LOUISIANA DEPARTMENT OF HEALTH

CLIA 2025: Navigating New Regulations and Personnel Qualification

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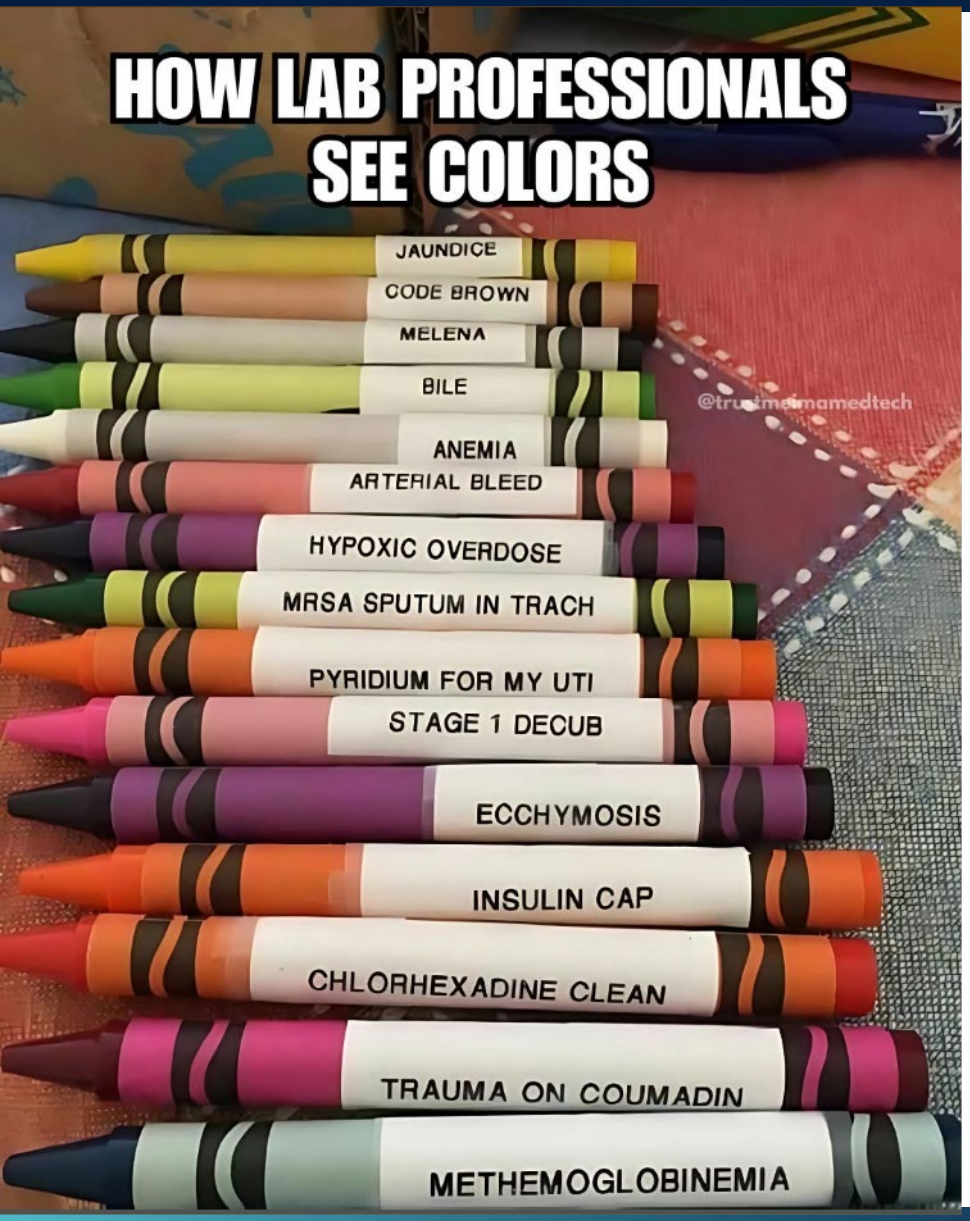
CLIA PROGRAM MANAGER


