Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
DEFINTIONS				
<b>§ 493.2 Definitions.</b> <i>Midlevel practitioner</i> 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.	<b>§ 493.2 Definitions.</b> <i>Continuing education (CE) credit hours</i> 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.	Added 6 new definitions and revised the definition of "Midlevel practitioner"	N/A	
	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			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
	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.			
	<i>Replacement certificate</i> means an active CLIA certificate that is reissued with no changes made.			
	<i>Revised certificate</i> 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.			
CLIA FEES	5 402 557/b)(4)	Amond & 402 FE7 in	NI / A	
<b>§ 493.557(b)(4)</b> Agree to pay the cost of the validation program administered in that State as specified in <u>§§</u> <u>493.645(a)</u> and <u>493.646(b)</u> .	<b>§ 493.557(b)(4)</b> Agree to pay the cost of the validation program administered in that State as specified in <u>§§ 493.649(a) and 493.655(b)</u> .	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)".	N/A	

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
<b>§ 493.575(i)</b> <i>Failure to pay fees.</i> CMS withdraws the approval of a State licensure program if the State fails to pay the applicable fees, as specified in <u>§§ 493.645(a)</u> and <u>493.646(b)</u> .	<b>§ 493.575(i)</b> <i>Failure to pay fees.</i> CMS withdraws the approval of a State licensure program if the State fails to pay the applicable fees, as specified in <u>§§ 493.649(a) and 493.655(b)</u> .	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)".	N/A	
<ul> <li>§ 493.638 Certificate fees.</li> <li>(a) <i>Basic rule</i>. Laboratories must pay a fee for the issuance of a registration certificate, certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance, as applicable.</li> <li>Laboratories must also pay a fee to reapply for a certificate for PPM procedures, certificate of accreditation, or a certificate of waiver, certificate of accreditation, or a certificate of 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 program under section 353 of the PHS Act.</li> <li>(1) For registration certificates and certificates of compliance,</li> </ul>	<ul> <li>§ 493.638 Certificate fees.</li> <li>(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 certificate with a gap in service, and other direct administrative 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 certification program under section 353 of the PHS Act.</li> <li>(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, or examinations listed on the application fall within the testing allowed for the requested certificate.</li> <li>(2) For a certificate of waiver, the fee includes the costs for issuing the</li> </ul>	Updated the regulatory language/text for this section.	N/A	
the costs include issuing the certificates, collecting the fees,	certificate; collecting the fees; evaluating whether the procedures, tests, or			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
evaluating and monitoring	examinations listed on the application fall			
proficiency testing programs,	within the testing appropriate for the			
evaluating which procedures,	requested certificate; and determining			
tests or examinations meet the	whether a laboratory test meets the			
criteria for inclusion in the	criteria for a waived test.			
appropriate complexity category,				
and implementing section 353 of	(3) For a certificate for PPM procedures,			
the PHS Act.	the fee includes the costs for issuing the			
	certificate, collecting the fees; and			
(2) For a certificate of waiver, the	evaluating whether the procedures, tests,			
costs include issuing the	or examinations listed on the application			
certificate, collecting the fees,	meet the criteria for inclusion in the			
determining if a certificate of	subcategory of PPM procedures.			
waiver should be issued,				
evaluating which tests qualify for	(4) For a certificate of accreditation, the			
inclusion in the waived category,	fee includes the costs for issuing the			
and other direct administrative	certificate, collecting the fees, evaluating			
costs.	the programs of accrediting bodies, and			
	evaluating whether the procedures, tests,			
(3) For a certificate for PPM	or examinations listed on the application			
procedures, the costs include	fall within the testing appropriate for the			
issuing the certificate, collecting	requested certificate.			
the fees, determining if a				
certificate for PPM procedures	(5) For a certificate of compliance, the fee			
should be issued, evaluating	includes the costs for issuing the			
which procedures meet the	certificates, collecting the fees, evaluating			
criteria for inclusion in the	and monitoring proficiency testing			
subcategory of PPM procedures,	programs, and evaluating whether the			
and other direct administrative	procedures, tests or examinations listed on			
costs.	the application fall within the testing			
	appropriate for the requested certificate.			
(4) For a certificate of				
accreditation, the costs include	(b) Fee amount.			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
issuing the certificate, collecting	(1) The certificate fee amount is set			
the fees, evaluating the programs	biennially by HHS. CMS will publish a			
of accrediting bodies, and other	notice in the Federal Register biennially			
direct administrative costs.	with any adjustments to the fee amounts,			
	including any adjustments due to inflation,			
(b) <i>Fee amount</i> . The fee amount	in accordance with § 493.680. For			
is set annually by HHS on a	certificates of waiver and certificates of			
calendar year basis and is based	PPM, the certificate fee amount is based			
on the category of test	on the category of test complexity			
complexity, or on the category of	performed by the laboratory. For all other			
test complexity and schedules or	certificate types, the fee amount is based			
ranges of annual laboratory test	on the category of test complexity			
volume (excluding waived tests	performed by the laboratory and			
and tests performed for quality	schedules or ranges of annual laboratory			
control, quality assurance, and	test volume (excluding waived tests and			
proficiency testing purposes) and	tests performed for quality control, quality			
specialties tested, with the	assurance, or proficiency testing purposes)			
amounts of the fees in each	and specialties tested, with the amounts of			
schedule being a function of the	the fees in each schedule being a function			
costs for all aspects of general	of the costs for all aspects of general			
administration of CLIA as set	administration of CLIA as set forth in			
forth in <u>§ 493.649 (b)</u> and	paragraph (c) of this section.			
(c) . This fee is assessed and	(2) Certificate fees are assessed and			
payable at least biennially. The	payable at least biennially.			
methodology used to determine				
the amount of the fee is found in	(3) The amount of the fee payable by the			
<u>§ 493.649</u> . The amount of the fee	laboratory is the amount listed in the most			
applicable to the issuance of the	recent notice published in the Federal			
registration certificate or the	Register at the time the application,			
issuance or renewal of the	renewal, change in certificate type, or			
certificate for PPM procedures,	reinstatement is processed by HHS or its			
certificate of waiver, certificate of	designee.			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
accreditation, or certificate of compliance is 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 the required fee for the requested certificate.	<ul> <li>(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 designee notifies the laboratory of the applicable fee amount.</li> <li>(c) Classification of laboratories for purposes of determining the fee amount for certificate types other than certificates of waiver or certificates of PPM.</li> <li>(1) 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 control, quality assessment, 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 procedures or examinations; for example, a chemistry profile consisting of 18 tests is counted as 18 separate procedures or tests.</li> <li>(2) For purposes of determining a laboratory's classification under this section, the specialties and subspecialties of service for inclusion are:     <ul> <li>(i) The specialty of Microbiology, which</li> </ul> </li> </ul>			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
	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.			
	(v) The specialty of Immunohematology,			
	which includes one or more of the			
	following subspecialties:			
	(A) ABO grouping and Rh typing.			
	(B) Unexpected antibody detection.			
	(C) Compatibility testing.			
	(D) Unexpected antibody			
	identification.			
	(vi) The specialty of Pathology, which			
	includes the following subspecialties:			
	(A) Cytology.			
	(B) Histopathology.			
	(C) Oral pathology.			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
	(vii) The specialty of Radiobioassay.			
	(viii) The specialty of Histocompatibility.			
	(ix) The specialty of Clinical Cytogenetics.			
	(3) There are 11 schedules of laboratories			
	for the purpose of determining the fee			
	amount a laboratory is assessed. Each			
	laboratory is placed into one of the 11			
	schedules in paragraphs (c)(3)(i) through			
	(xi) of this section based on the			
	laboratory's scope and volume of testing:			
	(i) Schedule V. The laboratory performs			
	not more than 2,000 laboratory tests			
	annually.			
	(ii) Schedule A. The laboratory performs			
	tests in no more than three specialties of			
	service with a total annual volume of			
	more than 2,000 but not more than			
	10,000 laboratory tests.			
	(iii) Schedule B. The laboratory performs			
	tests in at least four specialties of service			
	with a total annual volume of not more			
	than 10,000 laboratory tests.			
	(iv) Schedule C. The laboratory performs			
	tests in no more three specialties of service with a total annual volume of			
	more than 10,000 but not more than			
	25,000 laboratory tests.			

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	(v) Schedule D. The laboratory performs			
	tests in at least four specialties with a			
	total annual volume of more than 10,000			
	but not more than 25,000 laboratory			
	tests.			
	(vi) Schedule E. The laboratory performs			
	more than 25,000 but not more than			
	50,000 laboratory tests annually.			
	(vii) Schedule F. The laboratory performs			
	more than 50,000 but not more than			
	75,000 laboratory tests annually.			
	(viii) Schedule G. The laboratory			
	performs more than 75,000 but not			
	more than 100,000 laboratory tests			
	annually.			
	(ix) Schedule H. The laboratory performs			
	more than 100,000 but not more than			
	500,000 laboratory tests annually.			
	(x) Schedule I. The laboratory performs			
	more than 500,000 but not more than			
	1,000,000 laboratory tests annually.			
	(xi) Schedule J. The laboratory performs			
	more than 1,000,000 laboratory tests			
	annually.			
CERTIFICATE FEES				
§ 493.639 Fee for revised	§ 493.639 Fees for revised and replacement	Updated the regulatory	N/A	
certificate.	certificates.	language/text for this		

