APHL GUIDE FOR

CLIA INTERNAL AUDITS

RELATED TO HIGH COMPLEXITY TESTING

JANUARY 2022

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

CONTENTS

INTRODUCTION

This document was developed as a quality improvement tool for internal "self" assessments of CLIA laboratory activities.

Throughout the guide, State Operations Manual (SOM)/Code of Federal Regulations (CFR) numbers are hyperlinked within the tables for a full explanation of each requirement. Access the full documents:

- SOM: State Operations Manual Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services (Rev. 166, 02/03/17)
- CFR: Electronic Code of Federal Regulations (Title 42: Public Health, Part 493 – Laboratory Requirements)

The information and content in this document reflects the CFR requirements in place on March 31, 2021. APHL makes no representations of any kind, express or implied about the completeness, accuracy, reliability, or suitability of this checklist with respect to ongoing updates to reflect amendments to the eCFR website. Therefore, the use of this document is strictly at your own risk. However, the eCFR website link provided in this document is hyperlinked to the current eCFR website version.

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CMS CLIA

LIST OF ASSESSORS BY CLIA REGULATORY REQUIREMENT

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Laboratory Director: _____ Date: _____

1. FACILITIES & SAFETY

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
1.1	D3001 §493.1101(a)(1)	Does the laboratory have adequate space, ventilation and utilities necessary for conducting all phases of the testing process?	• Make laboratory floor plans available. • Observe during laboratory tours (space: crowded; ventilation: check air flow strips; adequate lighting; fumes; availability of electrical outlets). • Ask about backup power. • Arrange work areas to minimize problems in specimen handling, examination and testing, and the reporting of test results. • Place instruments, equipment and computer systems in locations where their operation is not adversely affected by physical or chemical factors, such as heat, direct sunlight, vibrations, power fluctuations.	**Requirement met?** ☐ Yes ☐ No **Notes:**
1.2	D6083, D6084 §493.1445(e)(2)	**Laboratory Director Responsibility (cannot be delegated):** Does the Laboratory Director ensure that the physical plant and environmental conditions of the laboratory: • Are appropriate for the testing performed? • Provide a safe environment in which employees are protected from physical, chemical, and biological hazards?	• Assure there are quality systems in place. • Ask about any safety incident(s) in the laboratory and what was done.	**Requirement met?** ☐ Yes ☐ No *See CLIA Personnel Review Worksheet Tool.* **Notes:**
1.3	D3003 §493.1101(a)(2)	Is the laboratory space maintained to minimize contamination of specimens, equipment, instruments, reagents, materials and supplies?	Observe during the lab tour: • Lab is clean and uncluttered • Eyewash or hand wash facilities are accessible • Ventilation is clear • Power strips are acceptable to use, but extension cords are not Lab bench decontamination log is available.	**Requirement met?** ☐ Yes ☐ No **Notes:**
1.4	D3005 §493.1101(a)(3)	Is lab space used for molecular amplification procedures arranged to provide unidirectional workflow with separate areas for: • Specimen prep, amplification and detection? • Reagent preparation (as applicable)? • Mechanism to detect cross-contamination of patient specimens?	• Observe unidirectional workflow (no workarounds) • Environmental swipe test and blank for contamination • Evidence of blank controls (NTCs) from QC logs or run sheets.	**Requirement met?** ☐ Yes ☐ No **Notes:**
1.5	D3007 §493.1101(b)	Does the laboratory have appropriate and sufficient equipment, instruments, reagents, materials and supplies for the type and volume of testing performed?	Observe during lab tour or assess through staff discussions about essential laboratory equipment, (e.g. autoclave, centrifuge, scales, correct reagents for instrumentation, equipment list, inventory list, etc.) Is there a purchasing process in place and is it sufficient?	**Requirement met?** ☐ Yes ☐ No **Notes:**

Table Key

Laboratory Director (LD) | General Supervisor (GS) | Clinical Consultant (CC) | Technical Supervisor (TS)

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
1.6	D3009 §493.1101(c)	The laboratory must be in compliance with applicable federal, state and local laboratory requirements.	• Ask for the current certificates or state licensure documents. • Ask for the laboratory's policy on compliance with these requirement even if there is no state licensure or certificates.	**Requirement met?** ☐ Yes ☐ No **Notes:**
1.7	D3011 §493.1101(d)	Are safety procedures established, accessible and observed to ensure protection from physical, chemical, biochemical and electrical hazards, and biohazardous materials?	Check that findings from any laboratory's safety survey report have been corrected. Laboratory specific documentation—including the biosafety manual, waste management plan, chemical hygiene plan and, if applicable, the laboratory's bloodborne pathogen exposure control plan and training documents—are reviewed during the annual safety survey.	**Requirement met?** ☐ Yes ☐ No *This includes all types of laboratories (e.g., permanent, mobile, temporary, etc.)* **Notes:**
1.8	D3027, 3029, 3031, 3033, 3037, 3039, and 3041 §493.1101(e)	Are records and, as applicable, slides, blocks, and tissues maintained and stored under conditions that ensure proper preservation?	How are records stored? What is your record retention policy? What is your policy for the temperature and humidity control for the records? What is your off-site archive and retrieval policy? Check state requirements as applicable—go with most stringent.	**Requirement met?** ☐ Yes ☐ No **Notes:**

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2. PERSONNEL

2.1 General CLIA Personnel Requirements (Laboratory Director Responsibilities Not Covered Elsewhere)

Refer to the CLIA Personnel Review Worksheet Tool for more information on each of the following requirements/responsibilities:

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
2.1.a	D6079 §493.1445 (a)(b) *Note: Also covered in 2.3.c*	Is the laboratory director responsible for the overall operation and administration of the laboratory, including: • Employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations? • Delegation of qualified personnel to perform the duties of Technical Supervisor, Clinical Consultant, General Supervisor, and Testing Personnel? • Ensuring all duties delegated are properly performed?	If a new CLIA director: • Ask for educational records, competency records, transcripts, certificates, diplomas, laboratory organizational charts, etc. • Identify technical supervisors and policy on delegation of duties.	**Requirement met?** ☐ Yes ☐ No **Notes:**
2.1.b	D6080 §493.1445(c) *Note: D6144, D6145 and D6146 §493.1463(a)(1-2) are covered in 2.3.e*	Is the laboratory director accessible to the laboratory to provide onsite, telephone or electronic consultation as needed?	Documentation addressed in other sections.	**Requirement met?** ☐ Yes ☐ No **Notes:**
2.1.c	D6082 §493.1445 (e)(1)	**Cannot be delegated:** Does the laboratory director ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the pre-analytic, analytic, and post-analytic phases of testing?	Documentation addressed in other sections.	**Requirement met?** ☐ Yes ☐ No **Notes:**
2.1.d	D6100 §493.1445 (e)(10)	**Cannot be delegated:** Does the laboratory director ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under §493.1489(b) (4)?	Documentation addressed in other sections.	**Requirement met?** ☐ Yes ☐ No **Notes:**
2.1.e	D6101 §493.1445 (e)(11)	**Cannot be delegated:** Does the laboratory director ensure the employment/assignment of a sufficient number of laboratory personnel with appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results?	Documentation addressed in other sections.	**Requirement met?** ☐ Yes ☐ No **Notes:**

Table Key

☐ Laboratory Director (LD) ☐ General Supervisor (GS)

☐ Clinical Consultant (CC) ☐ Technical Supervisor (TS)

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2.2 Qualifications

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
		For each person acting in the following personnel roles, are qualifications documented?	Since the previous internal audit/ inspection, the items below must be current for new employees: • Diploma indicating degree in a chemical, physical, biological, clinical laboratory science or medical technology, if applicable • Transcript, if diploma does not specify area of study (transcripts were requested by CMS inspectors for degrees in public health, zoology, epidemiology, forestry and veterinary medicine) • Foreign degree equivalency if educational requirement is from a foreign institution • Professional training records Consult regulations for specifics.	**Requirement met?** ☐ Yes ☐ No **Notes:**
2.2.a	D6078 §493.1443	Laboratory Director	Certificate or (state) license to indicate qualification to direct the laboratory, degree (MD or PhD) or other additional certifications.	**Requirement met?** ☐ Yes ☐ No *See CLIA Personnel Review Worksheet Tool* **Notes:**
2.2.b	D6111 §493.1449	Technical Supervisor	The laboratory director can also be the technical supervisor. Someone with a BS and MS degree with years of experience can be the technical supervisor with written designation.	**Requirement met?** ☐ Yes ☐ No *See CLIA personnel forms:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
2.2.c	D6135 §493.1455	Clinical Consultant	**MDs:** License to practice medicine from any US state or territory or board certification by a CMS-approved board. Note: No further documentation is required (no need to produce foreign educational equivalency), but the medical license must be current and active (must not be expired). **PhDs:** Degree in a chemical, physical, biological or clinical laboratory science, plus active certification by a HHS-approved board (e.g., ABMM or ABB). Note: Further documentation may be needed to produce foreign educational equivalency of the PhD.	**Requirement met?** ☐ Yes ☐ No *See CLIA personnel forms:* • *CLIA Personnel Review Worksheet Tool* • *Clinical Consultant Personnel Form* **Notes:**

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Laboratory Director (LD) General Supervisor (GS)

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
2.2.d	D6143 §493.1461	General Supervisor	Documentation of two years laboratory training or experience is required.	**Requirement met?** ☐ Yes ☐ No *See CLIA personnel forms:* • *CLIA Personnel Review Worksheet Tool* • *General Supervisor Personnel Form* **Notes:**
2.2.e	D6171 §493.1489	Testing Personnel	Documentation of a degree (doctoral, master's or bachelor's) in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution.	**Requirement met?** ☐ Yes ☐ No **Notes:**