HOW LAB PROFESSIONALS SEE COLORS
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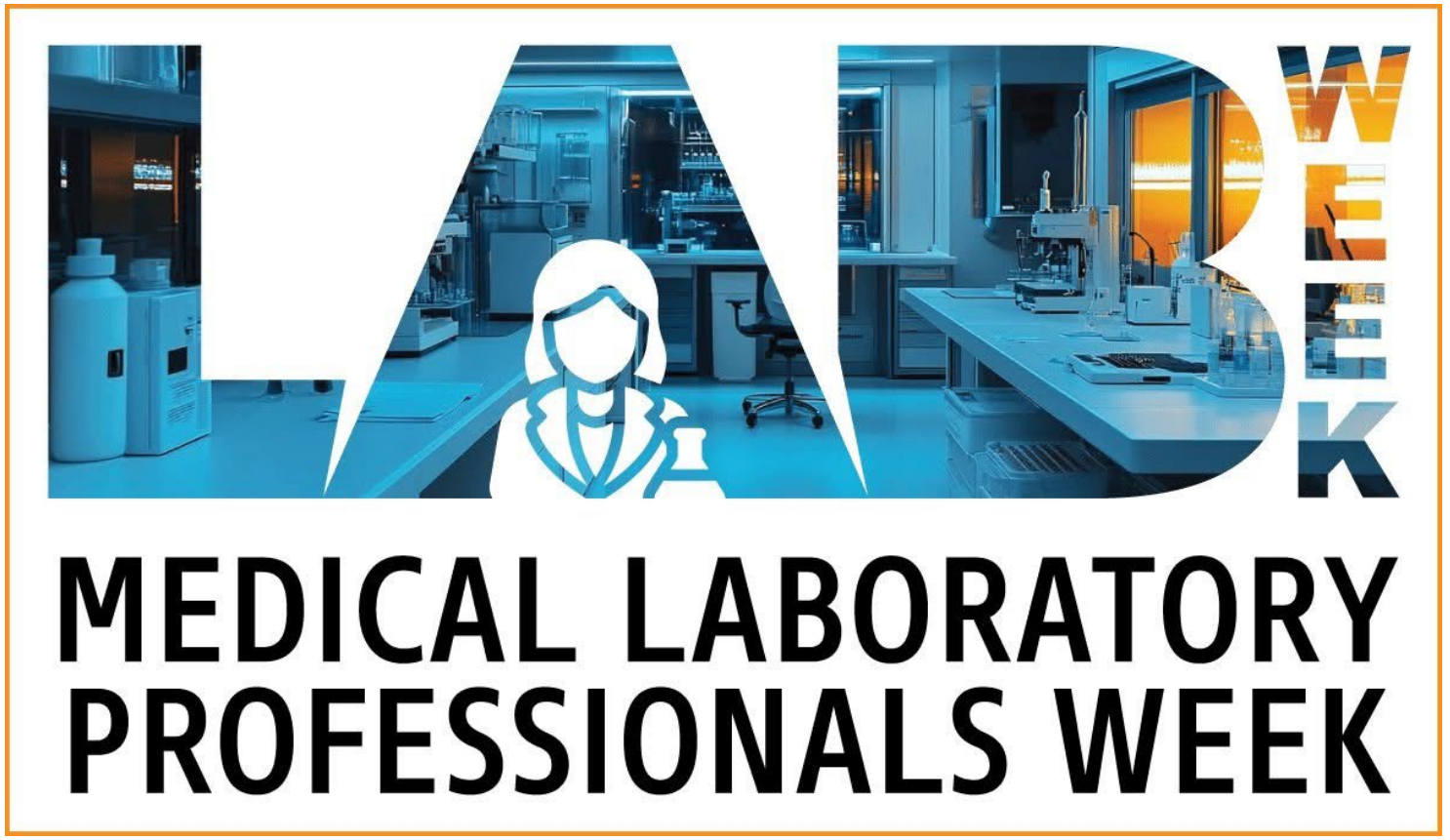
LAB WEEK
MEDICAL LABORATORY PROFESSIONALS WEEK

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Objectives

- Detail the CLIA personnel qualifications effective December 28, 2024
- Highlight regulatory changes throughout the new SOM
- Answer any regulatory and compliance related questions

Definitions applicable to Personnel Regulations

- **Continuing Education** (CE) credit hours: CME or CEUs must cover the applicable laboratory director responsibilities and be obtained prior to qualifying as a laboratory director
- **Doctoral degree**: earned post-baccalaureate degree with at least 3 years of graduate level study that includes research related to clinical laboratory testing or advanced study in CLS/MLS/MT
- **Experience directing or supervising**: director or supervisory experience must be obtained in a CLIA certified laboratory
- **Laboratory training:** training or experience must be obtained in a CLIA certified laboratory

Experience directing or supervising Laboratory training

Should **not** be self generated

- Letterhead from previous laboratory director
- Job Description or Delegation of Duties

Definitions applicable to Personnel Regulations

- **Midlevel practitioner:** nurse midwife, nurse practitioner, nurse anesthetist, clinical nurse specialist, or physician assistant licensed by the State
- **Grandfather:** allow individuals that are continuously employed to remain in their position after the effective date of December 28, 2024.