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
(a) If, after a laboratory is issued	(a) If, after a laboratory is issued a certificate,	section.		
a registration certificate, it	it requests a revised certificate, the			
changes its name or location, the	laboratory must pay a fee to cover the cost of			
laboratory must pay a fee to	issuing a revised certificate. The fee for a			
cover the cost of issuing a revised	revised certificate is based on the cost to			
registration certificate. The fee	issue the revised certificate to the laboratory.			
for the revised registration	The fee must be paid in full before the			
certificate is based on the cost to	revised certificate will be issued.			
issue the revised certificate to				
the laboratory.	(1) If laboratory services are added to a			
	certificate of compliance, the laboratory			
(b) A laboratory must pay a fee to	must pay an additional fee if required			
cover the cost of issuing a revised	under § 493.643(d)(2).			
certificate in any of the following				
circumstances:	(2) [Reserved]			
(1) The fee for issuing an	(b) If, after a laboratory is issued a certificate,			
appropriate revised certificate is	it requests a replacement certificate, the			
based on the cost to issue the	laboratory must pay a fee to cover the cost of			
revised certificate to the	issuing a replacement certificate. The fee for			
laboratory as follows:	a replacement certificate is based on the cost			
	of issuing the replacement certificate to the			
(i) If a laboratory with a	laboratory. The fee must be paid in full before			
certificate of waiver wishes to	issuing the replacement certificate.			
perform tests in addition to those				
listed in <u>§ 493.15(c)</u> as waived				
tests, it must, as set forth in §				
493.638, pay an additional fee for				
the appropriate certificate to				
cover the additional testing.				
(ii) If a laboratory with a				
certificate for PPM procedures				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
wishes to perform tests in				
addition to those specified as				
PPM procedures or listed in §				
493.15(c) as waived tests, it				
must, as set forth in <u>§ 493.638</u> ,				
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 <u>§ 493.643(d)</u>				
if it is necessary to determine				
compliance with additional				
requirements.)				
§ 493.643 Fee for determination	§ 493.643 Additional fees applicable to	Updated the regulatory	N/A	
of program compliance.	laboratories issued a certificate of	language/text for this		
(a) Fee requirement. In addition	compliance.	section.		
to the fee required under §	(a) Fee requirement. In addition to the fee			
493.638, a laboratory subject to	required under § 493.638, a laboratory			
routine inspections must pay a	subject to routine inspections must pay a fee			
fee to cover the cost of	to cover the cost of determining program			
determining program	compliance. Laboratories issued a certificate			
compliance. Laboratories issued	for PPM procedures, certificate of waiver, or a			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
a certificate for PPM procedures,	certificate of accreditation are not subject to			
certificate of waiver, or a	this fee for routine inspections.			
certificate of accreditation are				
not subject to this fee for routine	(b) Costs included in the fee. Included in the			
inspections.	fee for determining program compliance are			
	costs for evaluating qualifications of			
(b) <b>Costs included in the fee</b> .	laboratory personnel; monitoring laboratory			
Included in the fee for	proficiency testing; and conducting onsite			
determining program compliance	inspections of laboratories including:			
is the cost of evaluating	documenting deficiencies, evaluating			
qualifications of personnel;	laboratories' plans to correct deficiencies,			
monitoring proficiency testing;	creating training programs, training			
conducting onsite inspections;	surveyors, and necessary administrative			
documenting deficiencies;	costs.			
evaluating laboratories' plans to				
correct deficiencies; and	(c) <i>Fee amount</i> . The amount of the fee for			
necessary administrative costs.	determining program compliance is set			
HHS sets the fee amounts	biennially by HHS.			
annually on a calendar year basis.				
Laboratories are inspected	(1) The fee is based on the category of test			
biennially; therefore, fees are	complexity and schedules or ranges of			
assessed and payable biennially.	annual laboratory test volume and			
If additional expenses are	specialties tested, with the amounts of the			
incurred to conduct follow up	fees in each schedule being a function of			
visits to verify correction of	the costs for all aspects of determining			
deficiencies, to impose sanctions,	program compliance as set forth in			
and/or for surveyor preparation	§ 493.638(c).			
for and attendance at ALJ				
hearings, HHS assesses an	(2) The fee is assessed and payable			
additional fee to include these	biennially.			
costs. The additional fee is based				
on the actual resources and time	(3) The amount of the program compliance			
necessary to perform the	fee is the amount applicable to the			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
activities.	laboratory listed in the most recent notice			
	published in the Federal Register at the			
(c) Classification of laboratories	time that the fee is generated.			
that require inspection for				
purpose of determining amount	(d) Additional fees.			
of fee.	(1) If a laboratory issued a certificate of			
	compliance has been inspected and follow-			
(1) There are ten classifications	up visits are necessary because of			
(schedules) of laboratories for	identified deficiencies, HHS assesses the			
the purpose of determining the	laboratory a fee to cover the cost of these			
fee amount a laboratory is	visits. The fee is based on the actual			
assessed. Each laboratory is	resources and time necessary to perform			
placed into one of the ten	the follow-up visits. HHS revokes the			
following schedules based on the	laboratory's certificate of compliance for			
laboratory's scope and volume of	failure to pay the assessed fee.			
testing (excluding tests				
performed for quality control,	(2) If, after a certificate of compliance is			
quality assurance, and	issued, a laboratory adds services and			
proficiency testing purposes).	requests that its certificate be upgraded,			
	the laboratory must pay an additional fee			
(i)	if, to determine compliance with additional			
	requirements, it is necessary to conduct an			
	inspection, evaluate personnel, or monitor			
(A) Schedule A Low Volume. The	proficiency testing performance. The			
laboratory performs not more	additional fee is based on the actual			
than 2,000 laboratory tests	resources and time necessary to perform			
annually.	the activities. HHS revokes the laboratory's			
	certificate for failure to pay the compliance			
(B) <b>Schedule A.</b> The laboratory	determination fee.			
performs tests in no more than 3				
specialties of service with a total	(3) If it is necessary to conduct a complaint			
annual volume of more than	investigation, impose sanctions, or			
2,000 but not more than 10,000	conduct a hearing, HHS assesses the			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
laboratory tests.	laboratory holding a certificate of			
	compliance a fee to cover the cost of these			
(ii) Schedule B. The laboratory	activities. If a complaint investigation			
performs tests in at least 4	results in a complaint being			
specialties of service with a total	unsubstantiated, or if an HHS adverse			
annual volume of not more than	action is overturned at the conclusion of			
10,000 laboratory tests.	the administrative appeals process, the			
	Government's costs of these activities are			
(iii) Schedule C. The laboratory	not imposed upon the laboratory. Costs for			
performs tests in no more 3	these activities are based on the actual			
specialties of service with a total	resources and time necessary to perform			
annual volume of more than	the activities and are not assessed until			
10,000 but not more than 25,000	after the laboratory concedes the			
laboratory tests.	existence of deficiencies or an ALJ rules in			
	favor of HHS. HHS revokes the laboratory's			
(iv) Schedule D. The laboratory	certificate of compliance for failure to pay			
performs tests in at least 4	the assessed costs.			
specialties with a total annual				
volume of more than 10,000 but	(4) Laboratories with a certificate of			
not more than 25,000 laboratory	compliance must pay a fee if the			
tests.	laboratory fails to perform successfully in			
	proficiency testing for one or more			
(v) Schedule E. The laboratory	specialties, subspecialties, analytes, or			
performs more than 25,000 but	tests specified in subpart I of this part, and			
not more than 50,000 laboratory	it is necessary to conduct a desk review of			
tests annually.	the unsuccessful performance. The			
	additional fee is based on the actual			
	resources and time necessary to perform			
	the desk review. HHS revokes the			
(vi) Schedule F. The laboratory	laboratory's certificate of compliance for			
performs more than 50,000 but	failure to pay the assessed costs.			
not more than 75,000 laboratory				
tests annually.				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
() Coho dulo C. This laboration.				
(vii) <i>Schedule G.</i> The laboratory performs more than 75,000 but				
not more than 100,000				
laboratory tests annually.				
(viii) <b>Schedule H.</b> 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 numbers of determining a				
(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 control, quality				
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 procedures				
or examinations; for example, a				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
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.				
(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.				
(v) The specialty of				
Immunohematology, which				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
includes one or more of the				
following subspecialties:				
(A) ABO grouping and Rh typing.				
(B) Unexpected antibody				
detection.				
(C) Compatibility testing.				
(D) Unexpected antibody				
identification.				
(vi) The specialty of Pathology,				
which includes the following				
subspecialties:				
(A) Cytology.				
(B) Histopathology.				
(C) Oral pathology.				
(vii) The specialty of				
Radiobioassay.				
(viii) The specialty of				
Histocompatibility.				
(ix) The specialty of Clinical				
Cytogenetics.				
(d) Additional fees.				
(1) 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, in order				
to determine compliance with				
additional requirements, it is				
necessary to conduct an				
inspection, evaluate personnel,				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
or monitor proficiency testing				
performance. The additional fee				
is based on the actual resources				
and time necessary to perform				
the activities. HHS revokes the				
laboratory's certificate for failure				
to pay the compliance				
determination fee.				
(2) 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 to cover the				
cost of these activities. If a				
complaint investigation results in				
a complaint being				
unsubstantiated, or if an HHS				
adverse action is overturned at				
the conclusion of the				
administrative appeals process,				
the government's costs of these				
activities are not imposed upon				
the 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 concedes the				
existence of deficiencies or an				
ALJ rules in favor of HHS. HHS				
revokes the laboratory's				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
certificate of compliance for				
failure to pay the assessed costs.				
§ 493.645 Additional fee(s)	§ 493.645 Additional fees applicable to	Amend § 493.645	N/A	
applicable to approved State	laboratories issued a certificate of	a. By revising the section		
laboratory programs and	accreditation, certificate of waiver, or	heading;		
laboratories issued a certificate	certificate for PPM procedures.	b. By removing		
of accreditation, certificate of		paragraph (a);		
waiver, or certificate for PPM	(a) Accredited laboratories.	c. By redesignating		
procedures.		paragraphs (b) and (c) as		
	(1) A laboratory that is issued a certificate	paragraphs (a) and (b);		
(a) Approved State laboratory	of accreditation is assessed an additional	d. By revising newly		
programs. State laboratory	fee to cover the cost of performing	redesignated paragraph		
programs approved by HHS are	validation inspections described at	(a); and		
assessed a fee for the following:	§ 493.563. All accredited laboratories	e. By adding a paragraph		
	share in the cost of these inspections.	heading for newly		
(1) Costs of Federal inspections	These costs are 5 percent of the same	redesignated paragraph		
of laboratories in that State (that	costs as those that are incurred when	(b).		
is, CLIA-exempt laboratories) to	inspecting nonaccredited laboratories of			
verify that standards are being	the same schedule (or range) and are paid			
enforced in an appropriate	biennially by each accredited laboratory			
manner.	whether the accredited laboratory has a			
	validation inspection or not. HHS revokes			
(2) Costs incurred for	the laboratory's certificate of accreditation			
investigations of complaints	for failure to pay the fee.			
against the State's CLIA-exempt				
laboratories if the complaint is	(2) If a laboratory issued a certificate of			
substantiated.	accreditation has been inspected and			
	follow-up visits are necessary because of			
(3) Costs of the State's prorata	identified deficiencies, HHS assesses the			
share of general overhead to	laboratory an additional fee to cover the			
develop and implement CLIA.	cost of these visits. The fee is based on the			
	actual resources and time necessary to			
(b) Accredited laboratories.	perform the follow-up visits. HHS revokes			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
	the laboratory's certificate of accreditation			
(1) In addition to the certificate	for failure to pay the fee.			
fee, a laboratory that is issued a				
certificate of accreditation is also	(b) Complaint surveys.			
assessed a fee to cover the cost				
of evaluating individual				
laboratories to determine overall				
whether an accreditation				
organization's standards and				
inspection policies are equivalent				
to the Federal program. All				
accredited laboratories share in				
the cost of these 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 laboratory a fee to				
cover 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 accreditation for				
failure to pay the assessed fee.				
(c) If, in the case of a laboratory				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
that has been issued a certificate				
of accreditation, certificate of				
waiver, or certificate for PPM				
procedures, it is necessary to				
conduct a complaint				
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 and time 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 laboratory's				
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 conclusion of				
the administrative appeals				
process, the costs of these				
activities are not imposed upon				
the laboratory.				
§ 493.646 Payment of fees.	§ 493.646 [Removed]	Section 493.646 is	N/A	
		removed.		
(a) Except for CLIA-exempt				
laboratories, all laboratories are				
notified in writing by HHS or its				
designee of the appropriate				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
fee(s) and instructions for				
submitting the fee(s), including				
the 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 mail of the				
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 be made. In				
addition, if complaint				
investigations are conducted in				
laboratories within these States				
and are substantiated, HHS bills				
the State(s) the costs of the				
complaint investigations.				
§ 493.649 Methodology for	§ 493.649 Additional fees applicable to	Updated the regulatory	N/A	
determining fee amount.	approved State laboratory programs.	language/text for this section.		
(a) General rule. The amount of	(a) Approved State laboratory programs.			
the fee in each schedule for	State laboratory programs approved by HHS			
compliance determination	are assessed a fee for the following:			
inspections is based on the				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
average hourly rate (which	(1) Costs of Federal inspections of			
includes the costs to perform the	laboratories in that State (that is, CLIA-			
required activities and necessary	exempt laboratories) to verify that			
administration costs) multiplied	standards are being enforced in an			
by the average number of hours	appropriate manner.			
required or, if activities are				
performed by more than one of	(2) Costs incurred for investigations of			
the entities listed in paragraph	complaints against the State's CLIA-exempt			
(b) of this section, the sum of the	laboratories if the complaint is			
products of the applicable hourly	substantiated.			
rates multiplied by the average				
number of hours required by the	(3) The State's pro rata share of general			
entity to perform the activity.	overhead to administer the laboratory			
The fee for issuance of the	certification program under section 353 of			
registration certificate or	the PHS Act.			
certificate of compliance is based				
on the laboratory's scope and	(b) [Reserved]			
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 determines the 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:				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
(i) The costs incurred by the State				
survey agencies in evaluating				
personnel qualifications and				
monitoring each laboratory's				
participation in an approved				
proficiency testing program. The				
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 encompasses salary				
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 staff.				
(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				
established based on historical				
State requirements.				
(iii) Indirect costs as negotiated				
by HHS.				
·				
(2) Federal agencies. The hourly				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
rate for activities performed by				
Federal agencies is the most				
recent average hourly cost to				
HHS to staff and support a full				
time equivalent employee.				
Included in this cost are salary				
and fringe benefit costs,				
necessary administrative costs,				
such as printing, training,				
postage, express mail, supplies,				
equipment, computer system				
and building service charges				
associated with support services				
provided by organizational				
components such as a computer				
center, and any other oversight				
activities necessary to support				
the 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 independent government 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 in an approved				
proficiency testing program,				
provide specialized assistance in				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
the evaluation of laboratory performance in an approved proficiency testing program, perform assessments of cytology testing laboratories, conduct special studies, bill and collect fees, issue certificates, establish accounting, monitoring and reporting systems, and assist with necessary surveyor training. (c) <b>Determining number of</b> <b>hours.</b> The average number of hours used to determine the overall fee in each schedule is HHS's estimate, based on historical experience, of the average time needed by each entity to perform the activities				
for which it is responsible.	<ul> <li>§ 493.655 Payment of fees.</li> <li>(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 instructions for submitting the fee(s), including the due date for payment and where to make payment. The appropriate certificate is not issued until the applicable fees have been paid.</li> <li>(b) For approved State laboratory programs,</li> </ul>	Added new section	N/A	

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
	HHS estimates the cost of conducting			
	validation inspections as described at			
	§ 493.563 within the State on at least a			
	biennial period. HHS or its designee notifies			
	the State by mail of the 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 be made. In addition, if			
	complaint investigations are conducted in			
	laboratories within these States and are			
	substantiated, HHS bills the State(s) the costs			
	of the complaint investigations.			
N/A	§ 493.680 Methodology for determining the	Added new section	N/A	
	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 based on a two-			
	part calculation of the Consumer Price Index-			
	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			
	amounts equal to the calculated rate.			
	(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 of			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
	<ul> <li>the previous 2 years' obligations, CMS applies an additional across the board increase to each laboratory's fees by calculating the difference between the total fee amounts and actual program obligations.</li> <li>(b) <i>Baseline</i>. Any increase applied under paragraph (a) of this section is incorporated into the baseline fee amounts for any subsequent biennial increase.</li> <li>(c) <i>Publication</i>. Any increase applied under paragraph (a) of this section, including the calculation thereof, will be published as a notice in the Federal Register.</li> </ul>			
HISTOCOMPATIBILITY				
<ul> <li>§ 493.1278 Standard:</li> <li>Histocompatibility.</li> <li>(a) General. The laboratory must meet the following requirements:</li> <li>(1) An audible alarm system must be used to monitor the storage temperature of specimens</li> <li>(donor and beneficiary) and reagents. The laboratory must have an emergency plan for alternate storage.</li> </ul>	<ul> <li>§ 493.1278 Standard: Histocompatibility.</li> <li>(a) General. The laboratory must meet the following requirements: <ul> <li>(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.</li> </ul> </li> </ul>	Changed "an audible alarms system" to "a continuous monitoring and alert system".	D5729	
(2) All patient specimens must be easily retrievable.	(2) Establish and follow written policies and procedures for the storage and retention of specimens based on the specific type of specimen. All specimens	Expanded the regulatory language to include that the laboratory must establish and follow	D5731	

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
	must be easily retrievable. The laboratory	written policies and		
	must have an emergency plan for alternate	procedures for the		
	storage.	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.		
(3) Reagent typing sera inventory	N/A	Deleted the labeling	D5733	
prepared in-house must indicate		requirement for in-house		
source, bleeding date and		prepared typing sera		
identification number, reagent		reagent.		
specificity, and volume				
remaining.				
(4) If the laboratory uses	(3) If the laboratory uses immunologic	Revised this requirement	D5735	
immunologic reagents (for	reagents to facilitate or enhance the	by removing the		
example, antibodies, antibody-	isolation or identification of lymphocytes	examples (that is,		
coated particles, or complement)	or lymphocyte subsets, the efficacy of the	antibodies, antibody-		
to facilitate or enhance the	methods must be monitored with	coated particles, or		
isolation of lymphocytes, or	appropriate quality control procedures.	complement) to clarify		
lymphocyte subsets, the efficacy		that these technologies,		
of the methods must be		as well as current and		
monitored with appropriate		future technologies, are		
quality control procedures.		allowed for the isolation		
		of lymphocytes or		
		lymphocyte subsets.		
		Clarified the requirement		
		by adding "identification"		
		of lymphocytes, or		
		lymphocyte subsets.		
		Redesignated		

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
		§ 493.1278(a)(4) as		
		revised to § 493.1278(a)		
(5) Participate in at least one	(4) Participate in at least one national or	(3). Redesignated	D5739	
national or regional cell exchange	regional cell exchange program, if	§ 493.1278(a)(5) as	03737	
program, if available, or develop	available, or develop an exchange system	§ 493.1278(a)(4). This		
an exchange system with another	with another laboratory in order to	requirement remains		
laboratory in order to validate	validate interlaboratory reproducibility.	unchanged.		
interlaboratory reproducibility.	valuate internationatory reproducibility.	unchanged.		
(b) <b>HLA typing.</b> The laboratory	(b) Human leukocyte antigen (HLA)	Deleted requirements at	D5739	
must do the following:	<i>typing</i> . The laboratory must do the following:	§ 493.1278(b)(1) through	03737	
(1) Use a technique(s) that is	(1) Use HLA antigen terminology from the	(3) pertaining to		
established to optimally define,	World Health Organization (WHO)	establishing HLA typing		
as applicable, HLA Class I and II	Nomenclature Committee for Factors of	procedures. The		
specificities.	the HLA System.	requirement that the		
(2) HLA type all potential	N/A	laboratory must establish	D5739	
transplant beneficiaries at a level		and have written		
appropriate to support clinical		procedures that ensure		
transplant protocol and donor		quality test results are		
selection.		already addressed by the		
(3) HLA type cells from organ	N/A	general requirements for	D5739	
donors referred to the		all test systems under		
laboratory.		current § 493.1445(e)(1)		
		and (e)(3)(i) and revision		
		at § 493.1278(f),		
		respectively, and		
		therefore, are duplicative.		
(4) Use HLA antigen terminology	N/A	Redesignated and revised	D5739	
that conforms to the latest report		language the provisions		
of the World Health Organization		at paragraph (b)(4) to		
(W.H.O.) Committee on		paragraph (b)(1). At		
Nomenclature. Potential new		newly redesignated		
antigens not yet approved by this		paragraph (b)(1), we		

