

CLIA CORNER

State Hygienic Laboratory at The University of Iowa

First Quarter 2026

In This Issue...

- Moderate and high complexity laboratory testing personnel qualifications;
- Moderate and high complexity laboratory testing personnel responsibilities; and
- Electronic payment process, effective 3/1/2026.

On 12/28/2024, the new Clinical Laboratory Improvement Amendments (CLIA) personnel regulations took effect. In this edition of the CLIA Corner, we are going to review the CLIA qualifications and responsibilities for moderate and high complexity laboratory testing personnel. The new CLIA regulations can be found on the CMS website at [SOM-Appendix C](#).

Moderate Complexity Testing Personnel

With the updated CLIA personnel regulations and interpretive guidelines, there are now 9 pathways for an individual to qualify as moderate complexity testing personnel:

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; or
2. Have earned a doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution, or
3. Have earned a master's in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution, or
4. Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution, or
5. Meet the requirements in § 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or b(5)(i)(B), or



These are the qualifications for the moderate complexity laboratory director that use semester credit hours to qualify an individual, see [CLIA Corner First Quarter 2025](#)

6. Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution, or
7. Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or



Moderate Complexity Testing Personnel, continued:

8. Have earned a high school diploma or equivalent; and

Have documentation of laboratory training appropriate for the testing performed **prior** to analyzing patient specimens. Such training must ensure that the individual has the skills required for:

- Proper specimen collection, including patient preparation (if applicable), labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens;
- Implementing all standard laboratory procedures;
- Performing each test method and for proper instrument use;
- Performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;
- A working knowledge of reagent stability and storage;
- Implement the quality control policies and procedures of the laboratory;
- An awareness of the factors that influence test results; and
- Assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.




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

High Complexity Testing Personnel

With the updated CLIA personnel regulations and interpretive guidelines, there are now 9 pathways for an individual to qualify as a moderate complexity testing personnel:

1. **Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or**
2. **Have earned a doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution, or**
3. **Have earned a master's in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution, or**
4. **Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution, or**
5. **Meet the requirements in § 493.1443(b)(3) or § 493.1449(c)(4) or (5)**



 These are the qualifications for the high complexity laboratory director and technical supervisor that use semester credit hours to qualify an individual, see [CLIA Corner First Quarter 2025](#) and [CLIA Corner Fourth Quarter 2025](#)

High Complexity Testing Personnel, continued:

6. Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited laboratory; or
7. Have education and training equivalent to that of a doctoral, master's, or bachelor's degree with:
 - ➔ At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes:
 - 24 semester hours of medical laboratory technology courses; or
 - 6 semester hours of chemistry; and
 - 6 semester hours of biology; and
 - 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and
 - ➔ Have training that includes:
 - Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP; or
 - At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or
8. Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or
9. Notwithstanding any other provision of this section, an individual is considered qualified as a testing personnel under this section if they were qualified and serving as a testing personnel for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

What documentation is required to qualify military personnel?

An individual wishing to qualify under the military qualifications must present their military discharge paperwork. The DD Form 214 (military discharge form) will reflect the occupational specialty and includes weeks of training. The occupational specialty must be related to the laboratory and must be at least 50 weeks long.



Does a nursing degree qualify an individual to perform high complexity testing?

An individual with a bachelor's or associate's degree is qualified to perform moderate complexity testing. However, a bachelor's degree in nursing **DOES NOT** automatically qualify an individual to perform high complexity testing. An individual with a nursing degree will need to meet the personnel requirements with the appropriate science coursework semester hours in order to qualify to perform high complexity testing. **EXCEPTION:** Individuals with a Bachelor of Nursing degree may qualify as testing personnel for high complexity glucometer testing only. If there are questions, send the individual's transcript to the CLIA State Agency where the individual will be employed for review.

Moderate and High Complexity Testing Personnel Responsibilities

The responsibilities are the same for both moderate and high complexity testing personnel and include:



1. Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;
2. Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;

Moderate and High Complexity Testing Personnel Responsibilities, continued:

3. Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;
4. Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;
5. Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, technical supervisor, general supervisor, clinical consultant, or director; and
6. Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.