PPM Laboratory Director Responsibilities:

- Evaluate the competency of all testing personnel and ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently
  1. Direct observation
  2. Monitoring the recording and reporting of test results
  3. Review of test results or worksheets
  4. Assessment of test performance through testing internal blind testing or PT
  5. Assessment of problem-solving skills
- Evaluate and document the performance of individuals responsible for PPM testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations and documentation must be performed at least annually.

Laboratory Director, Moderate Complexity

1. Pathologist
2. MD/DO/DPM + 1 yr director or supervising moderate + 20 hr LD CE
3. Doctoral degree in chemical, biological or clinical laboratory science + board certification approved by HHS + 1 yr sup exp + 20 hr LD CE
4. Master's degree in chemical, biological or clinical lab science + 1 year experience in nonwaived testing + 1 yr supervising nonwaived testing + 20 hr LD CE
5. Bachelor's degree in chemical, biological or clinical lab science + 2 yr experience in non waived testing + 2 yr supervising nonwaived testing + 20 hr LD CE

Laboratory Director, onsite visit

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

Technical Consultant, Moderate Complexity

1. Pathologist
2. MD/DO/DPM + 1 yr in each specialty/subspecialty
3. Doctoral or Master's degree in chemical, biological or clinical laboratory science + 1 yr exp in each specialty/subspecialty
4. Bachelor's degree in chemical, biological or clinical lab science + 2 yr experience in each specialty/subspecialty
5. Associate degree in medical laboratory technology/science + 4 yr experience in each specialty/subspecialty

Blood Gas only:

- Bachelor's degree in respiratory therapy or cardiovascular technology + 2 yr experience of laboratory training or experience in blood gas analysis

Testing Personnel, Moderate Complexity

1. MD and/or DO
2. Doctoral, master's or bachelor degree in chemical, biological or clinical laboratory science or nursing degree
3. *equivalency doctoral, master's, bachelor pathways*
4. Associate degree in chemical, biological, clinical laboratory science or nursing
5. 50 weeks military medical lab course + Medical Lab Specialist (MLT)
6. High school diploma AND training
   - D6066 – 8 training components listed

Testing Personnel, Moderate Complexity Blood Gas ONLY

1. Any other testing personnel qualification
2. Bachelor's degree in respiratory therapy or cardiovascular technology + 1 yr of laboratory training or experience in blood gas analysis
3. Associate degree in pulmonary function + 2 yr of laboratory training or experience in blood gas analysis

Laboratory Director, High Complexity

1. Pathologist
2. MD/DO/DPM + 2 year director or supervising high complexity testing + 20 hr LD CE
3. Doctoral degree in chemical, biological or clinical laboratory science + board certification approved by HHS + 2 year clinical laboratory experience + 2 year supervising high complexity testing + 20 hr LD CE

Laboratory Director, High Complexity

Current approved board certifications:

- *ABB -American Board of Bioanalysis, ABB -Public Health Microbiology certification,*
- *ABCC -American Board of Clinical Chemistry,*
- *ABFT -American Board of Forensic Toxicology (limited to individuals with a doctoral degree)*,*
- *ACHI -American College of Histocompatibility and Immunogenetics (formerly known as American Board of Histocompatibility and Immunogenetics (ABHI)),*
- *ABMGG -American Board of Medical Genetics and Genomics (formerly ABMG American Board of Medical Genetics), ABMLI -American Board of Medical Laboratory Immunology,*
- *ABMM -American Board of Medical Microbiology, DMLI -Diplomate in Medical Laboratory Immunology, American Society for Clinical Pathology (ASCP) Board of Certification (BOC)*
- *NRCC -National Registry for Certified Chemists – Clinical Chemist or Toxicological Chemist certifications only (limited to individuals with a doctoral degree)*,*
- ***NOTE:** ABFT and NRCC also certify non-doctoral individuals; however, the director of high-complexity testing must have a doctoral degree.*

Laboratory Director, onsite visit

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

Technical Supervisor, High Complexity

Pathologist – Anatomic Pathology

Pathologist or Pathology Resident in final year – Cytology, Histopathology, Dermatopathology, Ophthalmic Pathology, Oral Pathology