<b>Current CLIA Regulation</b>	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
committee must have a		proposed deleting the		
designation that cannot be		language that states		
confused with W.H.O.		potential new antigens		
terminology.		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.		
(5) Have available and follow	N/A	At § 493.1278(b)(5)(i)	D5741	
written criteria for the following:		through (iv), deleted the		
(i) The preparation of cells or		requirements for		
cellular extracts (for example,		preparation of cells or		
solubilized antigens and nucleic		cellular extracts, selecting		
acids), as applicable to the HLA		typing reagents, ensuring		
typing technique(s) performed.		that reagents used for		
(ii) Selecting typing reagents,	N/A	typing are adequate, and	D5743	
whether prepared in-house or		assignment of HLA		
commercially.		antigens as they are		
(iii) Ensuring that reagents used	N/A	already addressed by the	D5745	
for typing are adequate to define		general requirements for		
all HLA-A, B and DR specificities		all test systems under		
that are officially recognized by		§§ 493.1445(e)(1) and (e)		
the most recent W.H.O.		(3)(i), 493.1251, and		
Committee on Nomenclature and		493.1252, and therefore,		
for which reagents are readily		are duplicative.		
available.				
(iv) The assignment of HLA	N/A		D5747	
antigens.				
(v) When antigen redefinition	(2) Have available and follow written	Updated reg. language.	D5749	

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
Current CLIA Regulation         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	New/Revised CLIA Regulation         criteria for determining when antigen and allele typing are required.         N/A	Notes 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.	D5751	CMS Comments
interpretation of results. (iii) Positive control materials for specific cell types when applicable (that is, T cells, B cells, and monocytes).				
(c) <i>Disease-associated studies.</i> The laboratory must check each typing for disease-associated HLA antigens using control materials	N/A	Deleted this requirement for control procedures and materials regarding disease related studies	D5753	

<b>Current CLIA Regulation</b>	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
to monitor the test components		because this is addressed		
and each phase of the test		by the general		
system to ensure acceptable		requirements for all test		
performance.		systems under		
		§§ 493.1256(d) and		
		493.1451(b)(4), and		
		therefore, is duplicative.		
(d) <b>Antibody Screening.</b> The	N/A	Changed the name of this	D5755	
laboratory must do the following:		section from "Antibody		
<ol><li>Use a technique(s) that</li></ol>		Screening" to "Antibody		
detects HLA-specific antibody		Screening and		
with a specificity equivalent or		Identification" for		
superior to that of the basic		clarification as both		
complement-dependent		processes apply to		
microlymphocytotoxicity assay.		histocompatibility testing.		
(2) Use a method that		The provisions covered		
distinguishes antibodies to HLA		under this section apply		
Class II antigens from antibodies		to both screening and		
to Class I antigens to detect		identification. Moved		
antibodies to HLA Class II		§ 493.1278(d) as revised		
antigens.		to § 493.1278(c).		
(3) Use a panel that contains all				
the major HLA specificities and		At § 493.1278(d)(1)		
common splits. If the laboratory		through (3) and (5)		
does not use commercial panels,		through (7), deleted these		
it must maintain a list of		requirements for		
individuals for fresh panel		antibody screening		
bleeding.		laboratory procedures as		
(4) Make a reasonable attempt to	(c) Antibody screening and identification.	they are addressed by the	D5757	
have available monthly serum	The laboratory must make a reasonable effort	general requirements for		
specimens for all potential	to have available monthly serum specimens	all test systems under		
transplant beneficiaries for	for all potential transplant recipients for	§§ 493.1445(e)(1) and (e)		
periodic antibody screening and	periodic antibody screening, identification,	(3)(i), 493.1251,		

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
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.	and crossmatch.	493.1252, and 493.1256, and therefore, are duplicative.		
<ul> <li>(6) Check each antibody screening by testing, at a minimum the following:</li> <li>(i) A positive control material containing antibodies of the appropriate isotype for the assay.</li> <li>(ii) A negative control material.</li> </ul>	N/A		D5759	
(7) As applicable, have available and follow written criteria and procedures for antibody identification to the level appropriate to support clinical transplant protocol.	N/A		D5761	
<ul> <li>(e) <i>Crossmatching.</i> The laboratory must do the following:</li> <li>(1) Use a technique(s) documented to have increased sensitivity in comparison with the basic complement-dependent microlymphocytotoxicity assay.</li> </ul>	<ul> <li>(d) <i>Crossmatching</i>. For each type of crossmatch that a laboratory performs, the laboratory must do the following, as applicable:</li> <li>(1) Establish and follow written policies and procedures for performing a crossmatch.</li> </ul>	At § 493.1278(e)(1) through (3), removed/deleted these three requirements regarding the laboratory having crossmatch procedures and controls as we believe the	D5763	
<ul> <li>(2) Have available and follow</li> <li>written criteria for the following:</li> <li>(i) Selecting appropriate patient</li> <li>serum samples for</li> </ul>	<ul> <li>(2) Have available and follow written</li> <li>criteria for the following:</li> <li>(i) Defining donor and recipient HLA</li> <li>antigens, alleles, and antibodies to be</li> </ul>	provisions to be removed are addressed by the general requirements for all test systems under	D5765	

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
crossmatching.	tested;	§§ 493.1445(e)(1),		
(ii) The preparation of donor cells	(ii) Defining the criteria necessary to	493.1251, 493.1256, and		
or cellular extracts (for example,	assess a recipient's alloantibody status;	493.1451(b)(4), and		
solubilized antigens and nucleic	(iii) Assessing recipient antibody	therefore, are duplicative.		
acids), as applicable to the	presence or absence on an ongoing			
crossmatch technique(s)	basis;	Added the requirements		
performed.	(iv) Typing the donor, to include those	summarized below, at		
	HLA antigens to which antibodies have	§ 493.1278(d), to increase		
	been identified in the potential recipient,	flexibility in the		
	as applicable;	regulations and remove		
	(v) Describing the circumstances in	perceived barriers. These		
	which pre- and post-transplant	requirements include:		
	confirmation testing of donor and	<ul> <li>Defining donor and</li> </ul>		
	recipient specimens is required;	recipient HLA antigens,		
	(vi) Making available all applicable donor	alleles, and antibodies to		
	and recipient test results to the	be tested;		
	transplant team;	• Defining the criteria		
	(vii) Ensuring immunologic assessments	necessary to assess a		
	are based on test results obtained from	recipient's alloantibody		
	a test report from a CLIA-certified	status;		
	laboratory; and	<ul> <li>Assessing recipient</li> </ul>		
	(viii) Defining time limits between	antibody presence or		
	recipient testing and the performance of	absence on an ongoing		
	a crossmatch.	basis;		
(3) Check each crossmatch and	(3) The test report must specify the type of	• Typing the donor at the	D5767	
compatibility test for HLA Class II	crossmatch performed.	serological level, to		
antigenic differences using		include those HLA		
control materials to monitor the		antigens to which		
test components and each phase		antibodies have been		
of the test system to ensure		identified in the potential		
acceptable performance.		recipient, as applicable;		
-		• Describing the		
		circumstances in which a		

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
		pre- and post-transplant		
		confirmation testing of		
		donor and recipient		
		specimens is required;		
		<ul> <li>Making available all</li> </ul>		
		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.		
(f) Transplantation. Laboratories	(e) Transplantation. Laboratories performing	Changed the words	D5769	
performing histocompatibility	histocompatibility testing for infusion and	"transfusion" and		
testing for transfusion and	transplantation purposes must establish and	"transfused" to "infusion"		
transplantation purposes must	follow written policies and procedures	and "infused",		
do the following:	specifying the histocompatibility testing (that	respectively.		
(1) Have available and follow	is, HLA typing, antibody screening and	Moved § 493.1278(f) as		
written policies and protocols	identification, and crossmatching) to be	revised to § 493.1278(e).		
specifying the histocompatibility	performed for each type of cell, tissue, or			
testing (that is, HLA typing,	organ to be infused or transplanted. The	At § 493.1278(f)(1),		
antibody screening, compatibility	laboratory's policies and procedures must	revised this requirement		
testing and crossmatching) to be	include, as applicable—	to state that laboratories		

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
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	<ul> <li>(1) Testing protocols that address:</li> <li>(i) Transplant type (organ, tissue, cell);</li> <li>(ii) Donor (living, deceased, or paired):</li> <li>and</li> <li>(iii) Recipient (high risk vs. unsensitized);</li> <li>(2) Type and frequency of testing required</li> </ul>	performing histocompatibility testing must establish and have written policies and procedures specifying the types of histocompatibility testing. Moved this language to	Current D-tag	
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).	to support clinical transplant protocols; and	§ 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		

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
		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		

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
		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).		
N/A	(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.	Added a new requirement for pre- transplant recipient specimens under § 493.1278(e)(3).	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.	N/A	At § 493.1278(f)(2) through (3), removed/deleted these requirements for renal and nonrenal transplantation crossmatch procedures.	D5771	
(3) For nonrenal transplantation, if HLA testing and final crossmatches were not performed prospectively because of an emergency situation, the	N/A		D5773	

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
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.			D5770	
(g) <b>Documentation.</b> The laboratory must document all control procedures performed, as specified in this section.	(f) <b>Documentation</b> . The laboratory must document all control procedures performed, as specified in this section.	The requirement at § 493.1278(g) is redesignated as § 493.1278(f). This requirement remains unchanged.	D5773	
PERSONNEL				
<ul> <li>§ 493.1359 Standard; PPM</li> <li>laboratory director</li> <li>responsibilities.</li> <li>(b)(2) Is performed in accordance</li> <li>with applicable requirements in</li> <li>subparts H, J, K, and M of this</li> <li>part.</li> </ul>	<ul> <li>§ 493.1359 Standard; PPM laboratory director responsibilities.</li> <li>(b)(2) Is performed in accordance with applicable requirements in this subpart and subparts H, J, and K of this part;</li> </ul>	Revised; slight edit made at (b)(2) by removing reference to subpart M.	D5987	
N/A	<ul> <li>(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— <ul> <li>(1) Direct observations of routine patient test performance, including, if applicable, specimen handling, processing, and</li> </ul></li></ul>	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.	N/A	

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
	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;			
N/A	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.	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.		
§ 493.1405 Standard; Laboratory	§ 493.1405 Standard; Laboratory director	Revised this section;	D6003	
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 posses	<ul> <li>qualifications.</li> <li>(b) The laboratory director must— <ul> <li>(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</li> <li>(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or</li> <li>(2)(i) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric</li> </ul> </li> </ul>	allowed alternative educational pathway for nontraditional degrees.		
	(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine,			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
to those required for such	osteopathy, or podiatry in the State in			
certification; or	which the laboratory is located; and			
(2)				
(i) Be a doctor of medicine,	(ii) Have had laboratory training or			
doctor of osteopathy, or doctor	experience consisting of:			
of podiatric medicine licensed to	(A) At least 1 year directing or			
practice medicine, osteopathy, or	supervising nonwaived laboratory			
podiatry in the State in which the	testing; and			
laboratory is located; and	(B) Have at least 20 CE credit hours in			
(ii) Have had laboratory training	laboratory practice that cover the			
or experience consisting of:	laboratory director responsibilities			
(A) At least one year directing or	defined in § 493.1407; or			
supervising non-waived				
laboratory testing; or	(3)(i)(A) Hold an earned doctoral degree in			
(B) Beginning September 1, 1993,	a chemical, biological, clinical or medical			
have at least 20 continuing	laboratory science or medical technology			
medical education credit hours in	from an accredited institution; or			
laboratory practice				
commensurate with the director	(B) Hold an earned doctoral degree;			
responsibilities defined in §	and			
<u>493.1407;</u> or	(1) Have at least 16 semester			
(C) Laboratory training equivalent	hours of doctoral level			
to <u>paragraph (b)(2)(ii)(B)</u> of this	coursework in biology,			
section obtained during medical	chemistry, medical technology			
residency. (For example,	(MT), clinical laboratory science			
physicians certified either in	(CLS), or medical laboratory			
hematology or hematology and	science (MLS); or			
medical oncology by the	(2) An approved thesis or			
American Board of Internal	research project in			
Medicine); or	biology/chemistry/MT/CLS/MLS			
(3) Hold an earned doctoral	related to laboratory testing for			
degree in a chemical, physical,	the diagnosis, prevention, or			
biological, or clinical laboratory	treatment of any disease or			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
science from an accredited	impairment of, or the			
institution; and	assessment of the health of,			
(i) Be certified by the American	human beings; and			
Board of Medical Microbiology,				
the American Board of Clinical	(ii) Have at least 20 CE credit hours in			
Chemistry, the American Board	laboratory practice that cover the			
of Bioanalysis, or the American	laboratory director responsibilities			
Board of Medical Laboratory	defined in § 493.1407; and			
Immunology; or	(A) Be certified and continue to be			
(ii) Have had at least one year	certified by a board approved by HHS;			
experience directing or	and			
supervising non-waived				
laboratory testing;	(B) Have had at least 1 year of			
(4)	experience directing or supervising			
(i) Have earned a master's degree	nonwaived laboratory testing; or			
in a chemical, physical, biological				
or clinical laboratory science or				
medical technology from an	(4)(i)(A) Have earned a master's degree in			
accredited institution;	a chemical, biological, clinical or medical			
(ii) Have at least one year of	laboratory science or medical technology			
laboratory training or experience,	from an accredited institution; or			
or both in non-waived testing;				
and	(B)(1) Meet bachelor's degree			
(iii) In addition, have at least one	equivalency; and			
year of supervisory laboratory				
experience in non-waived	(2) Have at least 16 semester			
testing; or	hours of additional graduate level			
(5)	coursework in biology, chemistry,			
(i) Have earned a bachelor's	medical technology, clinical or			
degree in a chemical, physical, or	medical laboratory science; or			
biological science or medical				
technology from an accredited	(C)(1) Meet bachelor's degree			
institution;	equivalency; and			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
(ii) Have at least 2 years of				
laboratory training or experience,	(2) Have at least 16 semester			
or both in non-waived testing;	hours in a combination of			
and	graduate level coursework in			
(iii) In addition, have at least 2	biology, chemistry, medical			
years of supervisory laboratory	technology, clinical or medical			
experience in non-waived	laboratory science coursework			
testing;	and an approved thesis or			
(6) Be serving as a laboratory	research project related to			
director and must have	laboratory testing for the			
previously qualified or could have	diagnosis, prevention, or			
qualified as a laboratory director	treatment of any disease or			
under <u>§ 493.1406;</u> or	impairment of, or the assessment			
(7) On or before February 28,	of the health of, human beings;			
1992, qualified under State law	and			
to direct a laboratory in the State				
in which the laboratory is	(ii) Have at least 1 year of laboratory			
located.	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			
	§ 493.1407; or			
	/			
	(5)(i)(A) Have earned a bachelor's degree			
	in a chemical, biological, clinical or medical			
	laboratory science or medical technology			
	from an accredited institution; or			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
	(B) At least 120 semester hours, or			
	equivalent, from an accredited			
	institution that, at a minimum,			
	includes either—			
	(1) 48 semester hours of medical			
	laboratory science or medical			
	laboratory technology courses; or			
	(2) 48 semester hours of science			
	courses that include—			
	(i) 12 semester hours of			
	chemistry, which must include			
	general chemistry and			
	biochemistry or organic			
	chemistry;			
	(ii) 12 semester hours of			
	biology, which must include			
	general biology and molecular			
	biology, cell biology or			
	genetics; and			
	(iii) 24 semester hours of			
	chemistry, biology, or medical			
	laboratory science or medical			
	laboratory technology in any			
	combination; and			
	(ii) Have at least 2 years of laboratory			
	training or experience, or both, in			
	nonwaived testing; and			
	(iii) Have at least 2 years of supervisory			
	laboratory experience in nonwaived			
	testing; and			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
	<ul> <li>(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1407.</li> <li>(6) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of moderate complexity testing under this section if they were qualified and serving as a laboratory director of moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024 and have done so continuously since December 28, 2024.</li> </ul>			
<ul> <li>§ 493.1406 Standard; Laboratory director qualifications on or before February 28, 1992.</li> <li>The laboratory director must be qualified to manage and direct the laboratory personnel and test performance.</li> <li>(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:</li> <li>(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American</li> </ul>	N/A	Section 493.1406 is removed/deleted.	D6003	