2.3 Responsibilities

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
2.3.a	D6107 §493.1445 (e)(15)	Has the laboratory director specified in writing the responsibilities and duties for all: • Clinical consultants? • Technical supervisors? • General supervisors? • Testing personnel?	Written documentation, policies, procedures or forms for all CLIA personnel signed by the laboratory director or designee: • Clinical consultants • Technical supervisors • General supervisors • Testing personnel Types of documentation: • Position descriptions • Competency documents • Training records • SOPs and authorizations	**Requirement met?** ☐ Yes ☐ No *See CLIA personnel forms:* • *Clinical Consultants* • *Technical Supervisors* • *General Supervisors* • *Testing Personnel* • *Supervisor Competency Assessment Procedure* • *CLIA Supervisory Competency Assessment for General Supervisor Form* • *CLIA Supervisory Competency Assessment for Clinical Consultant Form* • *CLIA Supervisory Competency Assessment for Technical Supervisor Form* **Notes:**
2.3.b	D6107 §493.1445 (e)(15)	For testing personnel, is there documentation that specifies: • Testing procedures the individual is authorized to perform? • Whether supervision is required for specimen processing, test performance or result reporting? • Whether supervisory or director review is required prior to reporting patient test results?	Written documentation, policies, procedures or forms for all testing personnel signed by the laboratory director or designee indicating the tests the individual is authorized to perform without supervision Note: supervisory review is required before patient test results are reported for all testing personnel. Types of documentation: • Position descriptions • Competency documents • Training records • SOPs and authorizations	**Requirement met?** ☐ Yes ☐ No *See CLIA Testing Personnel Form* **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
2.3.c	D6079 §493.1445 (a)(b) *Note: Also covered in 2.1.a*	**Laboratory Director Responsibility:** Is the laboratory director responsible for the overall operation and administration of the laboratory, including: • Employing personnel who are competent to perform test procedures; record and report test results promptly, accurately and proficiently; and assure compliance with the applicable regulations? • Delegating qualified personnel to perform the duties of technical supervisor, clinical consultant, general supervisor and testing personnel? • Ensuring all duties delegated are properly performed?	Written documentation of reapportionments.	**Requirement met?** ☐ Yes ☐ No *See CLIA Personnel Review Worksheet Tool* **Notes:**
2.3.d	D6136, D6137, D6138 and D6140 §493.1457 (a)(b)(d)	**Clinical Consultant Responsibility:** Does the laboratory have a clinical consultant available to provide: • Consultation to submitters? • Assist submitters to ensure appropriate test are ordered? • Communicate with submitters about the quality of test results reported and their interpretation concerning specific patient conditions?	Communication log that shows the clinical consultant provides consultation with submitters.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Clinical Consultant Personnel Form* **Notes:**
2.3.e	D6144, D6145 and D6146 §493.1463 (a)(1-2) *Note: Also covered in 2.1.b*	**General Supervisor Responsibility:** Does the general supervisor: • Provide day-to-day supervision of high complexity test performance? • Remain accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor?	Evidence of day-to-day review of records, such as QC record or organizational charts that display reporting lines.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *General Supervisor Personnel Form* **Notes:**
2.3.f	D6080 §493.1445(c) *Note: Also covered in 2.1.a*	**Laboratory Director Responsibility:** Is the laboratory director accessible to the laboratory to provide onsite, telephone or electronic consultation as needed?	Overall review of system compliance.	**Requirement met?** ☐ Yes ☐ No *See CLIA Personnel Review Worksheet Tool* **Notes:**
2.3.g	D6174 §493.1495(a)	**Testing Personnel Responsibility:** Is there documented evidence that testing person-nel limit patient testing to only those tests which they have been authorized to per-form by the laboratory director?	Review test results to ensure performed by an authorized testing personnel, or train-ing and competency assessment records.	**Requirement met?** ☐ Yes ☐ No *See CLIA Personnel Review Worksheet Tool* **Notes:**

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2.4 Training

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
2.4.a	D6102 §493.1445 (e)(12)	**Technical Supervisor Responsibility (Delegated by LD):** Does the technical supervisor ensure that, prior to testing patients' specimens, all personnel: • Have the appropriate education and experience? • Receive the appropriate training for the type and complexity of services offered? • Have demonstrated that they can perform all testing operations reliably to provide and report accurate results?	• Personnel qualification records (e.g., transcripts, diplomas, foreign evalutions, equivalency records, training records, competency assessment records, etc.). • LD or designee indicates TS responsibilities in writing.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
2.4.b	D6120 §493.1451 (b)(7)	**Technical Supervisor Responsibility:** Does the technical supervisor ensure that staff training needs are identified and that all testing personnel receive regular in-service training and education? *Note: This responsiblility can be delegated in writing to GS (see 2.4.c).*	Personnel training records.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
2.4.c	D6151 §493.1463 (b)(3)	**General Supervisor Responsibility (If delegated by LD or TS):** Does the general supervisor provide orientation to all testing personnel?	Personnel training records, onboarding checklist.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *General Supervisor Personnel Form* **Notes:**

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2.5 Competency Assessment

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
2.5.a	D6087 §493.1445 (e)(3)(iii)	**Technical Supervisor Responsibility (Delegated by LD):** Does the technical supervisor ensure that laboratory personnel are performing the test methods as required for accurate and reliable results? *Note: This responsibility can be delegated in writing to GS (see 2.5.e).*	• Competency assessment (CA) records • Training records • Quality assurance records	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* • *CLIA Testing Personnel Test System Authorization Form* **Notes:**
2.5.b	D6103 §493.1445 (e)(13)	**Technical Supervisor Responsibility (Delegated by LD):** Does the technical supervisor: • Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical and post-analytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently? • Identify needs for remedial training or continuing education to improve skills? *Note: This responsibility can be delegated in writing to GS (see 2.5.e).*	• CA records • Policy and procedure documents • Documents where staff have acknowledged that they understand the policies and procedures (signature page—digitally, electronically, manually, attestation, etc.)	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* • *CLIA Testing Personnel Test System Authorization Form* **Notes:**

2.5.c	D6120
	§493.1451 (b)(8)
		Technical Supervisor Responsibility: Does the technical supervisor ensure policies and procedures are established to evaluate the competency of all testing personnel and assure that staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently?
		Note: This responsibility can be delegated in writing to GS (see 2.5.e).
			• CA records:
			  • Are easy to follow, organized and standardized
			  • Have a summary of the schedule for all personnel in the front of the CA records (recommended).
			• Review policies and procedures related to compentencies.
			• Competency records.
				Requirement met? ☐ Yes ☐ No
				See:
				• *CLIA Personnel Review Worksheet Tool*
				• *Technical Supervisor Personnel Form*
				• *CLIA Testing Personnel Test System Authorization Form*
				Notes:

Laboratory Director: _____ Date: _____

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
2.5.d	D6121–D6126 §493.1451 (b)(8)(i-vi)	**Technical Supervisor Responsibility:** Do competency assessments include each of the following methods: • Direct observation of testing? • Monitoring the recording and reporting of results? • Review of intermediate results, QC, PT and PM? • Direct observation of maintenance and function checks? • Assessment of test performance through repeat, blind or external PT testing? • Assessment of problem solving skills? *Note: This responsibility can be delegated in writing to GS (see 2.5.e).*	CA records: • Are performed by an individual who has supporting documents and qualifications to do so (either GS or TS) • Have details of what test was assessed, including dates for each of the six methods of assessment • Include the results of test performance and evaluation including worksheets (if PT was used, specifics for PT event must be included or a copy of the PT event records) • Show evidence of supervisory review • Include documentation of successful retraining as necessary *Note: All six competencies must be assessed within the same calendar year, but not necessarily at the same time.*	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
2.5.e	D6151 §493.1463 (b)(4)	**General Supervisor Responsibility (if delegated by LD or TS):** Does the general supervisor annually evaluate and document the performance of all testing personnel.	Annual competency assessment records, to include dates.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *General Supervisor Personnel Form* • *CLIA Testing Personnel Test System Authorization Form* **Notes:**
2.5.f	D6179 §493.1495 (b)(5)	**Testing Personnel Responsibility:** Is there documented evidence that testing per-sonnel are capable of identifying problems that may adversely affect test system per-formance?	• Corrective action reports • Event logs • Root cause analysis • Instrument logs *Note: Documentation may be used as evidence for competency assessment.*	**Requirement met?** ☐ Yes ☐ No *See CLIA Personnel Review Worksheet Tool* **Notes:**
2.5.g	D6175 §493.1495 (b)(1)	**Testing Personnel Responsibility:** Is there documented evidence that testing personnel follow laboratory procedures for: • Specimen handling and processing? • Test analyses? • Reporting and maintaining records of patient test results?	Review of run reports with raw data, sample rejection logs, quality control logs, corrective action reports, review of result reports. *Note: Documentation may be used as evidence for competency assessment.*	**Requirement met?** ☐ Yes ☐ No *See CLIA Personnel Review Worksheet Tool* **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
2.5.h	D6177 §493.1495 (b)(3)	**Testing Personnel Responsibility:** Is there documented evidence that testing personnel adhere to quality control policies and document all quality control activities, instrument and procedural calibrations and maintenance performed?	• Quality control records • Instrument records • Maintenance records • Documents where staff have acknowledged that they understand the policies and procedures (signature page—digitally, electronically, manually, attestation, etc.) *Note: Documentation may be used as evidence for competency assessment.*	**Requirement met?** ☐ Yes ☐ No *See CLIA Personnel Review Worksheet Tool* **Notes:**
2.5.i	D6127–D6129 §493.1451 (b)(9)	**Technical Supervisor Responsibility:** Are testing personnel competency assessments conducted and documented: • Semiannually during the first year the individual tests patient specimens? • Annually thereafter? • When a new method or instrument change is introduced, individual is reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results?	Competency assessment records—may be delegated in writing to GS (see 2.5.e). • Check for new testing personnel CLIA testing start date and ensure the laboratory has records of two competency assessments during the 12 months following this start date, with at least one assessment within the first six months. • Check existing personnel records for new methods authorized to perform. • If the testing methodology changed, retraining will be needed at least once and documented as necessary. • Ensure there are records of annual competency assessment for existing personnel. • Records must show evidence of supervisory review.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
2.5.j	D5209 §493.1235	As specified in the personnel requirements in *Subpart M—Personnel for Nonwaived Testing*, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.	• Policies or procedures in place to assess personnel performing pre-analytical (accessioning), analytical or post-analytical (reporting) • Documents where staff have acknowledged that they understand the policies and procedures (signature page—digitally, electronically, manually, attestation, etc.)	**Requirement met?** ☐ Yes ☐ No *See CLIA Testing Personnel Test System Authorization Form* **Notes:**

