physical science" as a means to qualify.
Added new paragraph (b)(2)(ii) to state who may be qualified under § 493.1443(b)(3) or § 493.1449(c)(4) or (5) to allow individuals who do not have a chemical, biological, or clinical science or medical technology or clinical laboratory science degree to be eligible to qualify as a TC using the educational algorithm.
Moved the military provision out of the April 24, 1995, grandfather provision and made it a mechanism that individuals will be able to qualify for moderate complexity testing (§ 493.1423(b)(5)).
Removed paragraph (b)(4) introductory text and paragraph (b)(4)(i) [the text that currently states "On or before" through "graduated from a [ML] or [CL] training program approved or accredited by ABHES, CAHEA, or other organizations approved by HHS"] per the discussion under § 493.1483(b)(2).
The current military requirement at paragraph (b)(4)(ii) is redesignated as paragraph (b)(4).

Section 493.1491 is removed.

Current IG

No IG.

No IG.

No IG.

(b) The laboratory director must--

(b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

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

The laboratory director of federal jurisdictional laboratories simply needs to be licensed to practice medicine in any state, not necessarily the state in which the laboratory is located.

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

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

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

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

(b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and

Interpretive Guidelines §493.1405(b)(2)(i)

Individuals who have earned a Doctor of Optometry are qualified to serve as a laboratory director of certain

No IG.

Interpretive Guidelines §493.1407(c)

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

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

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

The laboratory director may delegate to a technical consultant, in writing, the responsibilities in: §§493.1407(e)(3), (4), (5), (6), (7), (11), (12), and (13).

The laboratory director may delegate to a clinical consultant, in writing, the responsibilities in: §§493.1407(e)(8) and (9).

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

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

(b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or

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

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

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

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

NOTE: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

No IG.

Interpretive Guidelines §493.1423(b)(1)

See §493.2 for the definition of an accredited institution.

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

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

Interpretive Guidelines §493.1423(b)(3)

Ensure that the military discharge paperwork (i.e., DD Form 214) reflects the occupational specialty and includes weeks of training. The occupational specialty must be related to the laboratory and must be at least 50 weeks long.

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

Interpretive Guidelines §493.1423(b)(4)

Personnel qualifying under this requirement must have a high school diploma or GED. There is no standardized approach to home schooling across the country. Should a surveyor be presented with home high school diploma, in general, they would accept the home high school diploma at face value and focus on the employee's training and competency. At this time, CMS is not aware that Primary Source Verification (PSV) companies verify home school programs.

Probes §1493.1423(b)(4)

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

No IG.

No IG.

(b) The laboratory director must--

(b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

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

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

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

(b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and

Interpretive Guidelines §493.1443(b)(2)

The laboratory director of federal jurisdictional laboratories simply needs to be licensed to practice medicine in any state not necessarily the state in which the laboratory is located.

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

Interpretive Guidelines §493.1443(b)(2)(i)
The residency program should provide the director the knowledge in principles and theories of laboratory practice including: quality control and quality assessment, proficiency testing, the phase of the total process (i.e., preanalytic, analytic and postanalytic), as well as general laboratory systems, facility administration, and development and implementation of personnel policy and procedure manuals. This training should also include hands-on laboratory testing.

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

Interpretive Guidelines §493.1445(c)

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

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

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

The laboratory director may reapportion to a technical supervisor, in writing, the responsibilities in: §§493.1445(e)(3), (4), (5), (6), (7), (12), (13), and (14).
The laboratory director may reapportion to a clinical consultant, in writing, the responsibilities in: §§493.1445(e)(8) and (9).
The only responsibilities that may be delegated to the general supervisor are listed at §§493.1463(b)(1)-(4).

(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor--

(b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification.

Interpretive Guidelines §493.1449(b)(2)

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

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

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

(c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

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

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

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

No IG.

No IG.

(c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must--

(c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and

Interpretive Guidelines §493.1461(c)(1)(i)

NOTE: See §493.2 for the definition of and guidance for an accredited institution.

(c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or

(c)(2)(i) Qualify as testing personnel under §493.1489(b)(2); and

(c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

(c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under §493.1462 on or before February 28, 1992.

(c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of §493.1462 on or before January 1, 1994.

(c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995--

(c)(4)(i) Meet one of the following requirements:

(c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS.

(c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

No IG.

No IG.

(b) Meet one of the following requirements:

(b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;

Interpretive Guidelines §493.1489(b)(1)

NOTE: See §493.2 for the definition of an accredited institution.