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
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				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
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:				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
(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 science as a major				
subject and subsequent to				
graduation had at least 6 years of				
pertinent full-time laboratory				
experience; or				
(iv) Achieved a satisfactory grade				
through an examination				
conducted by or under the				
sponsorship of the U.S. Public				
Health Service on or before July				
1, 1970; or				
(6) Qualify under State law to				
direct the laboratory in the State				
in which the laboratory is				
located.				
Note:				
The January 1, 1968 date for				
meeting the 12 months'				
laboratory direction requirement				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
in <u>paragraph (b)(5)</u> of this section				
may be extended 1 year for each				
year of full-time laboratory				
experience obtained before				
January 1, 1958 required by State				
law for a laboratory director				
license. An exception to the July				
1, 1971 qualifying date in				
paragraph (b)(5) of this section				
was made provided that the				
individual requested qualification				
approval by October 21, 1975				
and had been employed in a laboratory for at least 3 years of				
the 5 years preceding the date of				
submission of his qualifications.				
submission of his qualifications.				
§ 493.1407 Standard; Laboratory	§ 493.1407 Standard; Laboratory director	At § 493.1407(c), revised	D6005	
director responsibilities.	responsibilities.	the requirements so that		
(c) The laboratory director must	(c) The laboratory director must:	the LD must be on-site at		
be accessible to the laboratory to	(1) Be onsite at least once every 6 months,	the laboratory at least		
provide onsite, telephone or	with at least 4 months between the	once every 6 months,		
electronic consultation as	minimum two on-site visits. Laboratory	with at least a 4-month		
needed.	directors may elect to be on-site more	interval between the two		
	frequently and must continue to be	on-site visits. However,		
	accessible to the laboratory to provide	LDs may elect to be on-		
	telephone or electronic consultation as	site more frequently. The		
	needed; and	laboratory must provide		
		documentation of these		
	(2) Provide documentation of these visits,	visits, including evidence		
	including evidence of performing activities	of performing activities		
	that are part of the laboratory director	that are part of the LD		
	responsibilities.	responsibilities.		

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
§ 493.1411 Standard; Technical	§ 493.1411 Standard; Technical consultant	Revised this section;	D6035	
consultant qualifications.	qualifications.	allowed alternative		
(b) The technical consultant must	(b) The technical consultant must—	educational pathway for		
—	(1)(i) Be a doctor of medicine or doctor of	nontraditional degrees.		
(1)	osteopathy licensed to practice medicine			
(i) Be a doctor of medicine or	or osteopathy in the State in which the			
doctor of osteopathy licensed to	laboratory is located; and			
practice medicine or osteopathy				
in the State in which the	(ii) Be certified in anatomic or clinical			
laboratory is located; and	pathology, or both, by the American			
(ii) Be certified in anatomic or	Board of Pathology or the American			
clinical pathology, or both, by the	Osteopathic Board of Pathology; or			
American Board of Pathology or				
the American Osteopathic Board	(2)(i) Be a doctor of medicine, doctor of			
of Pathology or possess	osteopathy, or doctor of podiatric			
qualifications that are equivalent	medicine licensed to practice medicine,			
to those required for such	osteopathy, or podiatry in the State in			
certification; or	which the laboratory is located; and			
(2)				
(i) Be a doctor of medicine,	(ii) Have at least 1 year of laboratory			
doctor of osteopathy, or doctor	training or experience, or both, in			
of podiatric medicine licensed to	nonwaived testing, in the designated			
practice medicine, osteopathy, or	specialty or subspecialty areas of service			
podiatry in the State in which the	for which the technical consultant is			
laboratory is located; and	responsible (for example, physicians			
(ii) Have at least one year of	certified either in hematology or			
laboratory training or experience,	hematology and medical oncology by the			
or both in non-waived testing, in	American Board of Internal Medicine are			
the designated specialty or	qualified to serve as the technical			
subspecialty areas of service for	consultant in hematology); or			
which the technical consultant is				
responsible (for example,	(3)(i)(A) Hold an earned doctoral or			
physicians certified either in	master's degree in a chemical, biological,			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
hematology or hematology and	clinical or medical laboratory science, or			
medical oncology by the	medical technology from an accredited			
American Board of Internal	institution; or			
Medicine are qualified to serve				
as the technical consultant in	(B) Meet either requirements in			
hematology); or	§ 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or			
(3)	(b)(4)(i)(C); and			
(i) Hold an earned doctoral or				
master's degree in a chemical,	(ii) Have at least 1 year of laboratory			
physical, biological or clinical	training or experience, or both, in			
laboratory science or medical	nonwaived testing, in the designated			
technology from an accredited	specialty or subspecialty areas of service			
institution; and	for which the technical consultant is			
(ii) Have at least one year of	responsible; or			
laboratory training or experience,				
or both in non-waived testing, in	(4)(i)(A) Have earned a bachelor's degree			
the designated specialty or	in a chemical, biological, clinical or medical			
subspecialty areas of service for	laboratory science, or medical technology			
which the technical consultant is	from an accredited institution; or			
responsible; or				
(4)	(B) Meet § 493.1405(b)(5)(i)(B); and			
(i) Have earned a bachelor's				
degree in a chemical, physical or	(ii) Have at least 2 years of laboratory			
biological science or medical	training or experience, or both, in			
technology from an accredited	nonwaived testing, in the designated			
institution; and	specialty or subspecialty areas of			
(ii) Have at least 2 years of	service for which the technical			
laboratory training or experience,	consultant is responsible; or			
or both in non-waived testing, in				
the designated specialty or	(5)(i) Have earned an associate degree in			
subspecialty areas of service for	medical laboratory technology, medical			
which the technical consultant is	laboratory science, or clinical laboratory			
responsible.	science; and			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
Note:				
The technical consultant	(ii) Have at least 4 years of laboratory			
requirements for "laboratory	training or experience, or both, in			
training or experience, or both"	nonwaived testing, in the designated			
in each specialty or subspecialty	specialty or subspecialty areas of			
may be acquired concurrently in	service for which the technical			
more than one of the specialties	consultant is responsible.			
or subspecialties of service,				
excluding waived tests. For	(6) For blood gas analysis, the individual			
example, an individual who has a	must—			
bachelor's degree in biology and	(i) Be qualified under paragraph (b)(1),			
additionally has documentation	(2), (3), (4) of this section; or			
of 2 years of work experience				
performing tests of moderate	(ii)(A) Have earned a bachelor's degree			
complexity in all specialties and	in respiratory therapy or cardiovascular			
subspecialties of service, would	technology from an accredited			
be qualified as a technical	institution; and			
consultant in a laboratory				
performing moderate complexity	(B) Have at least 2 years of			
testing in all specialties and	laboratory training or experience, or			
subspecialties of service.	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			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
	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.			
<ul> <li>§ 493.1417 Standard; Clinical consultant qualifications.</li> <li>(a) Be qualified as a laboratory director under § 493.1405(b) (1), (2), or (3)(i); or</li> </ul>	<ul> <li>§ 493.1417 Standard; Clinical consultant qualifications.</li> <li>(a) Be qualified as a laboratory director under § 493.1405(b) (1), (2), or (3); or</li> </ul>	Updated cross-reference from (3)(i) to (3).	D6057	
<ul> <li>§ 493.1423 Standard; Testing personnel qualifications.</li> <li>(b) Meet one of the following requirements:</li> <li>(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</li> </ul>	<ul> <li>§ 493.1423 Standard; Testing personnel qualifications.</li> <li>(b) Meet one of the following requirements: <ul> <li>(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</li> <li>(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</li> </ul> </li> </ul>	Revised this section; allowed alternative educational pathway for nontraditional degrees. New; added qualifications for testing personnel performing blood gas analysis.	D6065	

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
laboratory science, or medical technology from an accredited	accredited institution; or			
institution; or	(3) Meet the requirements in			
(2) Have earned an associate	§ 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)			
degree in a chemical, physical or	(C) or (b)(5)(i)(B); or			
biological science or medical				
laboratory technology from an	(4) Have earned an associate degree in a			
accredited institution; or	chemical, biological, clinical or medical			
(3) Be a high school graduate or	laboratory science, or medical laboratory			
equivalent and have successfully	technology or nursing from an accredited			
completed an official military	institution; or			
medical laboratory procedures				
course of at least 50 weeks	(5) Be a high school graduate or equivalent			
duration and have held the	and have successfully completed an official			
military enlisted occupational specialty of Medical Laboratory	military medical laboratory procedures course of at least a duration of 50 weeks			
Specialist (Laboratory	and have held the military enlisted			
Technician); or	occupational specialty of Medical			
(4)	Laboratory Specialist (Laboratory			
(i) Have earned a high school	Technician); or			
diploma or equivalent; and				
	(6)(i) Have earned a high school diploma or			
	equivalent; and			
(ii) Have documentation of	(6)(ii) Have documentation of laboratory	Revised this section;	D6066	
training appropriate for the	training appropriate for the testing	allowed alternative		
testing performed prior to	performed prior to analyzing patient	educational pathway for		
analyzing patient specimens.	specimens. Such training must ensure that	nontraditional degrees.		
	the individual has—			
Such training must ensure that	(6)(ii)	Revised this section;	D6067	
the individual has—	(A) The skills required for proper	allowed alternative		
(b)(4)(ii)(A) The skills required for	specimen collection, including patient	educational pathway for		
proper specimen collection,	preparation, if applicable, labeling,	nontraditional degrees.		

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
including patient preparation, if	handling, preservation or fixation,			
applicable, labeling, handling,	processing or preparation,			
preservation or fixation,	transportation, and storage of			
processing or preparation,	specimens;			
transportation and storage of	(B) The skills required for			
specimens;	implementing all standard laboratory			
(b)(4)(ii)( (B) The skills required	procedures;			
for implementing all standard	(C) The skills required for performing			
laboratory procedures;	each test method and for proper			
(b)(4)(ii)( (C) The skills required	instrument use;			
for performing each test method	(D) The skills required for performing			
and for proper instrument use;	preventive maintenance,			
(b)(4)(ii)( (D) The skills required	troubleshooting, and calibration			
for performing preventive	procedures related to each test			
maintenance, troubleshooting	performed;			
and calibration procedures	(E) A working knowledge of reagent			
related to each test performed;	stability and storage;			
(b)(4)(ii)( (E) A working	(F) The skills required to implement			
knowledge of reagent stability	the quality control policies and			
and storage;	procedures of the laboratory;			
(b)(4)(ii)( (F) The skills required to	(G) An awareness of the factors that			
implement the quality control	influence test results; and			
policies and procedures of the	(H) The skills required to assess and			
laboratory;	verify the validity of patient test			
(b)(4)(ii)( (G) An awareness of the	results through the evaluation of			
factors that influence test results;	quality control sample values prior to			
and	reporting patient test results.			
(b)(4)(ii)( (H) The skills required				
to assess and verify the validity				
of patient test results through				
the evaluation of quality control				
sample values prior to reporting				
patient test results.				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
	<ul> <li>(7) For blood gas analysis, the individual must— <ul> <li>(i) Be qualified under paragraph (b)(1),</li> <li>(2), (3), (4), (5) or (6) of this section; or</li> </ul> </li> <li>(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and <ul> <li>(B) Have at least 1 year of laboratory training or experience, or both, in blood gas analysis; or</li> <li>(iii)(A) Have earned an associate degree related to pulmonary function from an accredited institution; and</li> <li>(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis.</li> </ul> </li> </ul>	New.	N/A	
N/A	(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.	New.	N/A	
§ 493.1443 Standard; Laboratory	§ 493.1443 Standard; Laboratory director	Revised this section;	D6078	

