

# CLIA CORNER

State Hygienic Laboratory at The University of Iowa

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On 12/28/2024, the new Clinical Laboratory Improvement Amendments (CLIA) personnel regulations went into effect. In this edition of the CLIA Corner, we will review the CLIA qualifications for moderate complexity technical consultants and high complexity technical supervisors and their responsibilities. The updated CLIA regulations and interpretive guidelines can be found in the memo [QSO-25-10-CLIA REVISED](#).



## Moderate Complexity Technical Consultant Qualifications

The regulations for moderate complexity technical consultant qualifications include a few changes and additional pathways. To qualify as a moderate complexity technical consultant, individuals must meet one of the following:

1. Be a doctor of medicine (MD), doctor of osteopathy (DO) licensed to practice medicine or osteopathy in the State in which the laboratory is located; AND
  - Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology.
2. Be a MD, DO, or doctor of podiatric medicine (DPM) licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND
  - Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.
3. Hold an earned doctoral or master's degree in a chemical, biological, CLS, MLS, MT from an accredited institution; AND
  - Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

## Moderate Complexity Technical Consultant Qualifications, continued

4. **Hold an earned doctoral degree; AND**
  - Have at least 16 semester hours of *doctoral level coursework* in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); **AND**
  - Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.
5. **Hold an earned doctoral degree; AND**
  - Have an approved thesis or research project in biology/chemistry/MT/MLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; **AND**
  - Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.
6. **Meet bachelor's degree equivalency; AND**
  - Have at least 16 semester hours of additional *graduate level coursework* in biology, chemistry, MT, CLS or MLS; **AND**
  - Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.
7. **Meet bachelor's degree equivalency; AND**
  - Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, MT, CLS or MLS and an approved thesis or research project in biology/chemistry/MT/MLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; **AND**
  - Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.
8. **Have earned a bachelor's degree in a chemical, biological, CLS, MLS, or MT from an accredited institution; AND**
  - Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.
9. **Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes:**
  - 48 semester hours of MLS or medical laboratory technology (MLT) courses; **AND**
  - Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.
10. **Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes:**
  - 48 semester hours of science courses that include:
    - ⇒ 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; **and**
    - ⇒ 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; **and**
    - ⇒ 24 semester hours of chemistry, biology, MLS or MLT in any combination; **AND**
  - Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.



## Moderate Complexity Technical Consultant Qualifications, continued

11. Have earned an associate degree in medical laboratory technology (MLT), MLS, CLS; AND
  - Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.
12. An individual is considered qualified if they were qualified and serving as a technical consultant in a moderate complexity CLIA certified laboratory prior to 12/28/2024 and have done so continuously since 12/28/2024.

## High Complexity Technical Supervisor Qualifications



The regulations for high complexity technical supervisor qualifications have been updated and require personnel to be qualified under one of the following:

An individual with the following educational documentation is qualified as the technical supervisor for *all specialties and subspecialties*:

1. Doctor of medicine (MD), doctor of osteopathy (DO) licensed to practice medicine or osteopathy in the State in which the laboratory is located; AND
  - Be certified in both anatomic and clinical pathology, by the American Board of Pathology or the American Osteopathic Board of Pathology.

All other individuals must meet education and experience requirements for the specialties/subspecialties over which they will supervise to be qualified as the technical supervisor. We will focus on the most common specialties/subspecialties, which are divided as such:

(c) Specialty: Microbiology; Subspecialties: Bacteriology, Mycobacteriology, Mycology, Parasitology and Virology

(d) Specialties: Diagnostic Immunology, Chemistry, Hematology, Radiobioassay, and Immunohematology

Technical supervisors for specialties/subspecialties listed under (c) and/or (d) must be qualified under one of the following:

1. Be a MD, DO, or DPM licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND
  - (c) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty.
  - (d) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the applicable specialty.
2. Have earned doctoral degree in chemical, biological, CLS, MLS or MT; AND
  - (c) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty.
  - (d) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the applicable specialty.
3. Hold an earned doctoral degree; AND
  - Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); AND
    - (c) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty.
    - (d) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the applicable specialty.

## High Complexity Technical Supervisor Qualifications

### 4. Hold an earned doctoral degree; AND

- Have an approved thesis or research project in biology/chemistry/MT/MLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; AND

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

(d) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the applicable specialty.



### 5. Have earned a master's degree in a chemical, biological, CLS, MLS or MT from an accredited institution; AND

(c) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty.

(d) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty.

### 6. Meet bachelor's degree equivalency; AND

- Have at least 16 semester hours of additional graduate level coursework in biology, chemistry, MT, CLS or MLS; AND

(c) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty.

(d) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty.

### 7. Meet bachelor's degree equivalency; AND

- Have at least 16 semester hours in combination of graduate level coursework in biology/chemistry/MT/MLS/MLS; AND
- Have an approved thesis or research project in biology/chemistry/MT/MLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; AND

(c) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty.

(d) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty.



### 8. Have earned a bachelor's degree in a chemical, biological, CLS, MLS, or MT from an accredited institution; AND

(c) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty.

(d) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty.

## High Complexity Technical Supervisor Qualifications, continued

9. Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes:

- 48 semester hours of medical laboratory technology courses; AND

(c) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty.

(d) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty.



10. Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes:

- 48 semester hours of science courses that include:

⇒ 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; AND

⇒ 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; AND

⇒ 24 semester hours of chemistry, biology, MLS or MLT in any combination; AND

(c) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty.