(b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or--

(b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes--

(b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either--

(b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or

(b)(2)(ii)(A)(2) 24 semester hours of science courses that include--

(b)(2)(ii)(A)(2)(i) Six semester hours of chemistry;

(b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and

(b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(b)(2)(ii)(B) Have laboratory training that includes either of the following:

(b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)

No IG.

New IG

Associated Current D-Tag

N/A

Alternative Sanctions/CLIA Fees/Histocompatibility/Personnel Final Rule (CMS-3326-F) C

RED font= revised regulatory language/text.

Alternative Sanctions/General Considerations

Current Regulation

§ 493.1804 General considerations.

(c)(1) CMS may impose alternative sanctions in lieu of, or in addition to principal sanctions. (Except for a condition level deficiency under §§ 493.41 or 493.1100(a), CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not routinely inspected for compliance with condition-level requirements.)

Crosswalk

Orange font=deleted regulation

New/Revised Regulation
§ 493.1804 General considerations. (c)(1) CMS may impose alternative sanctions in lieu of, or in addition to, principal sanctions.

BLUE font= redesignated regulations; same language/text.

Comments	Current IG.
Amended § 493.1804(c)(1) by removing the phrase "(Except for a condition level deficiency under §§ 493.41 or 493.1100(a), CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not routinely inspected for compliance with condition-level requirements.)"	No IG.

New IG.

Associated Current D-Tag

N/A

D5603

D5621

Alternative Sanctions/CLIA Fees/Histocompatibility/Personnel Final Rule (CMS-3326-F) Crosswal

RED font= revised regulatory language/text.

Other Conforming Amendments

Current Regulation

§ 493.945 Standard: Cytology; gynecologic examinations.

(b) * * *

(2) An individual qualified as a technical supervisor under § 493.1449 (b) or (k) who routinely interprets gynecologic slide preparations only after they have been examined by a cytotechnologist can either be tested using a test set that has been screened by a cytotechnologist in the same laboratory or using a test set that has not been screened. A technical supervisor who screens and interprets slide preparations that have not been previously examined must be tested using a test set that has not been previously screened.

(3) * * * * *

(i) Each slide set must contain 10 or 20 slides with point values established for each slide preparation based on the significance of the relationship of the interpretation of the slide to a
clinical condition and whether the participant in the testing event is a cytotechnologist qualified
under § 493.1469 or § 493.1483 or functioning as a technical supervisor in cytology qualified under § 493.1449 (b) or (k) of this part.

(ii) * * * * *

(C) Criteria for scoring system for a 10-slide test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (k):

(F) Criteria for scoring system for a 20-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (k):

§ 493.1273 Standard: Histopathology.

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

§ 493.1274 Standard: Cytology

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

(i) The review must be performed by an individual who meets one of the following qualifications:

(A) A technical supervisor qualified under § 493.1449(b) or (k).

k

Orange font=deleted regulation

New/Revised Regulation

§ 493.945 Standard: Cytology; gynecologic examinations.

(b) * * *

(2) An individual qualified as a technical supervisor under § 493.1449 (b) or (e) who routinely interprets gynecologic slide preparations only after they have been examined by a cytotechnologist can either be tested using a test set that has been screened by a cytotechnologist in the same laboratory or using a test set that has not been screened. A technical supervisor who screens and interprets slide preparations that have not been previously examined must be tested using a test set that has not been previously screened.

(3) * * * * *

(i) Each slide set must contain 10 or 20 slides with point values established for each slide preparation based on the significance of the relationship of the interpretation of the slide to a clinical condition and whether the participant in the testing event is a cytotechnologist qualified under § 493.1469 or § 493.1483 or functioning as a technical supervisor in cytology qualified under § 493.1449 (b) or (e) of this part.

(ii) * * * * *

(C) Criteria for scoring system for a 10-slide test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (e):

(F) Criteria for scoring system for a 20-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (e):

§ 493.1273 Standard: Histopathology.

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

§ 493.1274 Standard: Cytology
(c)(1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under § 493.1469 or § 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of this section).
(i) The review must be performed by an individual who meets one of the following qualifications:
(A) A technical supervisor qualified under § 493.1449(b) or (e).

BLUE font= redesignated regulations; same language/text.

Comments	Current IG
Current personnel CLIA reg.- cross-reference at reg. 493.1449(k) updated to 493.1449(e).	
Updated personnel CLIA reg. cross-reference from (l) to (f) and from (m) to (g).	No IG

Current personnel CLIA reg.- cross-reference at reg. No IG 493.1449(k) updated to 493.1449(e).

New IG