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
director qualifications.	qualifications.	allowed alternative		
(b) The laboratory director must	(b) The laboratory director must—	educational pathway for		
—	(1)(i) Be a doctor of medicine or doctor of	nontraditional degrees.		
(1)	osteopathy licensed to practice medicine			
(i) Be a doctor of medicine or	or osteopathy in the State in which the			
doctor of osteopathy licensed to	laboratory is located; and			
practice medicine or osteopathy				
in the State in which the				
laboratory is located; and	(ii) Be certified in anatomic or clinical			
(ii) Be certified in anatomic or	pathology, or both, by the American			
clinical pathology, or both, by the	Board of Pathology or the American			
American Board of Pathology or	Osteopathic Board of Pathology; or			
the American Osteopathic Board				
of Pathology or possess	(2)(i) Be a doctor of medicine, a doctor of			
qualifications that are equivalent	osteopathy, or doctor of podiatric			
to those required for such	medicine licensed to practice medicine,			
certification; or	osteopathy, or podiatry in the State in			
(2) Be a doctor of medicine, a	which the laboratory is located; and			
doctor of osteopathy or doctor of				
podiatric medicine licensed to	(ii) Have at least 2 years of experience			
practice medicine, osteopathy or	directing or supervising high complexity			
podiatry in the State in which the	testing; and			
laboratory is located; and				
(i) Have at least one year of	(iii) Have at least 20 CE credit hours in			
laboratory training during	laboratory practice that cover the			
medical residency (for example,	director responsibilities defined in			
physicians certified either in	§ 493.1445; or			
hematology or hematology and				
medical oncology by the	(3)(i)(A) Hold an earned doctoral degree in			
American Board of Internal	a chemical, biological, clinical or medical			
Medicine); or	laboratory science or medical technology			
(ii) Have at least 2 years of	from an accredited institution; or			
experience directing or	(B) Hold an earned doctoral degree;			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
supervising high complexity	and			
testing; or	(1) Have at least 16 semester			
(3) Hold an earned doctoral	hours of doctoral level coursework			
degree in a chemical, physical,	in biology, chemistry, medical			
biological, or clinical laboratory	technology (MT), clinical			
science from an accredited	laboratory science (CLS), or			
institution and—	medical laboratory science (MLS);			
(i) Be certified and continue to be	or			
certified by a board approved by				
HHS; or	(2) An approved thesis or research			
(ii)Before February 24, 2003,	project in			
must have served or be serving	biology/chemistry/MT/CLS/MLS			
as a director of a laboratory	related to laboratory testing for			
performing high complexity	the diagnosis, prevention, or			
testing and must have at least—	treatment of any disease or			
(A) Two years of laboratory	impairment of, or the assessment			
training or experience, or both;	of the health of, human beings;			
and	and			
(B) Two years of laboratory				
experience directing or	(ii) Be certified and continue to be			
supervising high complexity	certified by a board approved by HHS;			
testing.	and			
(4) Be serving as a laboratory				
director and must have	(iii) Have at least 2 years of:			
previously qualified or could have	(A) Laboratory training or			
qualified as a laboratory director	experience, or both: and			
under regulations at <u>42 CFR</u>				
493.1415, published March 14,	(B) Laboratory experience directing			
1990 at <u>55 FR 9538</u> , on or before	or supervising high complexity			
February 28, 1992; or	testing; and			
(5) On or before February 28,				
1992, be qualified under State	(iv) Have at least 20 CE credit hours in			
law to direct a laboratory in the	laboratory practice that cover the			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
State in which the laboratory is	director responsibilities defined in			
located; or	§ 493.1445; or			
(6) For the subspecialty of oral				
pathology, be certified by the	(4) Notwithstanding any other provision of			
American Board of Oral	this section, an individual is considered			
Pathology, American Board of	qualified as a laboratory director of high			
Pathology, the American	complexity testing under this section if			
Osteopathic Board of Pathology,	they were qualified and serving as a			
or possess qualifications that are	laboratory director of high complexity			
equivalent to those required for	testing in a CLIA-certified laboratory as of			
certification.	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	§ 493.1445 Standard; Laboratory director	At §§ 493.1445(c), revised	D6080	
director responsibilities.	responsibilities.	the requirements so that		
(c)The laboratory director must	(c) The laboratory director must:	the LD must be on-site at		
be accessible to the laboratory to	(1) Be onsite at least once every 6 months,	the laboratory at least		
provide onsite, telephone or	with at least 4 months between the	once every 6 months,		
electronic consultation as	minimum two on-site visits. Laboratory	with at least a 4-month		
needed.	directors may elect to be on-site more	interval between the two		
	frequently and must continue to be	on-site visits. However,		
(e) The laboratory director	accessible to the laboratory to provide	LDs may elect to be on-		
must-	telephone or electronic consultation as	site more frequently. The		
(10) Ensure that a general	needed; and	laboratory must provide		
supervisor provides on-site		documentation of these		
supervision of high complexity	(2) Provide documentation of these visits,	visits, including evidence		
test performance by testing	including evidence of performing activities	of performing activities		