REMINDER: Electronic Notifications Required for ALL certificates, effective March 1, 2026

Effective 3/1/2026, all CLIA renewal fees and certificates will be sent via email. If there is a change in your email contact, it is VERY important to notify your State Agency. For certificates of waiver, provider performed microscopy and accreditation, the renewal fees are mailed six months prior to the expiration date of the current CLIA certificate. For certificates of compliance, the CLIA compliance fee is sent one year prior to the current expiration date, which must be paid prior to completion of the survey. Once the survey has been completed, a certificate fee is sent to the facility. **THERE MUST BE AN ACTIVE EMAIL ADDRESS IN THE CMS DATABASE OR THESE BILLS WILL NOT BE RECEIVED AND THE CERTIFICATE WILL EVENTUALLY BE TERMINATED FOR NON-PAYMENT.** CMS sends a welcome email from noreply-cms-ccsq@ccsq.cms.hhs.gov as confirmation of enrollment for electronic notifications. If you have questions regarding electronic notifications, contact your State Agency.



Electronic Payments Only

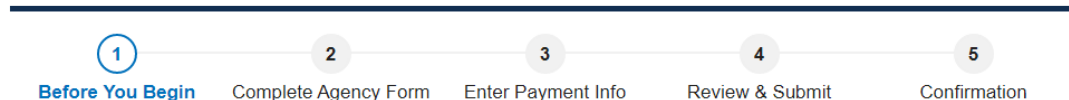
Effective 3/1/2026, CMS will only be accepting electronic payments for CLIA certificates, this includes credit card and electronic bank account (ACH) payments. Paper checks will no longer be accepted. CMS is terminating the lockbox that processes paper checks; all checks received will be returned to the sender. Please be sure your accounting department is aware of this change. Here are the steps for submitting payment online:

1. Go to the CLIA website: [Clinical Laboratory Improvement Amendments \(CLIA\) | CMS](#)
2. Click on the blue box that says "Pay CLIA fees Online".



3. Review Instructions and then click "Continue to the Form".

CLIA Laboratory User Fees



About this form

Use this form to pay your CLIA fees.

Accepted Payment Methods:

- Bank account (ACH)
- Debit or credit card

[Preview Form](#) [Cancel](#)



[Continue to the Form](#)

NEW: Electronic Payments, continued:

- Fill out each of the required blanks, the CLIA identification number and payment amount can be found on the Coupon Fee, then click **“Continue”**.
- Choose payment method and click **“Next”**.

Payment Information

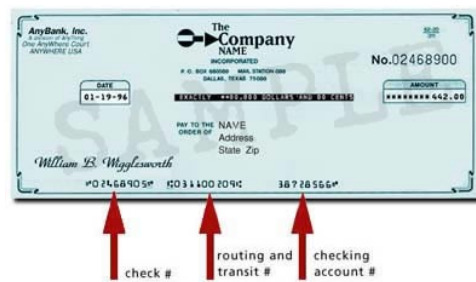
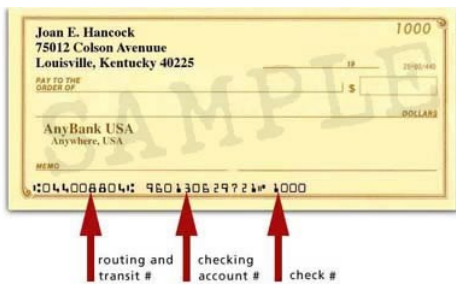
Payment Amount \$180.00

* I want to pay with my

Bank account (ACH)

Debit or credit card

- Fill in credit card or ACH payment information. If submitting payment using ACH method the routing number and account number can be found on your current check.



- Review demographic and payment information and then confirm payment.
- Once payment is posted, the new certificate will be emailed to the contact listed in the CMS database. All certificates are mailed approximately one month prior to the current certificate’s expiration date.



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