MD/DO or Doctoral degree + 4 years experience (specialty specific) – Histocompatibility, Cytogenetics

Technical Supervisor, High Complexity

Microbiology*, Diagnostic Immunology, Chemistry, Hematology, Radiobioassay, Immunohematology

1. Pathologist
2. MD/DO/DPM + 1 year experience in each specialty
3. Doctoral degree in chemical, biological or clinical laboratory science + 1 year experience in each specialty
4. Master's degree in chemical, biological or clinical laboratory science + 2 year experience in each specialty
5. Bachelor's degree in chemical, biological or clinical lab science + 4 year experience in each specialty

*Microbiology: minimum of 6 months in each subspecialty

General Supervisor, High Complexity

1. Qualify as Laboratory Director for high complexity (§493.1443)
2. Qualify as Technical Supervisor for high complexity (§493.1449)
3. MD/DO/DPM, doctoral, master, or bachelor in chemical, biological or clinical laboratory science + 1 year experience in high complexity
4. Associate degree in chemical, biological or clinical laboratory science + 2 year experience in high complexity testing

For Blood Gas analysis:

1. Bachelor's degree in respiratory therapy or cardiovascular technology + 1 yr of laboratory training or experience in blood gas analysis
2. Associate degree in pulmonary function + 2 yr of laboratory training or experience in blood gas analysis

General Supervisor Responsibility (Competency)

Evaluating and documenting the competency of all testing personnel

The general supervisor in laboratories that perform high complexity testing can perform semi-annual and annual competency assessment on high complexity testing personnel.

The delegation of general supervisor responsibility must be in writing.

Testing Personnel, High Complexity

1. MD and/or DO
2. Doctoral, master's or bachelor degree in chemical, biological or clinical laboratory science
3. Associate degree in clinical laboratory science + 3 months laboratory training in each specialty
4. 50 weeks military medical lab course + Medical Lab Specialist (MLT)

Testing Personnel, High Complexity Blood Gas ONLY

1. Any other testing personnel qualification
2. Bachelor's degree in respiratory therapy or cardiovascular technology
3. Associate degree in pulmonary function

Grandfather throughout

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

Equivalency Pathways

1. Associate Degree
   - MLT: 60 semester hours; 24 semester hours of clinical laboratory science OR
   - 60 semester hours; 24 science hours: Six (6) chem, Six (6) bio, twelve (12) combo of chem, bio, clinical laboratory science
2. Bachelor's degree
   - 120 semester hours; 48 semester hours of clinical laboratory science OR
   - 120 semester hours; 48 semester hours of science:
     - Twelve (12) chem, Twelve (12) bio, Twenty four (24) combo chem, bio, CLS

Equivalency Pathways

3. Master's degree
   - Bachelor's degree + 16 additional graduate level semester hours in biology, chemistry, or clinical laboratory science + approved thesis or research project…
4. Doctoral degree
   - Doctoral degree in chemical, biological or clinical laboratory science OR
   - Earned doctoral degree + 16 doctoral level semester hours in biology, chemistry or clinical lab science OR
   - Earned doctoral degree + An approved thesis or research project in biology/chemistry/CLS/MLS/MT related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings;

Moderate Complexity must have:
(1) Director
(2) Clinical consultant
(3) Technical consultant

PERSONNEL QUALIFICATIONS FOR CMS FORM 1557

High Complexity must have:
(1) Director
(2) Clinical consultant
(3) Technical supervisor
(4) General supervisor