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
personnel qualified under § 493.1489(b)( <mark>4);</mark>	that are part of the laboratory director responsibilities.	that are part of the LD responsibilities.		
	<ul> <li>(e) The laboratory director must-</li> <li>(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under § 493.1489(b)(5);</li> </ul>	Updated cross-reference from (b)(4) to (b)(5).		
§ 493.1449 Standard; Technical	§ 493.1449 Standard; Technical supervisor	Revised this section;	D6111	
supervisor qualifications.	qualifications.	allowed alternative		
(b) The laboratory may perform	The laboratory must employ one or more	educational pathway for		
anatomic and clinical laboratory	individuals who are qualified by education	nontraditional degrees.		
procedures and tests in all	and either training or experience to provide			
specialties and subspecialties of services except histocompatibility	technical supervision for each of the specialties and subspecialties of service in			
and clinical cytogenetics services	which the laboratory performs high			
provided the individual	complexity tests or procedures. The director			
functioning as the technical	of a laboratory performing high complexity			
supervisor—	testing may function as the technical			
(1) Is a doctor of medicine or	supervisor provided he or she meets the			
doctor of osteopathy licensed to	qualifications specified in this section.			
practice medicine or osteopathy				
in the State in which the	(a) The technical supervisor must possess a			
laboratory is located; and	current license issued by the State in which			
(2) Is certified in both anatomic	the laboratory is located, if such licensing is			
and clinical pathology by the	required; and			
American Board of Pathology or				
the American Osteopathic Board	(b) The laboratory may perform anatomic and			
of Pathology or Possesses	clinical laboratory procedures and tests in all			
qualifications that are equivalent	specialties and subspecialties of services			
to those required for such	except histocompatibility and clinical			
certification.	cytogenetics services provided the individual			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
(c) If the requirements of	functioning as the technical supervisor—			
paragraph (b) of this section are	(1) Is a doctor of medicine or doctor of			
not met and the laboratory	osteopathy licensed to practice medicine			
performs tests in the	or osteopathy in the State in which the			
subspecialty of bacteriology, the	laboratory is located; and			
individual functioning as the				
technical supervisor must—	(2) Is certified in both anatomic and clinical			
(1)	pathology by the American Board of			
(i) Be a doctor of medicine or	Pathology or the American Osteopathic			
doctor of osteopathy licensed to	Board of Pathology.			
practice medicine or osteopathy				
in the State in which the	(c) Bacteriology, Mycobacteriology, Mycology,			
laboratory is located; and	Parasitology or Virology- If the requirements			
(ii) Be certified in clinical	of paragraph (b) of this section are not met			
pathology by the American Board	and the laboratory performs tests in the			
of Pathology or the American	subspecialty of bacteriology,			
Osteopathic Board of Pathology	mycobacteriology, mycology, parasitology, or			
or possess qualifications that are	virology, the individual functioning as the			
equivalent to those required for	technical supervisor must—			
such certification; or	(1)(i) Be a doctor of medicine or doctor of			
(2)	osteopathy licensed to practice medicine			
(i) Be a doctor of medicine,	or osteopathy in the State in which the			
doctor of osteopathy, or doctor	laboratory is located; and			
of podiatric medicine licensed to				
practice medicine, osteopathy, or	(ii) Be certified in clinical pathology by			
podiatry in the State in which the	the American Board of Pathology or the			
laboratory is located; and	American Osteopathic Board of			
(ii) Have at least one year of	Pathology; or			
laboratory training or experience,				
or both, in high complexity	(2)(i) Be a doctor of medicine, doctor of			
testing within the specialty of	osteopathy, or doctor of podiatric			
microbiology with a minimum of	medicine licensed to practice medicine,			
6 months experience in high	osteopathy, or podiatry in the State in			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
complexity testing within the	which the laboratory is located; and			
subspecialty of bacteriology; or				
(3)	(ii) Have at least 1 year of laboratory			
(i) Have an earned doctoral	training or experience, or both, in high			
degree in a chemical, physical,	complexity testing within the specialty of			
biological or clinical laboratory	microbiology with a minimum of 6			
science from an accredited	months of experience in high complexity			
institution; and	testing within the applicable			
(ii) Have at least 1 year of	microbiology subspecialty; or			
laboratory training or experience,				
or both, in high complexity	(3)(i)(A) Have an earned doctoral degree in			
testing within the specialty of	a chemical, biological, clinical or medical			
microbiology with a minimum of	laboratory science, or medical technology			
6 months experience in high	from an accredited institution; or			
complexity testing within the				
subspecialty of bacteriology; or	(B) Meet the requirements in §			
(4)	493.1443(b)(3)(i)(B); and			
(i) Have earned a master's degree				
in a chemical, physical, biological	(C) [Reserved]			
or clinical laboratory science or				
medical technology from an	(ii) Have at least 1 year of laboratory			
accredited institution; and	training or experience, or both, in high			
(ii) Have at least 2 years of	complexity testing within the specialty			
laboratory training or experience,	of microbiology with a minimum of 6			
or both, in high complexity	months of experience in high			
testing within the specialty of	complexity testing within the applicable			
microbiology with a minimum of	subspecialty; or			
6 months experience in high				
complexity testing within the	(4)(i)(A) Have earned a master's degree in			
subspecialty of bacteriology; or	a chemical, biological, clinical or medical			
(5)	laboratory science, or medical technology			
(i) Have earned a bachelor's	from an accredited institution; or			
degree in a chemical, physical, or				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
biological science or medical	(B)(1) Meet bachelor's degree			
technology from an accredited	equivalency; and			
institution; and	(2) Have at least 16 semester			
(ii) Have at least 4 years of	hours of additional graduate level			
laboratory training or experience,	coursework in chemical, biological,			
or both, in high complexity	clinical or medical laboratory			
testing within the specialty of	science, or medical technology; or			
microbiology with a minimum of				
6 months experience in high	(C)(1) Meet bachelor's degree			
complexity testing within the	equivalency; and			
subspecialty of bacteriology.	(2) Have at least 16 semester			
(d) If the requirements of	hours in a combination of			
paragraph (b) of this section are	graduate level coursework in			
not met and the laboratory	biology, chemistry, medical			
performs tests in the	technology, or clinical or medical			
subspecialty of	laboratory science coursework and			
mycobacteriology, the individual	an approved thesis or research			
functioning as the technical	project related to laboratory			
supervisor must—	testing for the diagnosis,			
(1)	prevention, or treatment of any			
(i) Be a doctor of medicine or	disease or impairment of, or the			
doctor of osteopathy licensed to	assessment of the health of,			
practice medicine or osteopathy	human beings; and			
in the State in which the				
laboratory is located; and	(ii) Have at least 2 years of laboratory			
(ii) Be certified in clinical	training or experience, or both, in high			
pathology by the American Board	complexity testing within the specialty of			
of Pathology or the American	microbiology with a minimum of 6			
Osteopathic Board of Pathology	months of experience in high complexity			
or possess qualifications that are	testing within the applicable			
equivalent to those required for	subspecialty; or			
such certification; or				
(2)	(5)(i)(A) Have earned a bachelor's degree			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
(i) Be a doctor of medicine,	in a chemical, biological, clinical or medical			
doctor of osteopathy, or doctor	laboratory science, or medical technology			
or podiatric medicine licensed to	from an accredited institution; or			
practice medicine, osteopathy, or	(B) Have at least 120 semester hours,			
podiatry in the State in which the	or equivalent, from an accredited			
laboratory is located; and	institution that, at a minimum,			
(ii) Have at least 1 year of	includes either—			
laboratory training or experience,	(1) 48 semester hours of medical			
or both, in high complexity	laboratory technology courses; or			
testing within the specialty of				
microbiology with a minimum of	(2) 48 semester hours of science			
6 months experience in high	courses that include—			
complexity testing within the	(i) 12 semester hours of			
subspecialty of	chemistry, which must			
mycobacteriology; or	include general chemistry			
(3)	and biochemistry or organic			
(i) Have an earned doctoral	chemistry;			
degree in a chemical, physical,	(ii) 12 semester hours of			
biological or clinical laboratory	biology, which must include			
science from an accredited	general biology and			
institution; and	molecular biology, cell			
(ii) Have at least 1 year of	biology or genetics; and			
laboratory training or experience,	(iii) 24 semester hours of			
or both, in high complexity	chemistry, biology, or medical			
testing within the specialty of	laboratory science or			
microbiology with a minimum of	technology in any			
6 months experience in high	combination; and			
complexity testing within the				
subspecialty of	(ii) Have at least 4 years of laboratory			
mycobacteriology; or	training or experience, or both, in high			
(4)	complexity testing within the specialty of			
(i) Have earned a master's degree	microbiology with a minimum of 6			
in a chemical, physical, biological	months of experience in high complexity			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
or clinical laboratory science or	testing within the applicable			
medical technology from an	subspecialty.			
accredited institution; and				
(ii) Have at least 2 years of	(d) Diagnostic Immunology, Chemistry,			
laboratory training or experience,	Hematology, Radiobioassay, or			
or both, in high complexity	Immunohematology- If the requirements of			
testing within the specialty of	paragraph (b) of this section are not met and			
microbiology with a minimum of	the laboratory performs tests in the specialty			
6 months experience in high	of diagnostic immunology, chemistry,			
complexity testing within the	hematology, radiobioassay, or			
subspecialty of	immunohematology, the individual			
mycobacteriology; or	functioning as the technical supervisor must			
(5)	-			
(i) Have earned a bachelor's	(1)(i) Be a doctor of medicine or a doctor			
degree in a chemical, physical or	of osteopathy licensed to practice			
biological science or medical	medicine or osteopathy in the State in			
technology from an accredited	which the laboratory is located; and			
institution; and				
(ii) Have at least 4 years of	(ii) Be certified in clinical pathology by			
laboratory training or experience,	the American Board of Pathology or the			
or both, in high complexity	American Osteopathic Board of			
testing within the specialty of	Pathology; or			
microbiology with a minimum of				
6 months experience in high	(2)(i) Be a doctor of medicine, doctor of			
complexity testing within the	osteopathy, or doctor of podiatric			
subspecialty of	medicine licensed to practice medicine,			
mycobacteriology.	osteopathy, or podiatry in the State in			
(e) If the requirements of	which the laboratory is located; and			
paragraph (b) of this section are				
not met and the laboratory	(ii) Have at least 1 year of laboratory			
performs tests in the	training or experience, or both, in high			
subspecialty of mycology, the	complexity testing for the applicable			
individual functioning as the	specialty; or			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
technical supervisor must—				
(1)	(3)(i)(A) Have an earned doctoral degree in			
(i) Be a doctor of medicine or	a chemical, biological, clinical or medical			
doctor of osteopathy licensed to	laboratory science, or medical technology			
practice medicine or osteopathy	from an accredited institution; or			
in the State in which the	(B) Meet the education requirement			
laboratory is located; and	at § 493.1443(b)(3)(i)(B); and			
(ii) Be certified in clinical				
pathology by the American Board	(ii) Have at least 1 year of laboratory			
of Pathology or the American	training or experience, or both, in high			
osteopathic Board of Pathology	complexity testing within the applicable			
or possess qualifications that are	specialty; or			
equivalent to those required for				
such certification; or	(4)(i)(A) Have earned a master's degree in			
(2)	a chemical, biological, clinical or medical			
(i) Be a doctor of medicine,	laboratory science, or medical technology			
doctor of osteopathy, or doctor	from an accredited institution; or			
of podiatric medicine licensed to	(B) Meet the education requirement			
practice medicine, osteopathy, or	at paragraphs (c)(4)(i)(B) or (C) of this			
podiatry in the State in which the	section; and			
laboratory is located; and				
(ii) Have at least 1 year of	(ii) Have at least 2 years of laboratory			
laboratory training or experience,	training or experience, or both, in high			
or both, in high complexity	complexity testing for the applicable			
testing within the specialty of	specialty; or			
microbiology with a minimum of				
6 months experience in high	(5)(i)(A) Have earned a bachelor's degree			
complexity testing within the	in a chemical, biological, clinical or medical			
subspecialty of mycology; or	laboratory science, or medical technology			
(3)	from an accredited institution; or			
(i) Have an earned doctoral	(B) Meet the education requirement			
degree in a chemical, physical,	at paragraph (c)(5)(i)(B) of this			
biological or clinical laboratory	section; and			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
science from an accredited				
institution; and	(ii) Have at least 4 years of laboratory			
(ii) Have at least 1 year of	training or experience, or both, in high			
laboratory training or experience,	complexity testing for the applicable			
or both in high complexity testing	specialty.			
within the speciality of				
microbiology with a minimum of	(e) Cytology- If the requirements of			
6 months experience in high	paragraph (b) of this section are not met and			
complexity testing within the	the laboratory performs tests in the			
subspecialty of mycology; or	subspecialty of cytology, the individual			
(4)	functioning as the technical supervisor must			
(i) Have earned a master's degree	_			
in a chemical, physical, biological	(1)(i) Be a doctor of medicine or a doctor			
or clinical laboratory science or	of osteopathy licensed to practice			
medical technology from an	medicine or osteopathy in the State in			
accredited institution; and	which the laboratory is located; and			
(ii) Have at least 2 years of				
laboratory training or experience,	(ii) Be certified in anatomic pathology			
or both, in high complexity	by the American Board of Pathology or			
testing within the specialty of	the American Osteopathic Board of			
microbiology with a minimum of	Pathology; or			
6 months experience in high				
complexity testing within the	(2) An individual qualified under paragraph			
subspecialty of mycology; or	(b) or (e)(1) of this section may delegate			
(5)	some of the cytology technical supervisor			
(i) Have earned a bachelor's	responsibilities to an individual who is in			
degree in a chemical, physical or	the final year of full-time training leading			
biological science or medical	to certification specified in paragraph (b)			
technology from an accredited	or (e)(1)(ii) of this section provided the			
institution; and	technical supervisor qualified under			
(ii) Have at least 4 years of	paragraph (b) or (e)(1) of this section			
laboratory training or experience,	remains ultimately responsible for			
or both, in high complexity	ensuring that all of the responsibilities of			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
testing within the specialty of	the cytology technical supervisor are met.			
microbiology with a minimum of				
6 months experience in high	(f) Histopathology- If the requirements of			
complexity testing within the	paragraph (b) of this section are not met and			
subspecialty of mycology.	the laboratory performs tests in the			
(f) If the requirements of	subspecialty of histopathology, the individual			
paragraph (b) of this section are	functioning as the technical supervisor must			
not met and the laboratory	-			
performs tests in the	(1) Meet one of the following			
subspecialty of parasitology, the	requirements:			
individual functioning as the	(i)(A) Be a doctor of medicine or a			
technical supervisor must—	doctor of osteopathy licensed to			
(1)	practice medicine or osteopathy in the			
(i) Be a doctor of medicine or a	State in which the laboratory is located;			
doctor of osteopathy licensed to	and			
practice medicine or osteopathy				
in the State in which the	(B) Be certified in anatomic pathology			
laboratory is located; and	by the American Board of Pathology			
(ii) Be certified in clinical	or the American Osteopathic Board of			
pathology by the American Board	Pathology; or			
of Pathology or the American				
Osteopathic Board of Pathology	(ii) An individual qualified under			
or possess qualifications that are	paragraph (b) or (f)(1) of this section			
equivalent to those required for	may delegate to an individual who is a			
such certification; or	resident in a training program leading to			
(2)	certification specified in paragraph (b) or			
(i) Be a doctor of medicine,	(f)(1)(i)(B) of this section, the			
doctor of osteopathy, or doctor	responsibility for examination and			
of podiatric medicine licensed to	interpretation of histopathology			
practice medicine, osteopathy, or	specimens.			
podiatry in the State in which the				
laboratory is located; and	(2) For tests in dermatopathology, meet			
(ii) Have at least one year of	one of the following requirements:			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
laboratory training or experience,	(i)(A) Be a doctor of medicine or doctor			
or both, in high complexity	of osteopathy licensed to practice			
testing within the specialty of	medicine or osteopathy in the State in			
microbiology with a minimum of	which the laboratory is located; and			
6 months experience in high				
complexity testing within the	(B) Meet one of the following			
subspecialty of parasitology;	requirements:			
(3)	(1) Be certified in anatomic			
(i) Have an earned doctoral	pathology by the American Board			
degree in a chemical, physical,	of Pathology or the American			
biological or clinical laboratory	Osteopathic Board of Pathology;			
science from an accredited	or			
institution; and				
(ii) Have at least 1 year of	(2) Be certified in			
laboratory training or experience,	dermatopathology by the			
or both, in high complexity	American Board of Dermatology			
testing within the specialty of	and the American Board of			
microbiology with a minimum of	Pathology; or			
6 months experience in high				
complexity testing within the	(3) Be certified in dermatology by			
subspecialty of parasitology; or	the American Board of			
(4)	Dermatology; or			
(i) Have earned a master's degree				
in a chemical, physical, biological	(ii) An individual qualified under			
or clinical laboratory science or	paragraph (b) or (f)(2)(i) of this section			
medical technology from an	may delegate to an individual who is a			
accredited institution; and	resident in a training program leading			
(ii) Have at least 2 years of	to certification specified in paragraph			
laboratory training or experience,	(b) or (f)(2)(i)(B) of this section, the			
or both, in high complexity	responsibility for examination and			
testing within the specialty of	interpretation of dermatopathology			
microbiology with a minimum of	specimens.			
6 months experience in high				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
complexity testing within the	(3) For tests in ophthalmic pathology, meet			
subspecialty of parasitology; or	one of the following requirements:			
(5)	(i)(A) Be a doctor of medicine or doctor			
(i) Have earned a bachelor's	of osteopathy licensed to practice			
degree in a chemical, physical or	medicine or osteopathy in the State in			
biological science or medical	which the laboratory is located; and			
technology from an accredited				
institution; and	(B) Must meet one of the following			
(ii) Have at least 4 years of	requirements:			
laboratory training or experience,	(1) Be certified in anatomic			
or both, in high complexity	pathology by the American Board			
testing within the specialty of	of Pathology or the American			
microbiology with a minimum of	Osteopathic Board of Pathology;			
6 months experience in high	or			
complexity testing within the				
subspecialty of parasitology.	(2) Be certified by the American			
(g) If the requirements of	Board of Ophthalmology and have			
paragraph (b) of this section are	successfully completed at least 1			
not met and the laboratory	year of formal post-residency			
performs tests in the	fellowship training in ophthalmic			
subspecialty of virology, the	pathology; or			
individual functioning as the	(ii) An individual qualified under			
technical supervisor must—	paragraph (b) or (f)(3)(i) of this section			
(1)	may delegate to an individual who is a			
(i) Be a doctor of medicine or	resident in a training program leading			
doctor of osteopathy licensed to	to certification specified in paragraph			
practice medicine or osteopathy	(b) or (f)(3)(i)(B) of this section, the			
in the State in which the	responsibility for examination and			
laboratory is located; and	interpretation of ophthalmic			
(ii) Be certified in clinical	specimens; or			
pathology by the American Board				
of Pathology or the American	(g) Oral Pathology- If the requirements of			
Osteopathic Board of Pathology	paragraph (b) of this section are not met and			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
or possess qualifications that are	the laboratory performs tests in the			
equivalent to those required for	subspecialty of oral pathology, the individual			
such certification; or	functioning as the technical supervisor must			
(2)	meet one of the following requirements:			
(i) Be a doctor of medicine,	(1)(i) Be a doctor of medicine or a doctor			
doctor of osteopathy, or doctor	of osteopathy licensed to practice			
of podiatric medicine licensed to	medicine or osteopathy in the State in			
practice medicine, osteopathy, or	which the laboratory is located; and			
podiatry in the State in which the				
laboratory is located; and	(ii) Be certified in anatomic pathology			
(ii) Have at least 1 year of	by the American Board of Pathology or			
laboratory training or experience,	the American Osteopathic Board of			
or both, in high complexity	Pathology; or			
testing within the specialty of				
microbiology with a minimum of	(2) Be certified in oral pathology by the			
6 months experience in high	American Board of Oral Pathology; or			
complexity testing within the				
subspecialty of virology; or	(3) An individual qualified under paragraph			
(3)	(b) or (g)(1) or (2) of this section may			
(i) Have an earned doctoral	delegate to an individual who is a resident			
degree in a chemical, physical,	in a training program leading to			
biological or clinical laboratory	certification specified in paragraph (b) or			
science from an accredited	(g)(1) or (2) of this section, the			
institution; and	responsibility for examination and			
(ii) Have at least 1 year of	interpretation of oral pathology			
laboratory training or experience,	specimens.			
or both, in high complexity				
testing within the specialty of	(h) Histocompatibility- If the laboratory			
microbiology with a minimum of	performs tests in the specialty of			
6 months experience in high	histocompatibility, the individual functioning			
complexity testing within the	as the technical supervisor must either—			
subspecialty of virology; or				
(4)	(1)(i) Be a doctor of medicine, doctor of			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
(i) Have earned a master's degree	osteopathy, or doctor of podiatric			
in a chemical, physical, biological	medicine licensed to practice medicine,			
or clinical laboratory science or	osteopathy, or podiatry in the State in			
medical technology from an	which the laboratory is located; and			
accredited institution; and				
(ii) Have at least 2 years of	(ii) Have training or experience that			
laboratory training or experience,	meets one of the following			
or both, in high complexity	requirements:			
testing within the specialty of	(A) Have 4 years of laboratory training			
microbiology with a minimum of	or experience, or both, within the			
6 months experience in high	specialty of histocompatibility; or			
complexity testing within the				
subspecialty of virology; or	(B)(1) Have 2 years of laboratory			
(5)	training or experience, or both, in the			
(i) Have earned a bachelor's	specialty of general immunology; and			
degree in a chemical, physical or				
biological science or medical	(2) Have 2 years of laboratory			
technology from an accredited	training or experience, or both, in			
institution; and	the specialty of histocompatibility;			
(ii) Have at least 4 years of	or			
laboratory training or experience,				
or both, in high complexity	(2)(i) Have an earned doctoral degree in a			
testing within the specialty of	biological, clinical or medical laboratory			
microbiology with a minimum of	science, or medical technology from an			
6 months experience in high	accredited institution; or meet the			
complexity testing within the	education requirement at § 493.1443(b)(3)			
subspecialty of virology.	(i)(B); and			
(h) If the requirements of				
paragraph (b) of this section are	(ii) Have training or experience that			
not met and the laboratory	meets one of the following			
performs tests in the specialty of	requirements:			
diagnostic immunology, the	(A) Have 4 years of laboratory training			
individual functioning as the	or experience, or both, within the			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
technical supervisor must—	specialty of histocompatibility; or			
(1)				
(i) Be a doctor of medicine or a	(B)(1) Have 2 years of laboratory			
doctor of osteopathy licensed to	training or experience, or both, in the			
practice medicine or osteopathy	specialty of general immunology; and			
in the State in which the				
laboratory is located; and	(2) Have 2 years of laboratory			
(ii) Be certified in clinical	training or experience, or both, in			
pathology by the American Board	the specialty of histocompatibility.			
of Pathology or the American				
Osteopathic Board of Pathology	(i) Clinical cytogenetics- If the laboratory			
or possess qualifications that are	performs tests in the specialty of clinical			
equivalent to those required for	cytogenetics, the individual functioning as the			
such certification; or	technical supervisor must—			
(2)	(1)(i) Be a doctor of medicine, doctor of			
(i) Be a doctor of medicine,	osteopathy, or doctor of podiatric			
doctor of osteopathy, or doctor	medicine licensed to practice medicine,			
of podiatric medicine licensed to	osteopathy, or podiatry in the State in			
practice medicine, osteopathy, or	which the laboratory is located; and			
podiatry in the State in which the				
laboratory is located; and	(ii) Have 4 years of laboratory training			
(ii) Have at least 1 year of	or experience, or both, in genetics, 2 of			
laboratory training or experience,	which have been in clinical			
or both, in high complexity	cytogenetics; or			
testing for the specialty of				
diagnostic immunology; or	(2)(i) Hold an earned doctoral degree in a			
(3)	biological science, including biochemistry,			
(i) Have an earned doctoral	clinical or medical laboratory science, or			
degree in a chemical, physical,	medical technology from an accredited			
biological or clinical laboratory	institution; or meet the education			
science from an accredited	requirement at § 493.1443(b)(3)(i)(B); and			
institution; and				
(ii) Have at least 1 year of	(ii) Have 4 years of laboratory training			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
laboratory training or experience,	or experience, or both, in genetics, 2 of			
or both, in high complexity	which have been in clinical			
testing within the specialty of	cytogenetics.			
diagnostic immunology; or				
(4)	(j) Notwithstanding any other provision of			
(i) Have earned a master's degree	this section, an individual is considered			
in a chemical, physical, biological	qualified as a technical supervisor under this			
or clinical laboratory science or	section if they were qualified and serving as a			
medical technology from an	technical supervisor for high complexity			
accredited institution; and	testing in a CLIA-certified laboratory as of			
(ii) Have at least 2 years of	December 28, 2024 and have done so			
laboratory training or experience,	continuously December 28, 2024.			
or both, in high complexity				
testing for the specialty of	Note 1 to paragraphs (b) through (i): The			
diagnostic immunology; or	technical supervisor requirements for			
(5)	"laboratory training or experience, or both"			
(i) Have earned a bachelor's	in each specialty or subspecialty may be			
degree in a chemical, physical or	acquired concurrently in more than one of			
biological science or medical	the specialties or subspecialties of service.			
technology from an accredited	For example, an individual, who has a			
institution; and	doctoral degree in chemistry and additionally			
(ii) Have at least 4 years of	has documentation of 1 year of laboratory			
laboratory training or experience,	experience working concurrently in high			
or both, in high complexity	complexity testing in the specialties of			
testing for the specialty of	microbiology and chemistry and 6 months of			
diagnostic immunology.	that work experience included high			
(i) If the requirements of	complexity testing in bacteriology, mycology,			
paragraph (b) of this section are	and mycobacteriology, would qualify as the			
not met and the laboratory	technical supervisor for the specialty of			
performs tests in the specialty of	chemistry and the subspecialties of			
chemistry, the individual	bacteriology, mycology, and			
functioning as the technical	mycobacteriology.			
supervisor must—				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
(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 1 year of				
laboratory training or experience,				
or both, in high complexity				
testing for the specialty of				
chemistry; 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,				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
or both, in high complexity				
testing within the specialty of				
chemistry; 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 for the specialty of				
chemistry; or				
(5)				
(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 4 years of				
laboratory training or experience,				
or both, in high complexity				
testing for the specialty of				
chemistry.				
(j) If the requirements of				
paragraph (b) of this section are				
not met and the laboratory				
performs tests in the specialty of				
hematology, the individual				
functioning as the technical				
supervisor must—				
(1)				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
(i) Be a doctor of medicine or a				
doctor of osteopathy licensed to				
practice medicine or osteopathy				
in the State in which the				
laboratory is located; and				
(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 for the specialty of				
hematology (for example,				
physicians certified either in				
hematology or hematology and				
medical oncology by the				
American Board of Internal				
Medicine); or				
(3)				
(i) Have an earned doctoral				
degree in a chemical, physical,				
biological or clinical laboratory				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
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				
hematology; 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 for the specialty of				
hematology; or				
(5)				
(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 4 years of				
laboratory training or experience,				
or both, in high complexity				
testing for the specialty of				
hematology.				
(k)				
(1) If the requirements of				
paragraph (b) of this section are				
not met and the laboratory				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
performs tests in the				
subspecialty of cytology, the				
individual functioning as the				
technical supervisor must—				
(i) Be a doctor of medicine or a				
doctor of osteopathy licensed to				
practice medicine or osteopathy				
in the State in which the				
laboratory is located; and				
(ii) Meet one of the following				
requirements—				
(A) Be certified in anatomic				
pathology by the American Board				
of Pathology or the American				
Osteopathic Board of Pathology				
or possess qualifications that are				
equivalent to those required for				
such certification; or				
(B) Be certified by the American				
Society of Cytology to practice				
cytopathology or possess				
qualifications that are equivalent				
to those required for such				
certification;				
(2) An individual qualified under				
<u>§ 493.1449(b)</u> or paragraph (k)(1)				
of this section may delegate				
some of the cytology technical				
supervisor responsibilities to an				
individual who is in the final year				
of full-time training leading to				
certification specified in				
paragraphs (b) or (k)(1)(ii)(A) of				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
this section provided the				
technical supervisor qualified				
under <u>§ 493.1449(b)</u> or				
paragraph (k)(1) of this section				
remains ultimately responsible				
for ensuring that all of the				
responsibilities of the cytology				
technical supervisor are met.				
(I) If the requirements of				
paragraph (b) of this section are				
not met and the laboratory				
performs tests in the				
subspecialty of histopathology,				
the individual functioning as the				
technical supervisor must—				
(1) Meet one of the following				
requirements:				
(i)				
(A) Be a doctor of medicine or a				
doctor of osteopathy licensed to				
practice medicine or osteopathy				
in the State in which the				
laboratory is located; and				
(B) Be certified in anatomic				
pathology by the American Board				
of Pathology or the American				
Osteopathic Board of Pathology				
or possess qualifications that are				
equivalent to those required for				
such certification;				
(ii) An individual qualified under				
<u>§ 493.1449(b)</u> or <u>paragraph (l)(1)</u>				
of this section may delegate to				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
an individual who is a resident in				
a training program leading to				
certification specified in				
paragraph (b) or (l)(1)(i)(B) of this				
section, the responsibility for				
examination and interpretation				
of histopathology specimens.				
(2) For tests in				
dermatopathology, meet one of				
the following requirements:				
(i)				
(A) Be a doctor of medicine or				
doctor of osteopathy licensed to				
practice medicine or osteopathy				
in the State in which the				
laboratory is located and—				
(B) Meet one of the following				
requirements:				
(1) Be certified in anatomic				
pathology by the American Board				
of Pathology or the American				
Osteopathic Board of Pathology				
or possess qualifications that are				
equivalent to those required for				
such certification; or				
(2) Be certified in				
dermatopathology by the				
American Board of Dermatology				
and the American Board of				
Pathology or possess				
qualifications that are equivalent				
to those required for such				
certification; or				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
(3) Be certified in dermatology by				
the American Board of				
Dermatology or possess				
qualifications that are equivalent				
to those required for such				
certification; or				
(ii) An individual qualified under				
<u>§ 493.1449(b)</u> or paragraph (I)(2)				
(i) of this section may delegate to				
an individual who is a resident in				
a training program leading to				
certification specified in				
paragraphs (b) or (I)(2)(i)(B) of				
this section, the responsibility for				
examination and interpretation				
of dermatopathology specimens.				
(3) For tests in ophthalmic				
pathology, meet one of the				
following requirements:				
(i)				
(A) Be a doctor of medicine or				
doctor of osteopathy licensed to				
practice medicine or osteopathy				
in the State in which the				
laboratory is located and—				
(B) Must meet one of the				
following requirements:				
(1) Be certified in anatomic				
pathology by the American Board				
of Pathology or the American				
Osteopathic Board of Pathology				
or possess qualifications that are				
equivalent to those required for				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
such certification; or				
(2) Be certified by the American				
Board of Ophthalmology or				
possess qualifications that are				
equivalent to those required for				
such certification and have				
successfully completed at least 1				
year of formal post-residency				
fellowship training in ophthalmic				
pathology; or				
(ii) An individual qualified under				
<u>§ 493.1449(b)</u> or paragraph (1)(3)				
(i) of this section may delegate to				
an individual who is a resident in				
a training program leading to				
certification specified in				
paragraphs (b) or (1)(3)(i)(B) of				
this section, the responsibility for				
examination and interpretation				
of ophthalmic specimens; or				
(m) If the requirements of				
paragraph (b) of this section are				
not met and the laboratory				
performs tests in the				
subspecialty of oral pathology,				
the individual functioning as the				
technical supervisor must meet				
one of the following				
requirements:				
(1)				
(i) Be a doctor of medicine or a				
doctor of osteopathy licensed to				
practice medicine or osteopathy				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
in the State in which the				
laboratory is located and—				
(ii) Be certified in anatomic				
pathology by the American Board				
of Pathology or the American				
Osteopathic Board of Pathology				
or possess qualifications that are				
equivalent to those required for				
such certification; or				
(2) Be certified in oral pathology				
by the American Board of Oral				
Pathology or possess				
qualifications for such				
certification; or				
(3) An individual qualified under				
<u>§ 493.1449(b)</u> or paragraph (m)				
(1) or (2) of this section may				
delegate to an individual who is a				
resident in a training program				
leading to certification specified				
in <u>paragraphs (b)</u> or <u>(m) (1)</u> or <u>(2)</u>				
of this section, the responsibility				
for examination and				
interpretation of oral pathology				
specimens.				
(n) If the requirements of				
paragraph (b) of this section are				
not met and the laboratory				
performs tests in the specialty of				
radiobioassay, the individual				
functioning as the technical				
supervisor must—				
(1)				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
(i) Be a doctor of medicine or a				
doctor of osteopathy licensed to				
practice medicine or osteopathy				
in the State in which the				
laboratory is located; and				
(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 1 year of				
laboratory training or experience,				
or both, in high complexity				
testing for the specialty of				
radiobioassay; 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				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
testing within the specialty of				
radiobioassay; 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 for the specialty of				
radiobioassay; or				
(5)				
(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 4 years of				
laboratory training or experience,				
or both, in high complexity				
testing for the specialty of				
radiobioassay.				
(o) If the laboratory performs				
tests in the specialty of				
histocompatibility, the individual				
functioning as the technical				
supervisor must either—				
(1)				
(i) Be a doctor of medicine,				
doctor of osteopathy, or doctor				
of podiatric medicine licensed to				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
practice medicine, osteopathy, or				
podiatry in the State in which the				
laboratory is located; and				
(ii) Have training or experience				
that meets one of the following				
requirements:				
(A) Have 4 years of laboratory				
training or experience, or both,				
within the specialty of				
histocompatibility; or				
(B)				
(1) Have 2 years of laboratory				
training or experience, or both, in				
the specialty of general				
immunology; and				
(2) Have 2 years of laboratory				
training or experience, or both, in				
the specialty of				
histocompatibility; or				
(2)				
(i) Have an earned doctoral				
degree in a biological or clinical				
laboratory science from an				
accredited institution; and				
(ii) Have training or experience				
that meets one of the following				
requirements:				
(A) Have 4 years of laboratory				
training or experience, or both,				
within the specialty of				
histocompatibility; or				
(B)				
(1) Have 2 years of laboratory				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
training or experience, or both, in				
the specialty of general				
immunology; and				
(2) Have 2 years of laboratory				
training or experience, or both, in				
the specialty of				
histocompatibility.				
(p) If the laboratory performs				
tests in the specialty of clinical				
cytogenetics, the individual				
functioning as the technical				
supervisor must—				
(1)				
(i) Be a doctor of medicine,				
doctor of osteopathy, or doctor				
of podiatric medicine licensed to				
practice medicine, osteopathy, or				
podiatry in the State in which the				
laboratory is located; and				
(ii) Have 4 years of training or				
experience, or both, in genetics,				
2 of which have been in clinical				
cytogenetics; or				
(2)				
(i) Hold an earned doctoral				
degree in a biological science,				
including biochemistry, or clinical				
laboratory science from an				
accredited institution; and				
(ii) Have 4 years of training or				
experience, or both, in genetics,				
2 of which have been in clinical				
cytogenetics.				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
(q) If the requirements of				
paragraph (b) of this section are				
not met and the laboratory				
performs tests in the specialty of				
immunohematology, the				
individual functioning as the				
technical supervisor must—				
(1)				
(i) Be a doctor of medicine or a				
doctor of osteopathy licensed to				
practice medicine or osteopathy				
in the State in which the				
laboratory is located; and				
(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 for the specialty of				
immunohematology.				
Note:				