Additional supporting documents for this section:

- Supervisor Competency Assessment Procedure
- CLIA Supervisory Competency Assessment for General Supervisor Form
- CLIA Supervisory Competency Assessment for Clinical Consultant Form
- CLIA Supervisory Competency Assessment for Technical Supervisor Form

Table Key

☐ Laboratory Director (LD) ☐ General Supervisor (GS)

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3. PRE-ANALYTIC & POST-ANALYTIC SYSTEMS

3.1 Pre-analytic Systems

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
3.1.a	D5301 §493.1241(a)	Does the laboratory require written or electronic requests for patient testing?	• Specimen submission/requisition form should be available for specimen testing. • Quality assurance manual. • Policy or standard operating procedure addressing the need for orders (how long does the lab have to order?, turn around time, etc.).	**Requirement met?** ☐ Yes ☐ No **Notes:**
3.1.b	D5303 §493.1241(b)	If the laboratory accepts oral requests, are written or electronic confirmation requests received within 30 days?	• This may be stated in a policy or procedure for specimen receipt and handling, or the lab may have records of communication that provide evidence of compliance. • Quality assurance manual. • Policy or standard operating procedure addressing the need for orders (how long does the lab have to order?, turn around time, etc.).	**Requirement met?** ☐ Yes ☐ No **Notes:**
3.1.c	D5305 §493.1241 (c)(1-6, 8)	Do test requisitions contain the following information? • Information necessary to identify the authorized submitter to send test results and if appropriate, an individual contact person to enable reporting of imminently life threatening results or panic or alert values? • Patient's name or unique identifier? • The sex and age or date of birth of the patient? • The test(s) to be performed? • The specimen source, when appropriate? • Date and, if appropriate, time of specimen collection? • Any additional information relevant/ necessary for a specific test?	• Review a sampling of specimen submission/requisition forms for required information. • The laboratory may use a supplemental form to collect information relevant for specific tests. • State Operations Manual: Does the laboratory have a policy/procedure for what to do when a requisition is missing required information? Laboratories must either obtain the missing information, or report results and indicate on the test report any limitations of test results due to the omission of patient information (See page 1 of Appendix C for an inspector and laboratory guide).	**Requirement met?** ☐ Yes ☐ No **Notes:**
3.1.d	D5309 §493.1241(e)	Does the laboratory ensure that test requisitions transcribed into a record system (paper or electronic) are entered accurately?	• QA monitors in place for requisition accessioning; the laboratory is responsible to ensure data is entered correctly and must have a procedure to check data entered. This may be in a policy or procedure for specimen receipt and handling. • Demographic change logs, corrective report logs, QA monthly assessment or quarterly report, assessment using LIMS print out, pull metrics from double data entry from LIMS (error rates).	**Requirement met?** ☐ Yes ☐ No *See Demographic Change Log Example* **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
3.1.e	D5311 §493.1242 (a)(1-8)	Does the laboratory establish and follow written policies and procedures for each of the following, if applicable: • Patient preparation? • Specimen collection? • Specimen labeling, including patient name or unique identifier and, when appropriate, specimen source? • Specimen storage and preservation? • Conditions for specimen transportation? • Specimen processing? • Specimen acceptability and rejection? • Specimen referral?	Information in a test directory should be consistent with laboratory test procedures for the following: • Acceptable sample/specimen type for testing • Storage and preservation of specimen prior to shipping • Transport medium • Specimen labeling • Shipping instructions which include specimen handling requirements Documentation: • Test requisitions • Test menus • SOPs (ensure SOPs include acceptability and rejection) • Orders • Containers • At least two unique patient identifiers on specimen container labeling, proper identification of patient	**Requirement met?** ☐ Yes ☐ No *Note: Crosswalk all policies and procedures to all physical evidence.* **Notes:**
3.1.f	D5313 §493.1242(b)	Does the laboratory document the date and time of specimen receipt?	Date and time packages/samples are received is documented (e.g, requisition forms, sample receipt logs, LIMS sample logs, etc.).	**Requirement met?** ☐ Yes ☐ No **Notes:**
3.1.g	D5315 §493.1242(c)	Does the laboratory refer specimens only to other CLIA-certified laboratories?	Documentation: • Reference lab CLIA certificates • Specified in SOP or procedure	**Requirement met?** ☐ Yes ☐ No **Notes:**
3.1.h	D5317 §493.1242 (a)(1-8)	Does the laboratory provide clients written instructions to meet the laboratory's requirements for the information outlined in 3.1.e?	• Test menu/test directory • SOPs, policies	**Requirement met?** ☐ Yes ☐ No **Notes:**
3.1.i	D3027 §493.1105 (a)(1)	**Record Retention:** Are test requisitions and authorizations retained for at least two years? *Note: Longer retention times might be in place for other state, local, federal regulations and must also be followed. The CLIA two-year rule must be followed at a minimum.*	• Test requisistions available for at least two years (can be longer)—address discontinued procedures as well • SOPs, policies • Check state requirements as applicable—go with most stringent	**Requirement met?** ☐ Yes ☐ No **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
3.1.j	D6138 §493.1457(b)	**Clinical Consultant Responsibility:** Does the laboratory have a clinical consultant available to assist submitters in ensuring appropriate tests are ordered to meet the clinical expectations?	A CC, other than the LD, is identified. *Note: CC can also be the LD.*	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Clinical Consultant Personnel Form* **Notes:**
3.1.k	D6138, D6140 §493.1457 (b)(d)	**Clinical Consultant Responsibility:** Is the CC available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations?	CC: Inquire into records of communication between CC and submitter on specific patient test requests or test results (as applicable). *Note: CC can also be the LD.*	**Requirement met?** ☐ Yes ☐ No **Notes:**

3.2 Post-analytic

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
3.2.a	D5801 §493.1291 (a)(1-3)	Does the laboratory have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry to final report destination in a timely manner? Including the following: • Results reported from calculated data • Results and patient-specific data electronically reported to network or interfaced systems • Manually transcribed or electronically transmitted results and patient-specific information	Documentation of result reporting quality checks, such as: • Supervisory review of reports (can be LIS manager) • Audit log of electronic reports • Patient test managing report	**Requirement met?** ☐ Yes ☐ No *See Patient Test Management Evaluation Form* **Notes:**
3.2.b	D5803 §493.1291(b)	Is test report information readily available to the laboratory and to CMS or a CMS agent upon request?	Request a random sampling of patient testing records representing each test system performed and corrected report examples if available. Records should include the specimen requisition, testing worksheets/data printouts and the final test report. The laboratory must be able to retrieve test reports requested during the CMS inspection.	**Requirement met?** ☐ Yes ☐ No **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
3.2.c	D58051 §493.1291 (c)(1-7)	Does the patient test report include the following: • Patient's name and identification number or a unique identifier and identification number? • Name and address of the laboratory location where the test was performed? • Test report date? • Test performed? • Specimen source, when appropriate? • Test result and, if applicable, the units of measurement or interpretation, or both? • Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability?	Review the sampling of patient testing records (3.2.b.) requested for required information. • If any of the test results were from a laboratory outside of your laboratory's CLIA certificate, check that this is noted on the report. • Reports should include a disclaimer, if applicable. For example, test reports for laboratory developed tests must include a disclaimer indicating "The performance characteristics of this test were determined by (Laboratory Name). It has not been cleared or approved by the US Food and Drug Administration." • Include additional patient identifiers, ordering physician and date/time of specimen collection, if available.	**Requirement met?** ☐ Yes ☐ No **Notes:**
3.2.d	D6139 §493.1457(c)	**Clinical Consultant Responsibility:** Has the clinical consultant reviewed patient report templates to ensure the test results include pertinent information required for specific patient interpretation?	Documentation of review test report templates. Documentation that CC has reviewed reports for each type result reported to include any interpretation, comments or disclaimers and test report results are clear and easy to understand. Example documentation: • Mock up test report • List of disclaimer • Interpretation comments	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Clinical Consultant Personnel Form* **Notes:**
3.2.e	D6098 §493.1445 (e)(8)	**Clinical Consultant Responsibility (If delegated by LD):** Does the clinical consultant ensure that reports of test results include pertinent information required for interpretation?	See evidence for 3.2.d.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Clinical Consultant Personnel Form* **Notes:**
3.2.f	D5807 §493.1291(d)	Are pertinent reference intervals or normal values, as determined by the laboratory performing the test, available to individuals ordering the test or responsible for using the test results? *Note: The result of test performed by another laboratory must reflect the performing laboratory's reference or normal range, and other interpretation comments.*	Reference interval (normal value) information should be included in each test procedure (see 6.1.b). Examples: • List of reference intervals • Reports with reference intervals • SOPs should include reference intervals—if they don't, must have a list	**Requirement met?** ☐ Yes ☐ No **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
3.2.g	D5809 §493.1291(e)	Does the laboratory have a means to provide clients: • Test methods? • Performance specifications established or verified by the laboratory if applicable? • Information on interpretation of test results including interferences? Are pertinent updates on testing information provided to clients whenever changes occur that affect test results or interpretation of test results?	• A test directory • SOPs • Validation/verification data • Emails or letters to clients regarding updates	**Requirement met?** ☐ Yes ☐ No **Notes:**
3.2.h	D6099 §493.1445 (e)(9)	**Clinical Consultant Responsibility (If delegated by LD):** Does the clinical consultant ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions?	If delegated to CC in writing by the LD: • Look through communication logs for examples • Complaints or lack of complaints • Letter from clinical consultant stating hours and contact information	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Clinical Consultant Personnel Form* **Notes:**
3.2.i	D5811 §493.1291(f)	Are test results released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test?	• Policy statement • Review data entry if this is auto reported	**Requirement met?** ☐ Yes ☐ No **Notes:**
3.2.j	D5813 §493.1291(g)	Does the laboratory immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using test results when any test result indicates an imminently life-threatening condition, or panic or alert value?	Procedure for reporting alert or panic values should include: • Definition for laboratory test results that have been determined to indicate an imminently life-threatening condition, or panic or alert value • How alert values will be communicated • To whom alert values may be communicated (role/qualifications) Records should include: • Date, time and to whom test results were reported • Method used to communicate (phone, email, other) • Acknowledgement of receipt The laboratory should have a communication log of alert values.	**Requirement met?** ☐ Yes ☐ No **Notes:**
3.2.k	D5815 §493.1291(h)	Has the laboratory established timeframes for reporting test results? If there is a delay in urgent or timely requests, does the laboratory notify appropriate individuals?	The test directory should include turnaround times. Records of submitter notification based on how long delay is and the impact on patient care (e.g, documentation in the laboratory information system, call log of the notification, etc.).	**Requirement met?** ☐ Yes ☐ No **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
3.2.l	D5815 §493.1291 (i)(1-3)	If a laboratory refers patient specimens for testing, does the laboratory ensure the following requirements are met: • Results or information directly related to the interpretation of results provided by the testing laboratory are not revised by the referring laboratory. • If the testing laboratory is permitted to send test results directly to the authorized person who initially requested the test, the referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report. • The authorized person who initially requested the test must be notified by the referring laboratory of the name and address of the laboratory where testing was performed.	• Evidence that you verified reference laboratory's CLIA number (via certificate) • Copy of all the original reports from the reference laboratories • Final report must include testing laboratory's name, address and CLIA number • Test report does not require CLIA number	**Requirement met?** ☐ Yes ☐ No **Notes:**
3.2.m	D5815 §493.1291(j)	Are all test reports or records of the information on the test report maintained by the laboratory in a manner that permits ready identification and timely accessibility?	Test reports and records maintained are easily identified and accessible. Examples: • Copies of the reports • Demonstrate retrieval of reports Identification and accessibility of storage areas (only appropriate staff have access).	**Requirement met?** ☐ Yes ☐ No **Notes:**
3.2.n	D5815 §493.1291 (k)(1-3)	When errors in the reported patient test results are detected, are the following accomplished: • Authorized person ordering the test and, if applicable, the individual using the test results are promptly notified? • Prompt issuance of corrected report(s)? • Duplicates of the original and corrected reports are maintained?	Review corrected report examples from the requested sampling of patient testing records (3.2.b). State Operations Manual: "Corrected reports, either hard copy or electronic, must clearly indicate both the corrected result(s) and the fact that the report is a corrected report." In the event that a corrected report was issued, the following documentation is required: • Non-conforming event (NCE) logs or documentation • Documentation of notification • Copies of original reports are maintained	**Requirement met?** ☐ Yes ☐ No **Notes:**
3.2.o	D3041 §493.1105 (a)(6)	Record Retention: Are test reports (preliminary, final and corrected/ amended) retained for at least two years? *Note: Longer retention times might be in place for other state, local and federal regulations and must also be followed. The CLIA two-year rule must be followed at a minimum.*	Paper or electronic copy of original report that contains the exact information as sent to submitter, such as: • Destruction records • Record retention policy or procedure Check state requirements as applicable – go with most stringent.	**Requirement met?** ☐ Yes ☐ No **Notes:**