PERSONNEL: SHOW NUMBER OF PERSONS QUALIFIED UNDER EACH APPLICABLE REGULATORY SECTION

DIRECTOR- MODERATE COMPLEXITY **493.1405(a) License and** (b)(1) Pathologist (2) Doctor + 1yr exp. + 20 CEs (3) Doctoral* + board cert + 1yr sup. + 20 CEUs (4) MS* + 1yr exp. + 1yr sup. + 20 CEs (5) BS* + 2yr exp. + 2yr sup. + 20 CEs (6) LD continuous since 12/28/2024	**CLINICAL CONSULTANT- MODERATE COMPLEXITY** **493.1417 (a) License and** (a) LD §493.1405(b)(1), (2) or (3) (b) Doctor	**TECHNICAL CONSULTANT- MODERATE COMPLEXITY** **493.1411(a) License and** (b)(1) Pathologist (2) Doctor + 1yr exp. in the specialty (3) Doctoral/MS* + 1yr exp. in the specialty (4) BS* + 2yr exp. in the specialty (5) AS*- MLT + 4yr exp. in the specialty **Bld Gas** (b) (1-4) (6) BS Resp Therapy or Cardio Tech + 2yr exp. in blood gas analysis (7) TC continuous since 12/28/2024	**TEST PERSONNEL- MODERATE COMPLEXITY** **493.1423(a) License and** (b)(1-3) Doctor → BS* in science (4) Assoc. degree* in science, lab, nursing (5) High School/GED + Military lab (6) High School/GED + onsite training **Bld Gas** (7) Resp Therapy or Cardio Tech (7)(ii) BS Resp + 1yr exp. (7)(ii) AS Resp + 2yr exp. (8) TP continuous since 12/28/2024
DIRECTOR- HIGH COMPLEXITY **493.1443 (a) License and** (b)(1) Pathologist (2) Doctor + 2yr sup. + 20 CEs (3) Doctoral* + board cert + 2yr exp. + 2yr sup. + 20 CEs (4) LD continuous since 12/28/2024 (5) Oral Path – Path certification	**CLINICAL CONSULTANT- HIGH COMPLEXITY** **493.1455 (a) License and** (a) LD §493.1443 (b)(1),(2),(3) or (5-Oral Path) (b) Doctor	**TECHNICAL SUPERVISOR- HIGH COMPLEXITY** **493.1449 (a) License and** (b) Anatomic Path – Pathologist Path, Doctor+1, Doctoral +1, MS+2, BS+4: (d) Diag Immuno, Chem, Hem, Radiobio, Immunohem (c) Micro- 6 mnth/subspecialty Path/Resident/Doctor+board cert (e) Cytology (f) Histopath, Dermatopath, Ophthalmic (g) Oral Path Doctor or Doctoral+4, (h) Histocompat (i) Cytogen (j) LD continuous since 12/28/2024	**GENERAL SUPERVISOR- HIGH COMPLEXITY** **493.1461(a) License and** (b)(1) LD* under §493.1443 (b)(2) TS* under §493.1449 (c)(1) Doctor→ BS* + 1yr exp. (c)(2) TP under §493.1489(b)(3) +2yr exp. (c)(3) §493.1443(b)(3) or §493.1449(c)(4) or (5) (c)(4) GS continuous since 12/28/2024 (d)(1) For Bld Gas, Qual under (b)(1),(2) or (c) (d)(2) BS in Resp/Cardiac Therapy + 1yr exp. (d)(3) Assoc. in Pulmon.Function + 2yr exp.
TESTING PERSONNEL- HIGH COMPLEXITY 493.1489 (a) and (b)(1) Doctor → BS* in science (b)(3)(i) Assoc. degree* in lab (MLT) (b)(3)(ii) Assoc. degree* w/ 60 credit hours and (b)(3)(ii)(1) ABHES, CAAHEP training or (b)(3)(ii)(2) 3 mo. training in each specialty (b)(4) 50 week military Medical Lab Specialist (b)(5) TP continuous since 12/28/2024 (b)(6) For Bld Gas: Qual under §493.1489(b)(1),(2),(3),(4) or (5) + BS in Resp. Therapy or Cardio Tech, AA in Pulm Function (b)(7) For Histopath-Pathologist (microscopic) Gross exam – 1489 (b)(1-5) + TS w/in 24 hrs.	**CYTOTECHNOLOGIST-** **493.1483(a) License and** (b)(1) Cytotechnology School Grad (2) Certified in Cytotechnology (3) Cytotech continuous since 12/28/2024 **GENERAL SUPERVISOR – CYTOLOGY 493.1469(a)** (a) Qual under §493.1449(b) or (e) (b) Cytotech. + 3 yrs full-time exp. **TECHNICAL SUPERVISOR – CYTOLOGY 493.1449(a) and** (e) Pathologist (2) Path in training	***Equivalency*** Associate Degree MLT: 60 semester hours, 24 hours MLT; **or** 24 semester hours science: Six (6) chem, Six (6) bio, twelve (12) combo of chem, bio, MLT Bachelor's Degree: 120 semester hours, 48 hours of MLS; **or** 48 semester hours science: Twelve (12) chem, Twelve (12) bio, 24 combo chem, bio, MLS Master's Degree: BS + 16 semester hours of graduate level bio, chem, MLS + Thesis Doctoral Degree: Earned doctoral degree in chemical, biological or clinical laboratory science OR Hold earned doctoral degree + 16 semester hrs. of doctoral level coursework in bio, chem, MLS OR Hold earned doctoral degree + approved thesis or research project in *biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings* Doctor: MD, DO, DPM	

LD Director Quiz

What is a key requirement for all laboratory directors of moderate or high complexity laboratories, other than Pathologist?