<b>Current CLIA Regulation</b>	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
The technical supervisor				
requirements for "laboratory				
training or experience, or both"				
in each specialty or subspecialty				
may be acquired concurrently in				
more than one of the specialties				
or subspecialties of service. For				
example, an individual, who has				
a doctoral degree in chemistry				
and additionally has				
documentation of 1 year of				
laboratory experience working				
concurrently in high complexity				
testing in the specialties of				
microbiology and chemistry and				
6 months of that work				
experience included high				
complexity testing in				
bacteriology, mycology, and				
mycobacteriology, would qualify				
as the technical supervisor for				
the specialty of chemistry and				
the subspecialties of				
bacteriology, mycology, and				
mycobacteriology.				
§ 493.1451 Standard: Technical	§ 493.1451 Standard: Technical supervisor	Updated cross reference	D6129	
supervisor responsibilities .	responsibilities .	from (k) to (e).		
(c) In cytology, the technical	(c) In cytology, the technical supervisor or the			
supervisor or the individual	individual qualified under § 493.1449( <mark>e</mark> )(2)-			
qualified under § 493.1449( <mark>k</mark> )(2)-				
§ 493.1455 Standard: Clinical	§ 493.1455 Standard: Clinical consultant	Updated cross references,	D6135	
consultant qualifications.	qualifications.	(3)(i) to (3) and from (b)		
(a) Be qualified as a laboratory	(a) Be qualified as a laboratory director under	(6) to (b)(5).		

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
director under § 493.1443(b)(1),	§ 493.1443(b)(1), (2), or ( <mark>3</mark> ) or, for the			
(2), or <mark>(3)(i)</mark> or, for the	subspecialty of oral pathology, § 493.1443(b)			
subspecialty of oral pathology, §	( <mark>5</mark> );			
493.1443(b)( <mark>6</mark> );				
§ 493.1461 Standard: General	§ 493.1461 Standard: General supervisor	At § 493.1461(c)(1)(i),	D6143	
supervisor qualifications.	qualifications.	removed an earned		
(c) If the requirements of	(c) If the requirements of paragraph (b)(1) or	doctoral, master's, or		
paragraph (b)(1) or <u>paragraph (b)</u>	(2) of this section are not met, the individual	bachelor's degree in		
(2) of this section are not met,	functioning as the general supervisor must—	"physical science" as a		
the individual functioning as the	(1)(i) Be a doctor of medicine, doctor of	means to qualify.		
general supervisor must—	osteopathy, or doctor of podiatric	At § 493.1461(c)(3)		
(1)	medicine licensed to practice medicine,	through (5), deleted the		
(i) Be a doctor of medicine,	osteopathy, or podiatry in the State in	grandfather provisions as		
doctor of osteopathy, or doctor	which the laboratory is located or have	these requirements had		
of podiatric medicine licensed to	earned a doctoral, master's, or bachelor's	to have been met by		
practice medicine, osteopathy, or	degree in a chemical, biological, clinical or	February 28, 1992,		
podiatry in the State in which the	medical laboratory science, or medical	April 24, 1995, and		
laboratory is located or have	technology from an accredited institution;	September 1, 1992,		
earned a doctoral, master's, or	and	respectively, and		
bachelor's degree in a chemical,		individuals can no longer		
physical, biological or clinical	(ii) Have at least 1 year of laboratory	qualify under these		
laboratory science, or medical	training or experience, or both, in high	provisions.		
technology from an accredited	complexity testing; or	Added new paragraph (c)		
institution; and		(4) to specify a new		
(ii) Have at least 1 year of	(2)(i) Qualify as testing personnel under	grandfather provision for		
laboratory training or experience,	§ 493.1489(b)(3); and	those individuals who had		
or both, in high complexity		qualified prior to the		
testing; or	(ii) Have at least 2 years of laboratory	publication of the final		
(2)	training or experience, or both, in high	rule.		
(i) Qualify as testing personnel	complexity testing; or			
under <u>§ 493.1489(b)(2);</u> and				
(ii) Have at least 2 years of	(3) Meet the requirements at			

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
laboratory training or experience,	§ 493.1443(b)(3) or § 493.1449(c)(4) or (5);			
or both, in high complexity	or			
testing; or	(4) Notwithstanding any other provision of			
(3)	this section, an individual is considered			
(i) Except as specified in	qualified as a general supervisor under this			
paragraph (3)(ii) of this section,	section if they were qualified and serving			
have previously qualified as a	as a general supervisor in a CLIA-certified			
general supervisor under §_	laboratory as of December 28, 2024, and			
493.1462 on or before February	have done so continuously since			
28, 1992.	December 28, 2024.			
(ii) Exception. An individual who				
achieved a satisfactory grade in a	(d)(3)(i) Have earned an associate degree			
proficiency examination for	related to pulmonary function from an			
technologist given by HHS	accredited institution; and			
between March 1, 1986 and				
December 31, 1987, qualifies as a	(e)(1) In histopathology, by an individual who			
general supervisor if he or she	is qualified as a technical supervisor under			
meets the requirements of §	§ 493.1449(b) or (f)(1);			
493.1462 on or before January 1,				
1994."	(2) In dermatopathology, by an individual			
(4) On or before September 1,	who is qualified as a technical supervisor			
1992, have served as a general	under § 493.1449(b) or § 493.1449(f)(2);			
supervisor of high complexity				
testing and as of April 24, 1995—	(3) In ophthalmic pathology, by an			
(i) Meet one of the following	individual who is qualified as a technical			
requirements:	supervisor under § 493.1449(b) or §			
(A) Have graduated from a	493.1449(f)(3); and			
medical laboratory or clinical				
laboratory training program	(4) In oral pathology, by an individual who			
approved or accredited by the	is qualified as a technical supervisor under			
Accrediting Bureau of Health	§ 493.1449(b) or (g).			
Education Schools (ABHES), the				
Commission on Allied Health				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
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—				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
(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 §				
<u>493.1449(b)</u> or <u>§ 493.1449(l)(1);</u>				
(e)(4) In oral pathology, by an				
individual who is qualified as a				
technical supervisor under §				
<u>493.1449(b)</u> or <u>§ 493.1449(m)</u> .				
§ 493.1462 General supervisor	N/A	Section 493.1462 is	D6143 or N/A?	
qualifications on or before		removed/deleted.		
February 28, 1992.				
To qualify as a general supervisor				
under <u>§ 493.1461(c)(3)</u> , 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 <u>§ 493.1406(b)(1)</u> ,				
(2), (4), or (5) is also qualified as				
a general supervisor; therefore,				
depending upon the size and				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
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 <u>§ 493.1491;</u>				
and				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
<ul> <li>(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</li> <li>(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.</li> </ul>				
<ul> <li>§ 493.1463 Standard: General supervisor responsibilities.</li> <li>(b)(4) Annually evaluating and documenting the performance of all testing personnel.</li> </ul>	<ul> <li>§ 493.1463 Standard: General supervisor responsibilities.</li> <li>(b)(4) Evaluating and documenting the competency of all testing personnel.</li> </ul>	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.	D6151	
<ul> <li>§ 493.1469 Standard: Cytology General supervisor qualifications.</li> <li>(a) Be qualified as a technical supervisor under § 493.1449 (b) or (k); or</li> </ul>	<ul> <li>§ 493.1469 Standard: Cytology General supervisor qualifications.</li> <li>(a) Be qualified as a technical supervisor under § 493.1449 (b) or (e); or</li> </ul>	Updated cross-reference from (k) to (e).	D6155	