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4. ANALYTIC—TEST SYSTEMS, REAGENTS, MATERIALS & SUPPLIES

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
4.1	D5411 §493.1252(a)	Are test systems selected by the laboratory? Are tests performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications?	• Recent review of package insert • SOPs SOM lists specific parameters for: • Syphilis serology (antigen volume, incubation time and temperature, light source, rotator speed and circumference, and conjugate titer) • International Normalized Ratio calculation for coagulation testing	**Requirement met?** ☐ Yes ☐ No **Notes:**

4.2	D5413
	§493.1252 (b)(1-4)
		• Has the laboratory defined criteria for conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting?
		• Are the criteria consistent with the manufacturer's instructions, as applicable?
		• Are the conditions monitored and documented?
		• If specific conditions apply, do they include:
		  • Water quality?
		  • Temperature?
		  • Humidity?
		  • Protection of equipment/ instruments from electrical fluctuations?
			Observe during lab tour:
			• Records of reagent and media storage and handling consistent with manufacturer's instructions
			• Monitoring records for refrigerator, freezer and room temperature (room temperature must be defined according to method)
			• Water quality reports if using water from a water purification system for testing procedures
			• Humidity if a test procedure or reagent storage has specific humidity requirements
			• Evidence and maintenance of uninterruptible power supplies and power strips or surge protectors
				Requirement met? ☐ Yes ☐ No
				Notes:

4.3	D5785 §493.1282 (b)(3)	Does the laboratory document corrective actions taken when the criteria for proper storage of reagents and specimens are not met?	• Temperature monitoring records indicate whether the temperature observed is within the defined acceptable range • If temperatures are out of range, there is documentation of corrective action (e.g., reagents or specimens moved to another refrigerator) • Corrective action log • NCE logs • Policy/SOP for storage of reagents and specimens	**Requirement met?** ☐ Yes ☐ No **Notes:**
4.4	D5415 §493.1252 (c)(1-4)	Are reagents, solutions, culture media, control materials, calibration materials and other supplies, as appropriate, labeled to indicate: • Identity? • Titer, strength or concentration, if applicable? • Storage requirements? • Preparation and expiration dates? • Other pertinent information required for proper use?	Observe during lab tour: • Name • Titer, strength or concentration for stocks and working solutions • Preparation date or opened date • Expiration date • Storage requirements • SOP	**Requirement met?** ☐ Yes ☐ No **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
4.5	D5417 §493.1252(d)	Does the laboratory prohibit the use of reagents, solutions, culture media, control materials, calibration materials and other supplies that have exceeded their expiration date, have deteriorated or are of substandard quality?	• This should be stated in a policy or procedure. • The laboratory must assign an expiration date to any reagents and media that do not have a manufacturer-provided expiration date. The assigned expiration date should be based on known stability, frequency of use, storage conditions and risk of deterioration. • Physical observation during audit.	**Requirement met?** ☐ Yes ☐ No **Notes:**
4.6	D5419 §493.1252(e)	Does the laboratory prohibit the interchange of reagent kit components of different lot numbers unless otherwise specified by the manufacturer?	If applicable, this should be stated in a policy or procedure.	**Requirement met?** ☐ Yes ☐ No **Notes:**

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5. ANALYTIC—EQUIPMENT MAINTENANCE, FUNCTION CHECKS & CALIBRATION

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
5.1	D5429 §493.1254 (a)(1)	For unmodified manufacturer's equipment, instruments or test systems, does the laboratory perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer?	• Current versions of equipment manufacturer operator's manuals should be available (printed or electronic). • Review manufacturer operator's manual to determine maintenance, including frequency defined by the manufacturer. • Review laboratory equipment procedures, maintenance schedules and records to ensure the lab is performing and documenting maintenance as defined by the manufacturer. • Maintenance logs/preventative maintenance (PM) schedule. • Documentation of repairs and service requests.	**Requirement met?** ☐ Yes ☐ No *See:* • *ABI 7500 Semi-Annual Preventative Maintenance Form* • *ABI 7500 Weekly and Monthly Preventative Maintenance Form* **Notes:**
5.2	D5431 §493.1254 (a)(2)	For unmodified manufacturer's equipment, instruments or test systems, does the laboratory perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer? *Note: Function checks must be within the manufacturer's established limits before patient testing is conducted.*	• Current versions of equipment manufacturer operator's manuals should be available (printed or electronic). • Review manufacturer operator's manual to determine maintenance, including frequency defined by the manufacturer. • Review laboratory equipment procedures, maintenance schedules and records to ensure the lab is performing and documenting maintenance as defined by the manufacturer. • QC records and logs.	**Requirement met?** ☐ Yes ☐ No **Notes:**
5.3	D5433 §493.1254 (b)(1)	For equipment, instruments or test systems developed in-house, modified commercially available, or for which maintenance and function checks are not provided by the manufacturer, has the laboratory: • Established a maintenance protocol that ensures performance necessary for accurate and reliable test results? • Performed and documented the maintenance activities?	Procedure and/or maintenance schedule defining maintenance requirements and intervals for all equipment and records used for diagnostic testing. *Note: This applies to equipment built in-house, structurally-modified by the lab or that is truly without a manufacturer-defined PM.* See 5.1.	**Requirement met?** ☐ Yes ☐ No *See:* • *ABI 7500 Semi-Annual Preventative Maintenance Form* • *ABI 7500 Weekly and Monthly Preventative Maintenance Form* **Notes:**

Laboratory Director: _____ Date: _____

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
5.4	D5435 §493.1254 (b)(2)	For equipment, instruments or test systems developed in-house, modified commercially available, or for which maintenance and function checks are not provided by the manufacturer, has the laboratory: • Defined a function check protocol that ensures performance that is necessary for accurate and reliable test results and test result reporting? • Does the laboratory perform and document equipment, instrument and test system function checks, including background or baseline checks as defined in 5.3? • Does the laboratory ensure that function checks are within the laboratory's established limits before patient testing is conducted?	Procedure and/or schedule defining function check requirements for all equipment and records of required function check activities. If function checks are out of range, is there evidence that the laboratory ensures corrected prior to patient testing? See 5.2.	**Requirement met?** ☐ Yes ☐ No **Notes:**
5.5	D5437 §493.1255 (a)(1-3)	Does the laboratory perform and document calibration procedures: • Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer? • Using criteria verified or established by the laboratory? • Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value (including the number, type and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration)? • Whenever calibration verification fails to meet the laboratory's acceptable limits?	Generally applies to quantitative assays. If applicable, records of calibration: • QC logs • Equipment maintenance logs • Run worksheets • SOPs, including procedure for failures (QC failures) and supporting documentation/follow up. Review of laboratory test procedures to meet manufacturer requirements.	**Requirement met?** ☐ Yes ☐ No **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes

5.6	D5439
	§493.1255 (b)(1-3)
		Does the laboratory perform and document calibration verification procedures:
		• Following the manufacturer's calibration verification instructions; using the criteria verified or established by the laboratory?
		  • Including the number, type and concentration of the materials, as well as acceptable limits for calibration verification?
		  • Including at least a minimal (or zero), mid-point and maximum value near the upper limit of the range to verify the laboratory's reportable range?
		• Verifying calibration of test systems at least once every six months and whenever any of the following occur:
		  • A complete change of reagents for a procedure is introduced?
		  • There is major preventive maintenance or replacement of critical parts?
		  • Control materials reflect an unusual trend or shift, or are outside the laboratory's acceptable limits?
		  • The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification?
			Generally applies to quantitative assays; review laboratory test procedures to determine assays where this applies.
			If applicable, records of calibration.
			If an assay has a quantitative cut-off value (e.g., some ELISAs), calibration verification procedures may be needed (contact the LD).
				Requirement met? ☐ Yes ☐ No
				Notes:

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6. ANALYTIC—TESTING

6.1 Procedure Manual

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
6.1.a	D5401 §493.1251 (a)	Does the laboratory have written procedures for all tests, assays and examinations performed available to and followed by laboratory personnel?	A list of SOPs/test procedures/test menus available for each CLIA-regulated test performed may be stored and accessed: • Paper-based • Electronic Documentation for each test performed must include: • The original start date the procedure was used for CLIA-regulated testing, if available • Approval by the technical supervisor • Approved by the current CLIA laboratory director.	**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.b	D5403 §493.1251 (b)(1-14)	Do procedure manuals include the requirements laid out in 6.b.i-xiv below, when applicable, for a test procedure?	SOP/test procedures must include the required elements specified in 6.1.bi - xiv. If these items are not found in the SOP, they must be found elsewhere. May refer to another procedure, such as: • Laboratory's specimen submission and handling procedure • Sample rejection policy, to include information on what labeling is accepted and not accepted • Sample collection instructions • Sample requisition form • Quality control • Corrective action/ non-conforming event • Laboratory result reporting procedure	**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.b.i	D5403 §493.1251 (b)(1)	Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing and referral; and criteria for specimen acceptability and rejection as described in §493.1242.		**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.b.ii	D5403 §493.1251 (b)(2)	If microscopic examination is performed, must include the detection of inadequately prepared slides.		**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.b.iii	D5403 §493.1251 (b)(3)	Step-by-step performance of the procedure, including test calculations and interpretation of results.		**Requirement met?** ☐ Yes ☐ No **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
6.1.b.iv	D5403 §493.1251 (b)(4)	Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing.		**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.b.v	D5403 §493.1251 (b)(5)	Calibration and calibration verification procedures.		**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.b.vi	D5403 §493.1251 (b)(6)	The reportable range for test results for the test system as established or verified in §493.1253.		**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.b.vii	D5403 §493.1251 (b)(7)	Control procedures.		**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.b.viii	D5403 §493.1251 (b)(8)	Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.		**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.b.ix	D5403 §493.1251 (b)(9)	Limitations in the test methodology, including interfering substances.		**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.b.x	D5403 §493.1251 (b)(10)	Reference intervals (normal values).		**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.b.xi	D5403 §493.1251 (b)(11)	Imminently life-threatening test results, or panic or alert values.		**Requirement met?** ☐ Yes ☐ No **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
6.1.b.xii	D5403 §493.1251 (b)(12)	Pertinent literature references.		**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.b.xiii	D5403 §493.1251 (b)(13)	The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic or alert values.		**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.b.xiv	D5403 §493.1251 (b)(14)	Description of the course of action to take if a test system becomes inoperable.		**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.c	D5405 §493.1251 (c)	If the laboratory uses manufacturer's test systems or operator's manuals (e.g., LRN or EUA), does the laboratory provide supplemental information to meet requirements of §493.1251 (b)(1-14)?	Supplemental documention may include: • Laboratory-specific specimen acceptance/rejection criteria • Reference (normal) values • Alert values	**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.d	D5407 §493.1251 (d)	Are procedures and changes to procedures approved, signed and dated by the current laboratory director before use?	Documentation of CLIA laboratory director approval for CLIA regulated test procedures.	**Requirement met?** ☐ Yes ☐ No **Notes:**
6.1.e	D6106 §493.1445 (e)(14)	**Technical Supervisor Responsibility (Delegated by LD):** Does the technical supervisor ensure that an approved procedure manual is available to all personnel responsi-ble for any aspect of the testing process?	See evidence above for 6.1.a.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
6.1.f	D5409 §493.1251 (e) D3029 §493.1105 (a)(2)	**Record Retention:** Is a copy of test procedures retained for at least two years after the procedure has been discontinued and does the procedure include dates of initial use and discontinuance? *Note: Check state requirements as applicable—go with most stringent.*	Are discontinued SOP/test procedures available if requested and include the dates of initial use and date testing was discontinued? SOPs or testing procedures must be available from the past two years, including ones that have been discontinued. Longer retention times might be in place for other state, local and federal regulations and must also be followed. The CLIA two-year rule must be followed at a minimum.	**Requirement met?** ☐ Yes ☐ No **Notes:**

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6.2 Analytic Systems—Verification and Validation (establishment of performance specifications)

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
6.2.a	D5419 §493.1253 (a)	Has the laboratory verified or established performance specifications (validated) all tests put into place or modified on or after April 24, 2003 prior to reporting patient results? *Note: Verification or validation for tests used prior to April 24, 2003 is highly recommended.*	• There is an SOP that includes verification and validation procedure. • Validation or verification records for each test.	**Requirement met?** ☐ Yes ☐ No **Notes:**
6.2.b	D6085 §493.1445 (e)(3)(i)	**Technical Supervisor Responsibility (Delegated by LD):** Does the technical supervisor ensure that test methodologies selected have the capability of providing the quality of results required for patient care?	See evidence for 6.2.c and 6.2.e.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
6.2.c	D5421 §493.1253 (b)(1)	For unmodified FDA-cleared/approved test systems, has the laboratory verified the following prior to reporting patient results: • The lab can obtain performance specifications comparable to those established by the manufacturer for accu-racy, precision and reportable range? • The manufacturer's reference intervals (normal values) are appropriate for their population?	• Documentation and records of verification/validation must be available for inspection. • Records must include evidence of review and approval by the technical supervisor.	**Requirement met?** ☐ Yes ☐ No **Notes:**
6.2.d	D6086 §493.1445 (e)(3)(ii)	**Technical Supervisor Responsibility (Delegated by LD):** Does the technical supervisor ensure that verification procedures used are adequate to determine the accuracy, precision and other pertinent performance characteristics of the method?	See evidence for 6.2.c and 6.2.e.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
6.2.e	D5423 §493.1253 (b)(2)	For all modified FDA-cleared/approved test systems or a laboratory developed test system in which the performance specifications are not provided by the manufacturer, has the laboratory established the following performance characteristics: • Accuracy? • Precision? • Analytical sensitivity? • Analytical specificity to include interfering substances? • Reportable range of test results? • Reference intervals (normal values)? • Any other performance characteristic required for test performance?	• Documentation and records of verification/validation must be available for inspection. • Records must include evidence of review and approval by the technical supervisor.	**Requirement met?** ☐ Yes ☐ No **Notes:**
6.2.f	D6095 §493.1445 (e)(6)	Technical Supervisor Responsibility (Delegated by LD): Does the technical supervisor ensure the establishment and maintenance of acceptable levels of analytical perfor-mance for each test system?	New or modified test procedure verification/validation studies are submitted to the LD for review and approval See evidence for 6.2.c and 6.2.e.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
6.2.g	D5425 §493.1253 (b)(3)	Has the laboratory determined each test system's calibration and control procedures based upon the performance specifications verified or established under §493.1253(b)(1) or §493.1253(b)(2)?	• Determination of calibration, if applicable, and control requirements must be in validation records • Test procedures	**Requirement met?** ☐ Yes ☐ No **Notes:**
6.2.h	D5427 §493.1253 (c)	Does the laboratory document all activities for all method verification and establishment of performance specifications?	The laboratory must have documentation and records available for inspection for verification/validation activities including records of the actual measurements taken, reactions and/or observations.	**Requirement met?** ☐ Yes ☐ No **Notes:**
6.2.i	D3033 §493.1105 (a)(3)(i)	Record Retention: Are records of test system performance specifications that the laboratory establishes or verifies under §493.1253 retained for the period of time the laboratory uses the test system but no less than two years? *Note: Longer retention times might be in place for other state, local, federal regulations and must also be followed. The CLIA two-year rule must be followed at a minimum.*	Verfication/validation procedures must be available for the period of the time that the laboratory uses the testing system, but no less than two years. Check state requirements as applicable—go with most stringent.	**Requirement met?** ☐ Yes ☐ No **Notes:**

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7. ANALYTIC—QUALITY CONTROL

7.1 QC—General

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
7.1.a	D5441 §493.1256 (a)(b)(c)(1-2)	Has the laboratory established quality control (QC) procedures for each test system that monitor the accuracy and precision of the complete analytic process? Does the QC procedure: • Detect immediate errors that occur due to test system failure, adverse environmental conditions and operator performance? • Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance? • Comply with the recommendations of the manufacturer? Does the QC procedure establish the number, type and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory?	• Quality Control policy/procedure • Records • Logs or worksheets *Note: Specifics for number, type and frequency needs to be defined in each individual test procedure.*	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.b	D6117 §493.1451 (b)(4)	Technical Supervisor Responsibility: Has the technical supervisor established a quali-ty control program appropriate for the testing performed covering the entire path of work flow.	QC policies and procedures.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
7.1.c	D6093 §493.1445 (e)(5)	**Technical Supervisor Responsibility (Delegated by LD):** Does the technical supervisor ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify fail-ures in quality as they occur?	QC policies/procedures and records of review.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
7.1.d	D6148 §493.1463 (a)(4)	**General Supervisor Responsibility:** Does the general supervisor monitor test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained?	QC is reviewed and failed QC is documented and investigated.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *General Supervisor Personnel Form* **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes

7.1.e	D5445
	§493.1256 (d)(1-2)
		Does the laboratory perform control procedures as:
		• Defined in this section and/or as specified in the additional specialty and subspecialty requirements,
		• Recommended by the manufacturer or established by the laboratory ONLY when they meet or exceed the requirement in this section, or
		• Developed and customized by the laboratory using an Individualized Quality Control Plan (IQCP) to meet requirements, with IQCP records reviewed and verified annually as appropriate to the test methods.
			• QC policies/procedures
			• QC records, logs or worksheets includes lot number, date received, opened or prepared date and expiration date.
			• IQCP documentation reviewed annually for potential new risks and adequacy of the QC plan.
			• Actual measurements, reactions and/or observations should be recorded.
			• Evaluation of QC failures and, if applicable, nonconforming event and corrective actions records that include:
			  • Retrospective review of patient results from testing since the last time the system was known to be performing within specification
			  • Issuing corrected patient results or contacting physicians to notify of potential error.
			• Evidence of supervisory review.
			• Check that patient results were not reported when QC was unacceptable.
				Requirement met? ☐ Yes ☐ No
				See Quality Assessment Worksheet
				Notes:

7.1.f	§493.1256 (d)(3)	Does the laboratory perform QC procedures at least once each day patient speci-mens are assayed for the following (7.1f.i-v):	See evidence for 7.1.e. Check QC records to ensure appropriate controls are performed for each test procedure.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.f.i	D5447 §493.1256 (d)(3)(i)	For **quantitative procedures**, include two control materials of different concentrations.	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.f.ii	D5449 §493.1256 (d)(3)(ii)	For **qualitative procedures**, include a negative and positive control material.	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.f.iii	D5451 §493.1256 (d)(3)(iii)	For **test procedures producing a graded or titered result**, include a negative control material and a control material with graded or titered reactivity.	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
7.1.f.iv	D5453 §493.1256 (d)(3)(iv)	For **test systems that have an extraction phase**, include two control materials, including one that is capable of detecting errors in the extraction process.	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.f.v	D5453 §493.1256 (d)(3)(v)	For **molecular amplification procedures,** include two controls and, if reaction inhibition is a significant source of false negative results, a control material capable of detect-ing the inhibition?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.g	D5457 §493.1256 (d)(4)	For **thin layer chromatography (TLC),** spot each plate or card with a calibrator containing all known substances or drug groups, as appropriate which are identified by TLC and reported by the laboratory; and include at least one control material on each plate or card which is processed through each step of patient testing, including extrac-tion?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.h	D5459 §493.1256 (d)(5)	For **electrophoresis procedures**, include, concurrent with patient specimens, at least one control material containing the substances being identified or measured?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.i	D5461 §493.1256 (d)(6)	Does the laboratory perform specified quality control before resuming patient testing when a: • Complete change of reagents is introduced? • Major preventive maintenance is performed or a critical part that may influence test performance is replaced?	• Quality control policy/procedure • Records • Logs or worksheets • IQCP documentation • Instrument logs • Non-conforming event (NCE) log • Reagent log	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.j	D5463 §493.1256 (d)(7)	Does the laboratory rotate control material testing among all personnel who perform patient testing?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.k	D5465 §493.1256 (d)(8)	Does the laboratory test control materials in the same manner as patient specimens?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
7.1.l	D5467 §493.1256 (d)(9)	For quantitative procedures, when using calibration material as a control material, are different lot numbers used from the calibration material used to calibrate the test system?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.m	D5459 §493.1256 (d)(10)	For **quantitative procedures**, has the laboratory established or verified the criteria for acceptability of all control materials? • Are statistical parameters (e.g., mean and standard deviation) defined for each lot of control materials from which quantitative results are derived? • If the laboratory uses commercially assayed control material values, are the method and instrumentation values verified by the laboratory? • If the laboratory uses unassayed control material, are statistical parameters established over time through con-current testing of control materials having previously determined statistical parameters?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.n	D5471, D5473, D5475 §493.1256 (e)(1-3)	For **reagent, media and supply checks**, does the laboratory perform and document the following: • Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera (excluding bacteriology) and identification systems (using two or more substrates or reagents) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable? • Each day of use, test staining material for intended reactivity? Controls are to include both positive and nega-tive reactivity. • Each time of use, check fluorescent and immunohistochemical stains for positive and negative reactivity?	• See evidence for 7.1.e • See media logs	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.o	D5477 §493.1256 (e)(4)	Before or concurrent with initial use media, does the laboratory check and document each batch for: • Sterility, if sterility is required for testing? • Ability to support growth and, as applicable, select or inhibit specific organisms or produce biochemical responses? • Physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer?	• See evidence for 7.1.e • See media logs	**Requirement met?** ☐ Yes ☐ No **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
7.1.p	D5479 §493.1256 (e)(5)	Does the laboratory follow the manufacturer's specifications for using reagents, media and supplies?	• See evidence for 7.1.e • Compare to manufacturer's package insert.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.q	D5481 §493.1256 (f)(g)	Does the laboratory document quality control testing and evaluate control results to ensure established criteria for acceptability are met before reporting patient test results?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.1.r	D6118 §493.1451 (b)(5)	**Technical Supervisor Responsibility:** Does the technical supervisor ensure that technical problems are resolved and that remedial actions are taken and documented when laboratory test systems deviate from established performance specifications?	QC policies and procedures documented; if delegated in writing to the GS (see 7.1.t).	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
7.1.s	D6119 §493.1451 (b)(6)	**Technical Supervisor Responsibility:** Does the technical supervisor ensure that patient test results are not reported until corrective actions have been taken and test sys-tems are functioning properly?	QC policies and procedures documented; if delegated in writing to the GS (see 7.1.t).	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
7.1.t	D6149, D6150 §493.1463 (b)(1-2)	**General Supervisor Responsibility (If delegated by LD or TS):** Does the general supervisor assure all remedial actions are taken whenever test systems deviate from the la-boratory's established performance specifications and ensure patient test results are not reported until all corrective actions have been taken and the test system is properly functioning?	• Failed QC is documented and investigated. • NCE corrective action followed up for effectiveness, etc. • Patient results are not reported when QC out of range.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *General Supervisor Personnel Form* **Notes:**
7.1.u	D6096, D6097 §493.1445 (e)(7)	**Technical Supervisor Responsibility (Delegated by LD):** Does the technical supervisor ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results reported only when the system is functioning properly?	QC policies and procedures documented; if delegated in writing to the GS (see 7.1.t).	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
7.1.v	D3031 §493.1105 (a)(3)	Record Retention: Are quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic activities (specified in §493.1252 through 493.1289) retained for at least two years? *Note: Longer retention times might be in place for other state, local and federal regulations and must also be followed. The CLIA two-year rule must be followed at a minimum.*	QC records must be available from the past two years, including ones that have been discontinued. The records must include instrument charts, graphs, printouts, transcribed data and manufacturers' assay information sheets for control and calibration materials. If data are transcribed, ensure that the original and the transcribed copy are retained for two years. Printouts from an instrument that is not directly interfaced with the laboratory information system must be retained for two years. *Note: Check state requirements as applicable—go with most stringent.*	**Requirement met?** ☐ Yes ☐ No **Notes:**

7.2 QC—Bacteriology

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
7.2.a	D5501, D5503, D5505 §493.1261 (a)(1-3)	Does the laboratory check the following for positive and negative reactivity using control organisms: • Each day of use for beta lactamase methods other than Cefinase™? • Each week of use for gram stains? • When each batch (prepared in house), lot number (commercially prepared) and shipment of antisera is pre-pared or opened, and once every six months thereafter?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.2.b	D5507 §493.1261 (b)(1-2)(c)	For antimicrobial susceptibility tests, does the laboratory: • Check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with initial use, using approved control organisms? • Test approved control organisms each day of testing? • Document and evaluate zone sizes or MICs for control organisms to ensure that they are within established limits before reporting patient results? • Document all control procedures performed?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**

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7.3 QC—Mycobacteriology

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
7.3.a	D5511 §493.1262 (a)	On each day of use, does the laboratory check all reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.3.b	D5513 §493.1262 (b)(1-3)(c)	For antimycobacterial susceptibility tests, does the laboratory check each batch of media and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use using appropriate control organism(s)? If so, • Has the laboratory established limits for acceptable control results? • Does the laboratory use appropriate control organism(s) each week tests are performed to check the procedure? • Are the results of control organism(s) verified to be within established limits before patient results are reported? • Does the laboratory document all control procedures performed?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**

7.4 QC—Mycology

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
7.4.a	D5517 §493.1263 (a)	Does the laboratory check each batch (prepared in-house), lot number (commercially prepared) and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control organism(s)?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.4.b	D5519 §493.1263 (b)(1-3)(c)	For antifungal susceptibility tests, does the laboratory check each batch of media and each lot number and shipment of antifungal agent(s) before, or concurrent with, initial use using appropriate control organism(s)? If so, • Has the laboratory established limits for acceptable control results? • Does the laboratory use appropriate control organism(s) each week tests are performed to check the procedure? • Are the results of control organism(s) verified to be within established limits before patient results are reported? • Does the laboratory document all control procedures performed?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**

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7.5 QC—Parasitology

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
7.5.a	D5523 §493.1264 (a)	Does the laboratory have a reference collection of slides or photographs available and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.5.b	D5525 §493.1264 (b)	Does the laboratory calibrate and use ocular micrometers for determining the size of ova and parasites, if size is critical?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**
7.5.c	D5527 §493.1264 (c)(d)	Does the laboratory check permanent stains each month of use using a fecal sample control material that will demonstrate staining characteristics? Does the laboratory document all control procedures performed?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**

7.6 QC—Virology

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
7.6.a	D5531 §493.1265 (a)(b)	When using cell cultures to isolate or identify viruses, does the laboratory simultaneously incubate a cell substrate control or uninoculated cells as a negative control? Does the laboratory document all control procedures performed?	See evidence for 7.1.e.	**Requirement met?** ☐ Yes ☐ No **Notes:**

7.7 QC—Other than Microbiology

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
7.7.a				**Requirement met?** ☐ Yes ☐ No **Notes:**

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8. PROFICIENCY TESTING (PT) & ALTERNATIVE ASSESSMENT

8.1 PT—Enrollment

For all requirements below, refer to the Proficiency Testing and Alternative Assessment Review Worksheet Tool.