How often must a laboratory director be on-site?

LD Director Quiz

What is a key requirement for all laboratory directors of moderate or high complexity laboratories, other than Pathologist?

20 hours of laboratory director continuing education (CE)

How often must a laboratory director be on-site?

At least once every six months

Supervisory Qualifications

What is the minimum qualification for a General Supervisor in a high complexity laboratory?

What is a minimum qualification of Technical Consultant for blood gas analysis only?

Supervisory Qualifications

What is the minimum qualification for a General Supervisor in a high complexity laboratory?

Associate degree in clinical laboratory science or equivalent and 2 year of experience in high-complexity testing

What is a minimum qualification of Technical Consultant for blood gas analysis only?

Bachelor's degree in respiratory therapy or cardiovascular technology with 2 year of lab training or experience

LOUISIANA DEPARTMENT OF HEALTH

Other Regulatory Changes

Estimated Glomerular Filtration Rate (eGFR)

Does the laboratory use the race-free equation for the estimated glomerular filtration rate (eGFR)?

Clinical Consultant (D6061 & D6139)

Has the clinical consultant reviewed the reports to ensure that the correct reference range is listed (i.e. the race-free equation is being used to calculate the estimated glomerular filtration rate (eGFR))?

Cybersecurity

D5201 *How does the laboratory ensure confidentiality of patient information for their Laboratory Information System (LIS)? For example, does the LIS require the authorized user to enter a user identification and password to access the patient records and LIS?*

D3041 *What is the laboratory's procedure for record retrieval when the information system is not functioning due to a security breach, change in system, or extended downtime?*

D5431 *The laboratory must follow the manufacturer's instructions for installing all software updates, including cybersecurity updates.*

D5801 *Laboratories must have current policies and procedures to remediate or mitigate vulnerabilities in electronic systems.*

D5891 *Laboratories should assess data security protocols as part of the laboratory's quality assessment.*

Electronic Signature

Secure or digital electronic signatures are acceptable. The electronic signature should have an electronic date/time stamp. If electronic signatures are being used, the laboratory should be able to show evidence that only the authorized person can utilize the electronic signature.

Quality Assessment

When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves **investigation**, identification, and resolution of the problem, **followed by** development of policies that will prevent recurrence.

The laboratory must:

- **Establish and/or revise written policies and procedures to prevent recurrence of the problems identified;**
- **Communicate the established and/or revised policies to the laboratory personnel and other staff, clients, etc., as appropriate; and**
- **Document that the established and/or revised policies and procedures to prevent recurrence have been followed.**

Over time, the laboratory must **document** monitoring of the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem.

Maintenance and Function Checks

(a)(1) The laboratory is responsible to ensure the performance of all manufacturer-required maintenance regardless of any service contract.

(a)(2) The laboratory must follow the manufacturer's instructions for installing all software updates, including cybersecurity updates.

Calibration and Calibration Verification

Laboratories must follow the manufacturer's instructions on carrying out the calibration and must follow or exceed the manufacturer's frequency recommendations for calibration. However, if a calibration system proves less stable than expected by the manufacturer, additional calibration materials and/or more frequent calibration may be required, as established or verified by the laboratory under §493.1253(b)(3).

Test Report

(a) *How does the laboratory ensure data safety for internal and external electronic communications?*

(c)(3) Test Report Date

If a preliminary result is generated, it must be clearly labeled and include the date of the preliminary report, to differentiate it from the final test result in the final report or in the electronic reporting system.

If a laboratory test order contains multiple tests and these tests are completed on different days, the report must show when each test was completed.

(c)(6) *How does the laboratory convey updates of the analysis and interpretation software to the individual ordering or using the test results?*

Electronic Communications

CMS is moving to *exclusively* electronic communications in March 2026

- All fee coupons and CLIA certificates will be received by email **only**, no longer issued by physical mail.
- CLIA laboratories should enroll in electronic communications prior to the March 2026 date
  - Email CLIA State Agency to enroll in electronic communications, including **Facility name**, **CLIA ID** and **email address** to be listed on file
  - Louisiana Laboratories: Alexa.Little@la.gov
  - Out of State Laboratories: State Agency Contact List

Links

SOM Chapter 6

LDH CLIA

QCOR - Laboratory Demographic Lookup (CLIA Certificate Access)

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