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
<ul> <li>\$ 493.1483 Standard:</li> <li>Cytotechnologist qualifications.</li> <li>(b) Meet one of the following requirements:</li> <li>(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</li> <li>(2) Be certified in cytotechnology by a certifying agency approved by HHS; or</li> <li>(3) Before September 1, 1992- <ul> <li>(i) Have successfully completed 2</li> <li>years in an accredited institution with at least 12 semester hours in science, 8 hours of which are in biology; and</li> <li>(A) Have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by HHS; or</li> <li>(B) Have received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by HHS; or</li> </ul> </li> </ul>	<ul> <li>\$ 493.1483 Standard: Cytotechnologist qualifications.</li> <li>Each person examining cytology slide preparations must meet the qualifications of \$ 493.1449 (b) or (e), or—</li> <li>(b) Meet one of the following requirements: <ul> <li>(1) Have graduated from a school of cytotechnology accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP); or</li> <li>(2) Be certified in cytotechnology by a certifying agency approved by HHS; or</li> <li>(3) Notwithstanding any other provision of this section, an individual is considered qualified as a cytotechnologist under this section if they were qualified and serving as a cytotechnologist in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.</li> </ul> </li> </ul>	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).	D6164	

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
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 <u>§ 493.1449(b)</u> 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				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
physician qualified under §				
<u>493.1449(b)</u> or <u>(k)(1);</u> and				
(ii) On or before September 1,				
1995, have met the requirements				
in either <u>paragraph (b)(1)</u> or <u>(2)</u>				
of this section.				
§ 493.1489 Standard; Testing	§ 493.1489 Standard; Testing personnel	Removed paragraph (b)	D6171	
personnel qualifications.	qualifications.	(3) as the February 28,		
(b) Meet one of the following	(b) Meet one of the following requirements:	1992 grandfather		
requirements:		provision must have been		
(1) Be a doctor of medicine,	(1) Be a doctor of medicine, doctor of	met by February 28,		
doctor of osteopathy, or doctor	osteopathy, or doctor of podiatric	1992.		
of podiatric medicine licensed to	medicine licensed to practice medicine,			
practice medicine, osteopathy, or	osteopathy, or podiatry in the State in	Redesignated paragraphs		
podiatry in the State in which the	which the laboratory is located; or	(b)(2)(i) and (ii) to		
laboratory is located or have		paragraphs (b)(3)(i) and		
earned a doctoral, master's or	(2)(i) Have earned a doctoral, master's, or	(ii), respectively.		
bachelor's degree in a chemical,	bachelor's degree in a chemical, biological,	At § 493.1489(b)(2)(ii)(B)		
physical, biological or clinical	clinical or medical laboratory science, or	(1), replaced "CAHEA"		
laboratory science, or medical	medical technology from an accredited	with "CAAHEP" and		
technology from an accredited	institution; or	removing "or other		
institution;		organization approved by		
(2)	(ii) Be qualified under the requirements	HHS."		
(i) Have earned an associate	of § 493.1443(b)(3) or § 493.1449(c)(4)	Revised paragraph (b)(1)		
degree in a laboratory science, or	or (5); or	to separate the provisions		
medical laboratory technology		into two paragraphs (that		
from an accredited institution or	(3)(i) Have earned an associate degree in a	is, paragraph (b)(1) and		
-	laboratory science or medical laboratory	new paragraph (b)(2)(i)).		
(ii) Have education and training	technology from an accredited institution	Removed an earned		
equivalent to that specified in	or—	doctoral, master's, or		
paragraph (b)(2)(i) of this section		bachelor's degree in		
that includes—	(ii) Have education and training	"physical science" as a		
(A) At least 60 semester hours, or	equivalent to that specified in	means to qualify.		

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
equivalent, from an accredited	paragraph (b)(2)(i) of this section that	Added new paragraph (b)		
institution that, at a minimum,	includes—	(2)(ii) to state who may		
include either—	(A) At least 60 semester hours, or	be qualified under		
(1) 24 semester hours of medical	equivalent, from an accredited	§ 493.1443(b)(3) or §		
laboratory technology courses; or	institution that, at a minimum,	493.1449(c)(4) or (5) to		
(2) 24 semester hours of science	includes either—	allow individuals who do		
courses that include—	(1) 24 semester hours of medical	not have a chemical,		
(i) Six semester hours of	laboratory technology courses;	biological, or clinical		
chemistry;	or	science or medical		
(ii) Six semester hours of biology;	(2) 24 semester hours of science	technology or clinical		
and	courses that include—	laboratory science degree		
(iii) Twelve semester hours of	(i) 6 semester hours of	to be eligible to qualify as		
chemistry, biology, or medical	chemistry;	a TC using the		
laboratory technology in any	(ii) 6 semester hours of	educational algorithm.		
combination; and	biology; and	Moved the military		
(B) Have laboratory training that	(iii) 12 semester hours of	provision out of the		
includes either of the following:	chemistry, biology, or medical	April 24, 1995,		
(1) Completion of a clinical	laboratory technology in any	grandfather provision and		
laboratory training program	combination; and	made it a mechanism that		
approved or accredited by the	(B) Have laboratory training that	individuals will be able to		
ABHES, the CAHEA, or other	includes:	qualify for moderate		
organization approved by HHS.	(1) Completion of a clinical	complexity testing		
(This training may be included in	laboratory training program	(§ 493.1423(b)(5)).		
the 60 semester hours listed in	approved or accredited by the	Removed paragraph (b)		
paragraph (b)(2)(ii)(A) of this	ABHES or the CAAHEP (this	(4) introductory text and		
section.)	training may be included in the	paragraph (b)(4)(i) [the		
(2) At least 3 months	60 semester hours listed in	text that currently states		
documented laboratory training	paragraph (b)(3)(ii)(A) of this	"On or before" through		
in each specialty in which the	section); or	"graduated from a [ML]		
individual performs high	(2) At least 3 months	or [CL] training program		
complexity testing.	documented laboratory training	approved or accredited		
(3) Have previously qualified or	in each specialty in which the	by ABHES, CAHEA, or		
could have qualified as a	individual performs high	other organizations		

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
technologist under <u>§ 493.1491</u>	complexity testing; or	approved by HHS"] per		
on or before February 28, 1992;		the discussion under		
(4) On or before April 24, 1995 be	(4) Successful completion of an official U.S.	§ 493.1483(b)(2).		
a high school graduate or	military medical laboratory procedures	The current military		
equivalent and have either—	training course of at least 50 weeks	requirement at paragraph		
(i) Graduated from a medical	duration and having held the military	(b)(4)(ii) is redesignated		
laboratory or clinical laboratory	enlisted occupational specialty of Medical	as paragraph (b)(4).		
training program approved or	Laboratory Specialist (Laboratory			
accredited by ABHES, CAHEA, or	Technician); or			
other organization approved by				
HHS; or	(5) Notwithstanding any other provision of			
(ii) Successfully completed an	this section, an individual is considered			
official U.S. military medical	qualified as a high complexity testing			
laboratory procedures training	personnel under this section if they were			
course of at least 50 weeks	qualified and serving as a high complexity			
duration and have held the	testing personnel in a CLIA-certified			
military enlisted occupational	laboratory as of December 28, 2024, and			
specialty of Medical Laboratory	have done so continuously since			
Specialist (Laboratory	December 28, 2024.			
Technician);				
(5)	(6) For blood gas analysis—			
(i) Until September 1, 1997—	(i) Be qualified under paragraph (b)(1),			
(A) Have earned a high school	(2), (3), (4), or (5) of this section; or			
diploma or equivalent; and				
(B) Have documentation of	(ii) Have earned a bachelor's degree in			
training appropriate for the	respiratory therapy or cardiovascular			
testing performed before	technology from an accredited			
analyzing patient specimens.	institution; or			
Such training must ensure that				
the individual has—	(iii) Have earned an associate degree			
(1) The skills required for proper	related to pulmonary function from an			
specimen collection, including	accredited institution; or			
patient preparation, if applicable,				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
labeling, handling, preservation	(7) For histopathology, meet the			
or fixation, processing or	qualifications of § 493.1449(b) or (f) to			
preparation, transportation and	perform tissue examinations.			
storage of specimens;				
(2) The skills required for				
implementing all standard				
laboratory procedures;				
(3) The skills required for				
performing each test method				
and for proper instrument use;				
(4) The skills required for				
performing preventive				
maintenance, troubleshooting,				
and calibration procedures				
related to each test performed;				
(5) A working knowledge of				
reagent stability and storage;				
(6) The skills required to				
implement the quality control				
policies and procedures of the				
laboratory;				
(7) An awareness of the factors				
that influence test results; and				
(8) The skills required to assess				
and verify the validity of patient				
test results through the				
evaluation of quality control				
values before reporting patient				
test results; and				
(ii) As of September 1, 1997, be				
qualified under <u>§ 493.1489(b)(1)</u> ,				
(b)(2), or (b)(4), except for those				
individuals qualified under				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
paragraph (b)(5)(i) of this section				
who were performing high				
complexity testing on or before				
April 24, 1995;				
(6) For blood gas analysis—				
(i) Be qualified under §				
<u>493.1489(b)(1), (b)(2), (b)(3), (b)</u>				
(4), or (b)(5);				
(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 (I) to perform tissue				
examinations.				
§ 493.1491 Technologist	N/A	Section 493.1491 is	D6171	
qualifications on or before		removed.		
February 28, 1992.				
In order to qualify as high				
complexity testing personnel				
under <u>§ 493.1489(b)(3)</u> , 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				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
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				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
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,				
<b>1963.</b> 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,				
<b>1963.</b> (1) 16 semester hours in				
chemistry courses that included				
at least 6 semester hours in				
inorganic chemistry and that are				
acceptable toward a major in				
chemistry;				
(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				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
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.				
GENERAL CONSIDERATIONS/ALTERNATIVE SANCTIONS				
§ 493.1804 General	§ 493.1804 General considerations.	Amended § 493.1804(c)	N/A	

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
considerations.	(c)(1) CMS may impose alternative sanctions	(1) by removing the		
(c)(1) CMS may impose	in lieu of, or in addition to, principal	phrase "(Except for a		
alternative sanctions in lieu of, or	sanctions.	condition level deficiency		
in addition to principal sanctions.		under <u>§§ 493.41</u> or		
(Except for a condition level		<u>493.1100(a)</u> , CMS does		
deficiency under <u>§§ 493.41</u> or		not impose alternative		
<u>493.1100(a)</u> , CMS does not		sanctions on laboratories		
impose alternative sanctions on		that have certificates of		
laboratories that have certificates		waiver because those		
of waiver because those		laboratories are not		
laboratories are not routinely		routinely inspected for		
inspected for compliance with		compliance with		
condition-level requirements.		condition-level		
		requirements.)"		
Other Conforming Amendments:				

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
§ 493.945 Cytology; gynecologic	§ 493.945 Cytology; gynecologic	Current personnel CLIA	N/A	
examinations	examinations	reg cross-reference at		
(b)(2) An individual qualified as a	(b)(2) An individual qualified as a technical	reg. 493.1449(k) updated		
technical supervisor under §	supervisor under § 493.1449 (b) or (e) who	to 493.1449(e).		
493.1449 (b) or (k) who routinely	routinely interprets gynecologic slide			
interprets gynecologic slide	preparations only after they have been			
preparations only after they have	examined by a cytotechnologist can either be			
been examined by a	tested using a test set that has been screened			
cytotechnologist can either be	by a cytotechnologist in the same laboratory			
tested using a test set that has	or			
been screened by a				
cytotechnologist in the same	(b)(3)(i) Each slide set must contain 10 or 20			
laboratory or	slides with point values established for each			
	slide preparation based on the significance of			
(b)(3)(i) Each slide set must	the relationship of the interpretation of the			
contain 10 or 20 slides with point	slide to a clinical condition and whether the			
values established for each slide	participant in the testing event is a			
preparation based on the	cytotechnologist qualified under § 493.1469			
significance of the relationship of	or § 493.1483 or functioning as a technical			
the interpretation of the slide to	supervisor in cytology qualified under §			
a clinical condition and whether	493.1449 (b) or <mark>(e)</mark> of this part.			
the participant in the testing				
event is a cytotechnologist	(b)(3)(ii)(C) Criteria for scoring system for a			
qualified	10-slide test set. (See table at (b)(3)(ii)(A) of			
under § 493.1469 or § 493.1483	this section for a description of the response			
or functioning as a technical	categories.) For technical supervisors			
supervisor in cytology qualified	qualified under § 493.1449(b) or <mark>(e):</mark>			
under § 493.1449 (b) or <mark>(k)</mark> of this				
part.	(b)(3)(ii)(F) Criteria for scoring system for a			
	20-slide test set. (See table at paragraph (b)			
(b)(3)(ii)(C) Criteria for scoring	(3)(ii)(A) of this section for a description of			
system for a 10-slide test set.	the response categories.) For technical			
(See table at (b)(3)(ii)(A) of this	supervisors qualified under § 493.1449(b) or			
section for a description of the	└ <mark>(e):</mark>	0 (444		

Current CLIA Regulation	New/Revised CLIA Regulation	Notes	Current D-tag	CMS Comments
<ul> <li>§ 493.1273 Standard: Histopathology</li> <li>(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 material for for for for for for for for for for</li></ul>	§ 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).	Current personnel CLIA reg cross-reference at reg. 493.1449(I) updated to 493.1449(f), and 493.1449(m) updated to 493.1449(g).	D5603	
under § 493.1449(b), (I), 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).	<ul> <li>§ 493.1274 Standard: Cytology</li> <li>(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).</li> <li>(i) The review must be performed by an individual who meets one of the following qualifications:</li> <li>(A) A technical supervisor qualified under § 493.1449(b) or (e).</li> </ul>	Current personnel CLIA reg cross-reference at reg. 493.1449(k) updated to 493.1449(e).	D5621	