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
8.1.a	D2001 §493.801 (a)	Is the laboratory enrolled in a CMS-approved PT program offering three (3) events per year (two (2) events for mycobacteriology) with a minimum of five (5) samples per event for all regulated analytes tested?	• Compare test lists to PT enrollment • Records of participation in an approved PT program for labs testing regulated analytes	**Requirement met?** ☐ Yes ☐ No **Notes:**
8.1.b	D6088 §493.1445 (e)(4)	**Technical Supervisor Responsibility (Delegated by LD):** Does the technical supervisor ensure that the laboratory is enrolled in an HHS-approved proficiency testing program, if available, for the testing performed?	See evidence for 8.1.a *Note: Duplicate of 8.1.c if delegated in writing by the LD.*	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
8.1.c	D6116 §493.1451 (b)(3)	Technical Supervisor Responsibility: Does the technical supervisor ensure that the laboratory is enrolled and participates in an HHS approved proficiency testing program commensurate with the services offered?	See evidence for 8.1.a.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
8.1.d	D5217, D5219 §493.1236 (c)(1-2)	Does the laboratory verify the accuracy at least twice annually using an alternative assessment procedure (AAP) such as other external assessment programs, blind testing, or split samples for other testing such as: • Tests where no compatible PT samples are offered by a CMS approved PT program? • Tests for nonregulated analytes?	• Compare test lists to what is not covered in PT enrollment and must perform an AAP • Procedure and records indicating at least twice annual alternative assessment for all other testing • Records should be easy to follow and should include a summary page with expected results, actual results and evaluation of performance	**Requirement met?** ☐ Yes ☐ No **Notes:**

8.2 PT—Testing of Samples

For all requirements below, refer to the Proficiency Testing and Alternative Assessment Review Worksheet Tool.

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
8.2.a	D2006 §493.801 (b)	Does the laboratory examine PT samples in the same manner as it tests patient specimens?	• Policy/procedure to ensure compliance • QA manual • Attestation statements provided by CAP, other PT provider or created in-house	**Requirement met?** ☐ Yes ☐ No *See the Audit Attestation Form* **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
8.2.b	D6089 §493.1445 (e)(4)(i)	**Technical Supervisor Responsibility (Delegated by LD):** Does the technical supervisor ensure that proficiency testing samples are tested as required by §493.801?	See evidence for 8.2.a.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
8.2.c	D6176 §493.1495 (b)(2)	**Testing Personnel Responsibility:** Do testing personnel maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens?	• Worksheets and sample logs • Policies and procedures • QA manual	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Testing Personnel Form* **Notes:**
8.2.d	D2007 §493.801 (b)(1)	Are PT samples examined along with the lab's regular workload by personnel who routinely perform testing using the lab's routine methods?	• PT records indicate that testing was performed by testing personnel authorized to perform the assay • Attestation statements • PT records to confirm testing personnel are rotated	**Requirement met?** ☐ Yes ☐ No **Notes:**
8.2.e	D2009 §493.801 (b)(1)	Does the individual testing the PT samples and the technical supervisor (delegated by the LD) sign an attestation statement that PT samples are integrated into the patient workload using the laboratory's routine methods?	• Attestation statements provided by the College of American Pathologists, other PT provider or created in-house • Policies and procedures	**Requirement met?** ☐ Yes ☐ No **Notes:**
8.2.f	D2010 §493.801 (b)(2)	Are PT samples tested the same number of times as patient samples are routinely tested?	• Worksheets and sample logs • Policies and procedures	**Requirement met?** ☐ Yes ☐ No **Notes:**
8.2.g	D2011, D2013 §493.801 (b)(3-4)	Does the laboratory have procedures to ensure: • No inter-laboratory communication regarding PT samples/results occurs until after the result submission deadline date has passed? • PT samples are not referred to another laboratory for analysis, or if PT samples are received from another laboratory for testing, the samples are not tested and CMS is notified?	• Policies and procedures • QA manual • Worksheets, sample logs and final reports for verification	**Requirement met?** ☐ Yes ☐ No **Notes:**
8.2.h	D2015 §493.801 (b)(5)	Does the laboratory document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all PT samples?	• Policies and procedures • QA manual • Worksheets, sample logs and final reports for verification • Attestation statements	**Requirement met?** ☐ Yes ☐ No **Notes:**

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8.3 PT—Evaluation of Performance

For all requirements below, refer to the Proficiency Testing and Alternative Assessment Review Worksheet Tool.

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
8.3.a	D6090 §493.1445 (e)(4)(ii)	**Technical Supervisor Responsibility (Delegated by LD):** Does the technical supervisor ensure that PT results are returned within the timeframes established by the PT program?	PT records are reviewed and complete.	**Requirement met?** ☐ Yes ☐ No **Notes:**
8.3.b	D5211 §493.1236 (a)	Does the laboratory review and evaluate the results obtained on PT?	Has the laboratory had unsatisfactory PT responses? Records should indicate: • PT result evaluations are reviewed and signed by the technical supervisor • Documentation of investigation of the incorrect result, including any corrective action or retraining required • For assays where failed results are common, results should be logged for trends that might likely cause the failed results • NCEs, self-assessments, corrective actions	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
8.3.c	D6091 §493.1445 (e)(4)(iii)	**Technical Supervisor Responsibility (Delegated by LD):** Does the technical supervisor ensure that all PT reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective actions?	PT performance is reviewed with appropriate staff.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**
8.3.d	D5213–D5215 §493.1236 (b)	Does the laboratory verify the accuracy of any PT result that was not scored for any reason?	Records of review and evaluation of ungraded PT challenges.	**Requirement met?** ☐ Yes ☐ No **Notes:**
8.3.e	D5221 §493.1236 (d)	Are PT evaluations and verification activities documented? *Note: This applies even if the overall PT event was successful.*	Records available.	**Requirement met?** ☐ Yes ☐ No **Notes:**
8.3.f	D6092 §493.1445 (e)(4)(iv)	**Technical Supervisor Responsibility (Delegated by LD):** Does the technical supervisor ensure that an approved corrective actions plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory?	Documentation of review/approval.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**

Table Key

Laboratory Director (LD) | General Supervisor (GS) | Clinical Consultant (CC) | Technical Supervisor (TS)

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
8.3.g	D3037 §493.1105 (a)(4)	**Record Retention:** Are records of PT examination and documentation of activities retained for a minimum of two years after the PT event? *Note: Longer retention times might be in place for other state, local and federal regulations and must also be followed. The CLIA two-year rule must be followed at a minimum.*	Obtain signed attestation statements, PT results and scores from the provider, documentation of review and records of any corrective actions, either electronic or hard copies. *Note: Check state requirements as applicable—go with most stringent.*	**Requirement met?** ☐ Yes ☐ No **Notes:**

8.4 Comparison of Test Results

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
8.4.a	D5775 §493.1281 (a)(c)	If the laboratory performs the same test using different methodologies, instruments or testing sites, does the laboratory have a procedure that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments or testing sites? Does the laboratory document test result comparison?	Procedure and records for comparison of results when the same test is: • Performed by another testing site • Performed using multiple instruments • Performed by a different methodology. The laboratory must have written criteria for acceptable differences in test values. This comparison must be done twice a year and must be approved by the technical supervisor.	**Requirement met?** ☐ Yes ☐ No *See examples of instrument comparison records:* • *EVOLIS Instrument Comparability Chart* • *PCR Instrument Comparison Example* **Notes:**
8.4.b	D5777 §493.1281 (a)(c)	Does the laboratory have a system to assess patient test results that appear inconsistent with the following relevant criteria, when available: • Patient Age? • Patient Sex? • Diagnosis or pertinent clinical data? • Distribution of patient test results? • Relationship with other test parameters?	If applicable, documentation within a test SOP.	**Requirement met?** ☐ Yes ☐ No **Notes:**

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9. GENERAL LABORATORY SYSTEMS & RETENTION REQUIREMENTS

9.1 General Laboratory Systems §493.1230

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
9.1.a	D5787, D5789 §493.1283 (a)(1-4)(b)	Does the laboratory maintain an information or record system that includes the following: • Positive identification of the specimen? • Date and time of specimen receipt into the laboratory? • The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability? • Records and dates of specimen testing, including the identity of the personnel who performed the test(s)? • Records of patient testing including, if applicable, instrument printouts?	• Unique identifiers to provide positive identification of specimens from accessioning through storage. • Receipt date and time is recorded for all specimens. • Condition of specimens and disposition is recorded. • Verify procedure for positive specimen identification, log date, time of receipt and log rejected specimens. • Worksheets should indicate date and time of testing and include the identity of the individual performing the test (initials, signature or electronically logged). • Instruments printouts maintained, if applicable.	**Requirement met?** ☐ Yes ☐ No **Notes:**
9.1.b	D5201 §493.1231	Does the laboratory ensure confidentiality of patient information throughout all phases of the total testing processes that are under its control?	• Controlled access of laboratory areas where patient info may easily be viewed in a hard copy format or electronically. • Required security awareness training for all employees. • Observe during walkthrough if patient reports are lying out in open view. • Staff access permissions forms, if applicable.	**Requirement met?** ☐ Yes ☐ No **Notes:**
9.1.c	D5203 §493.1232	Has the laboratory established and does it follow written policies and procedures that ensure positive identification and optimum integrity of patient samples from time of receipt through completion of testing and reporting of results?	• Policy/procedure to ensure compliance. • Unique identifiers to provide positive identification of specimens from accessioning through storage. • Observe during walkthrough how aliquots are labeled on the bench.	**Requirement met?** ☐ Yes ☐ No **Notes:**
9.1.d	D5205 §493.1233	Does the laboratory have a system in place to document all complaints and problems reported to the laboratory and does the laboratory conduct and document investigations of complaints, when appropriate?	• Log of communications and complaints including follow up and date closed, reviewed for trends of problems and corrective action taken (NCEs) • Policy and procedure on how to define and address complaints.	**Requirement met?** ☐ Yes ☐ No **Notes:**
9.1.e	D5207 §493.1234	Does the laboratory have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results?	Review communication logs, NCE logs and reports for problems that may be related to communication. *Example: Ongoing inquiries from submitters for clarification concerning appropriate specimen, proper collection, transport, etc.*	**Requirement met?** ☐ Yes ☐ No **Notes:**

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10. QUALITY ASSESSMENT & CORRECTIVE ACTION