(d) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty.

11. An individual is considered qualified if they were qualified and serving as a technical supervisor in a high complexity CLIA certified laboratory prior to 12/28/2024 and have done so continuously since 12/28/2024.

*For the specialties of cytology, histopathology, dermatopathology, ophthalmic pathology, oral pathology, histocompatibility, and clinical cytogenetics, see Subpart M of the CLIA regulations.*

## Technical Consultant and Technical Supervisor Responsibilities

The technical consultant (moderate complexity) and technical supervisor (high complexity) are responsible for the technical and scientific oversight of the laboratory. They are not required to be onsite at all times testing is performed; however, they must be available to the laboratory as needed to provide on-site, telephone, or electronic consultation as need for the following:

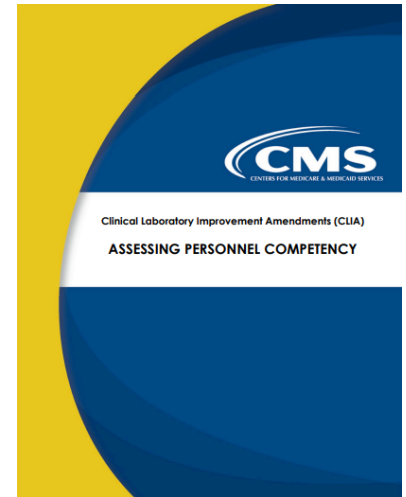
1. Selection of test methodology appropriate for the clinical use of the test results;
2. Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;
3. Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;
4. Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;
5. Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

## Technical Consultant and Technical Supervisor Responsibilities, continued

6. Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;
7. Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;
8. Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently;

***\*Refer to the [CMS CLIA Brochure: Assessing Personnel Competency](#) for additional requirements related to assessing personnel competency, including the 6 required elements of competency assessment.***

9. Evaluating and documenting the performance of individuals responsible for moderate (technical consultant) or high (technical supervisor) complexity testing at least semiannually during the first year the individual tests patient specimens; and
10. Performing competency assessment evaluations at least annually after the first year the individual tests patient specimens. If the test methodology or instrumentation changes, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.



## Delegation of Responsibilities to the Technical Consultant and Technical Supervisor

**The laboratory director may delegate to the technical consultant (moderate complexity) and technical supervisor (high complexity), in writing, the following responsibilities to ensure that:**



1. The test methodologies selected have the capability of providing the quality of results required for patient care;
2. Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;
3. Laboratory personnel are performing the test methods as required for accurate and reliable results;
4. The laboratory is enrolled in an HHS approved proficiency testing program for the testing performed;
5. Proficiency testing samples are tested as required under subpart H of this part;
6. Proficiency testing results are returned within the timeframes established by the proficiency testing program;
7. All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;
8. An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;
9. Quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;
10. The laboratory establishes and maintains acceptable levels of analytical performance for each test system;
11. All necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that patient test results are reported only when the system is functioning properly;

## Delegation of Responsibilities to the Technical Consultant and Technical Supervisor, continued

12. Prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;
13. Policies and procedures are established for monitoring individuals who conduct preanalytical, 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, and whenever necessary, identify needs for remedial training or continuing education to improve skills; and
14. An approved procedure manual is available to all personnel responsible for any aspect of the testing process.

### REMINDER: Electronic Notifications Required for ALL Certificates by March 1, 2026

The Centers for Medicare and Medicaid Services (CMS) is improving the Clinical Laboratory Improvement Amendments (CLIA) program by switching to electronic fee coupons and CLIA certificates. By March 1, 2026, laboratories and providers that perform laboratory testing must switch to email notifications to start receiving electronic CLIA fee coupons and certificates. After this date, CMS will no longer send through the mail:

- Paper fee coupons
- Paper certificates

Laboratories must send **written notification** to their [State Agency](#) to opt into electronic notifications. This can be done by completing and submitting a [CMS-116 CLIA Application form](#) or by sending an email. **PREFERRED FOR THE STATE OF IOWA: When sending an email, please include the laboratory's CLIA ID, email address to which all electronic notifications must be sent, and a statement indicating intent to enroll in electronic notifications.**

**NOTE:** The current database utilized by all state agencies does not allow for the input of more than one email address for all notifications and contact information. It is recommended that laboratories submit an email address that can be accessed by more than one individual. For example, the Iowa State Agency office email address is SHL-CLIA@uiowa.edu. All emails sent to this address reach both Kristi and Melinda, and whoever is available responds to the email. If one of the two should leave their position, the other will still receive all emails sent to the email address.



Electronic notifications from CMS will arrive from the following email address: [noreply-cms-ccsq@ccsq.cms.hhs.gov](mailto:noreply-cms-ccsq@ccsq.cms.hhs.gov). After the State Agency opts a laboratory into receiving electronic notifications, the designated email address will receive a welcome email from CMS within a few days. Many laboratories already enrolled have reported that emails from this address have been found in junk, clutter, and spam folders. There have also been reports of organization firewalls blocking the CMS email address. It is highly recommended that laboratories reach out to their Information Technology (IT) department to ensure the CMS email address is flagged as "safe." Be sure to search all folders and contact your IT department before contacting the State Agency.



If you would like to be added to the CLIA Corner Google Group,  
send an email to Kristi Rotzoll & Melinda Bochmann: [SHL-CLIA@uiowa.edu](mailto:SHL-CLIA@uiowa.edu)