10.1 Quality Assessment

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
10.1.a	D5291 §493.1239 (a)	**General Laboratory Systems** Has the laboratory established and does it follow written policies and procedures for an ongoing quality assessment mechanism to monitor, assess, continuously improve and, when indicated, correct problems identified in the general laboratory systems?	SOPs, quality metrics, internal audits, non-conforming events, corrective action reports. QA of general lab systems includes assessing practices/issues related to: • Patient confidentiality • Specimen identification and integrity • Complaint investigations • Communications • Personnel Competency • Proficiency testing performance	**Requirement met?** ☐ Yes ☐ No **Notes:**
10.1.b	D5391 §493.1249 (a)	**Pre-analytic Systems** Has the laboratory established and does it follow written policies and procedures for an ongoing quality assessment mechanism to monitor, assess, continuously improve and, when indicated, correct problems identified in the preanalytic systems?	SOPs, quality metrics, internal audits, non-conforming events, corrective action reports. QA of pre-analytic lab systems includes assessing practices/issues related to: • Test requests • Specimen submission • Specimen handling • Tracking of rejected specimens and reasons why • Verification of requisitions • Patient identifiers Does the laboratory track problems with incorrect or incomplete information on test requisitions?	**Requirement met?** ☐ Yes ☐ No **Notes:**
10.1.c	D5791 §493.1289 (a)	**Analytic Systems** Has the laboratory established and does it follow written policies and procedures for an ongoing quality assessment mechanism to monitor, assess, continuously improve and, when indicated, correct problems identified in the analytic systems?	SOPs, quality metrics, internal audits, non-conforming events, corrective action reports. QA of analytic lab systems includes assessing practices/issues related to: • Test procedures • Accurate and reliable test systems, equipment, instruments, reagents, materials and supplies • Specimen and reagent storage conditions • Equipment/instrument/test/system maintenance and function checks • Establishment and verification of method performance specifications • Calibration and calibration verification • Control procedures • Semiannual comparison of tests results for the same analyte • Corrective actions • Test records • Patient identifiers	**Requirement met?** ☐ Yes ☐ No **Notes:**

Table Key

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
10.1.d	D5891 §493.1299 (a)	**Post-analytic Systems** Has the laboratory established and does it follow written policies and procedures for an ongoing quality assessment mechanism to monitor, assess, continuously improve and, when indicated, correct problems identified in the post-analytic systems?	SOPs, quality metrics, internal audits, non-conforming events, corrective action reports. QA of post-analytic lab systems includes assessing practices/issues related to: • Accuracy and completeness • Turn-around time monitoring and notification • Notification for abnormal or panic values • Tracking corrected reports • Patient identifiers	**Requirement met?** ☐ Yes ☐ No **Notes:**
10.1.e	D5293 §493.1239 (b)	**General Laboratory Systems** Does the general laboratory systems quality assessment include a review of the following: • Effectiveness of corrective actions taken to resolve problems? • Effectiveness of revisions to policies and procedures to prevent recurrence of problems? • Discussion of general laboratory systems quality assessment reviews with appropriate staff?	• Management review or minutes from quality management meetings with staff. • Quality management reports. • Corrective action reports include actions to prevent recurrence of problem and plan to monitor effectiveness.	**Requirement met?** ☐ Yes ☐ No *Refer to 10.1.a-d.* **Notes:**
10.1.f	D5393 §493.1249 (b)	**Pre-analytic Systems** Does the pre-analytic systems quality assessment include a review of the following: • Effectiveness of corrective actions taken to resolve problems? • Effectiveness of revisions to policies and procedures to prevent recurrence of problems? • Discussion of general laboratory systems quality assessment reviews with appropriate staff?	• Management review or minutes from quality management meetings with staff. • Quality management reports. • Corrective action reports include actions to prevent recurrence of problem and plan to monitor effectiveness.	**Requirement met?** ☐ Yes ☐ No *Refer to 10.1.a-d.* **Notes:**
10.1.g	D5793 §493.1289 (b)	**Analytic Systems** Does the analytic systems quality assessment include a review of the following: • Effectiveness of corrective actions taken to resolve problems? • Effectiveness of revisions to policies and procedures to prevent recurrence of problems? • Discussion of general laboratory systems quality assessment reviews with appropriate staff?	• Management review or minutes from quality management meetings with staff. • Quality management reports. • Corrective action reports include actions to prevent recurrence of problem and plan to monitor effectiveness.	**Requirement met?** ☐ Yes ☐ No *Refer to 10.1.a-d.* **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
10.1.h	D5893 §493.1299 (b)	**Post-analytic Systems** Does the post-analytic systems quality assessment include a review of the following: • Effectiveness of corrective actions taken to resolve problems? • Effectiveness of revisions to policies and procedures to prevent recurrence of problems? • Discussion of general laboratory systems quality assessment reviews with appropriate staff?	• Management review or minutes from quality management meetings with staff. • Quality management reports. • Corrective action reports include actions to prevent recurrence of problem and plan to monitor effectiveness.	**Requirement met?** ☐ Yes ☐ No *Refer to 10.1.a-d.* **Notes:**
10.1.i	D5293 §493.1239 (c)	**General Laboratory Systems** Does the laboratory document all quality assessment activities for general laboratory systems?	Documented evidence includes: • Records generated per SOPs related to QA activities • Documentation of quality metrics • NCEs • Corrective action reports • Management review presentations or minutes from quality management meetings with staff • Quality management reports. Records must show evidence of management or supervisory review.	**Requirement met?** ☐ Yes ☐ No *Refer to 10.1.a-d.* **Notes:**
10.1.j	D5393 §493.1249 (c)	**Pre-analytic Systems** Does the laboratory document all quality assessment activities for pre-analytic systems?	Documented evidence includes: • Records generated per SOPs related to QA activities • Documentation of quality metrics • NCEs • Corrective action reports • Management review presentations or minutes from quality management meetings with staff • Quality management reports. Records must show evidence of management or supervisory review.	**Requirement met?** ☐ Yes ☐ No *Refer to 10.1.a-d.* **Notes:**
10.1.k	D5793 §493.1289 (c)	**Analytic Systems** Does the laboratory document all quality assessment activities for analytic systems?	Documented evidence includes: • Records generated per SOPs related to QA activities • Documentation of quality metrics • NCEs • Corrective action reports • Management review presentations or minutes from quality management meetings with staff • Quality management reports. Records must show evidence of management or supervisory review.	**Requirement met?** ☐ Yes ☐ No *Refer to 10.1.a-d.* **Notes:**

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#	SOM/CFR*	Requirement	Examples of Compliance	Notes
10.1.l	D5893 §493.1299 (c)	**Post-analytic Systems** Does the laboratory document all quality assessment activities for post-analytic systems?	Documented evidence includes: • Records generated per SOPs related to QA activities • Documentation of quality metrics • NCEs • Corrective action reports • Management review presentations or minutes from quality management meetings with staff • Quality management reports. Records must show evidence of management or supervisory review.	**Requirement met?** ☐ Yes ☐ No *Refer to 10.1.a-d.* **Notes:**
10.1.m	D3039 §493.1105 (a)(5)	**Record Retention:** Are quality assessment records retained for at least two years? *Note: Longer retention times might be in place for other state, local, federal regulations and must also be followed. The CLIA two-year rule must be followed at a minimum.*	Records available for two years. *Note: Check state requirements as applicable —go with most stringent.*	**Requirement met?** ☐ Yes ☐ No **Notes:**
10.1.n	D6094 §493.1445 (e)(5)	**Technical Supervisor Responsibility (Delegated by LD):** Does the technical supervisor ensure that QC and QA programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur?	• QA policies/procedures and records. • Competency assessment of the technical supervisor.	**Requirement met?** ☐ Yes ☐ No *See:* • *CLIA Personnel Review Worksheet Tool* • *Technical Supervisor Personnel Form* **Notes:**

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10.2 Corrective Action

#	SOM/CFR*	Requirement	Examples of Compliance	Notes
10.2.a	D5779 §493.1282 (a)	Has the laboratory established corrective action policies and procedures? Are the policies and procedures available and followed in a manner that ensures accurate and reliable patient test results and reports?	Nonconforming event (NCE) and corrective action procedure and records.	**Requirement met?** ☐ Yes ☐ No **Notes:**
10.2.b	D5781 §493.1282 (b)(1)	Does the laboratory document corrective actions taken when test systems do not meet the laboratory's verified/established performance specifications including: • Equipment or methodologies are performed outside of established operating parameters or performance specifications? • Patient test values are outside of the laboratory's reportable range for the test? • When the laboratory determines that the reference intervals for a test procedure are inappropriate for the laboratory's patient population?	NCE and corrective action reports show evidence the laboratory is monitoring and evaluating laboratory performance and the quality of services. NCE documentation should include all specifics to be able to trace the event. *Example: Temperature-controlled spaces, equipment and instruments must be monitored and results documented for acceptable temperature ranges. If corrective action is needed when acceptable temperature ranges are exceeded, the serial number should be included in the NCE.*	**Requirement met?** ☐ Yes ☐ No **Notes:**
10.2.c	D6178 §493.1495 (b)(4)	**Testing Personnel Responsibility:** Is there documented evidence that testing personnel follow the laboratory's established policies and procedures whenever test systems are not within established acceptable levels of performance?	Documentation of corrective action or NCE.	**Requirement met?** ☐ Yes ☐ No *See CLIA Personnel Review Worksheet Tool* **Notes:**
10.2.d	D6181 §493.1495 (b)(6)	**Testing Personnel Responsibility:** Do testing personnel document corrective actions taken when test systems deviate from established performance specifications?	Documentation of corrective action or NCE.	**Requirement met?** ☐ Yes ☐ No *See CLIA Personnel Review Worksheet Tool* **Notes:**
10.2.e	D5783 §493.1282 (b)(2)	Does the laboratory document corrective actions taken when results of control or calibration materials fail to meet established criteria for acceptability including: • Evaluation of all patient results obtained in the failed run and previous runs since the most recent acceptable run for acceptability? • The corrective action necessary to ensure the reporting of accurate and reliable patient test results?	NCE and corrective action procedure and records include: • Retrospective review of patient results from testing since the last time the system was known to be performing within specification • Issuing corrected patient results or contacting physicians to notify of potential error • Documentation of review with staff, including signatures, action items, follow-up checks for effectiveness and evidence of trend monitoring.	**Requirement met?** ☐ Yes ☐ No **Notes:**

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Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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