IOWA | State Hygienic Laboratory

CLIA CORNER

State Hygienic Laboratory at The University of Iowa Second Quarter 2025

In This Issue…

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 and high complexity clinical consultants and high complexity general supervisors. The updated CLIA regulations and interpretive guidelines can be found in the memo QSO-25-10-CLIA.

Moderate Complexity Clinical Consultant Qualifications

The regulations for moderate complexity clinical consultant qualifications did not change with the CLIA personnel updates, however, the regulatory reference did change to reflect the updates made to the laboratory director qualifications for moderate complexity testing. There is no grandfather clause. To qualify as a moderate complexity clinical consultant, individuals must meet one of the following:

1. **Be qualified as a laboratory director under *493.1405(b)(1), (2), or (3); OR**

    * **493.1405(b)(1)**: MD or DO licensed to practice medicine in the State in which the laboratory is located **AND** Board certification in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology
    * **493.1405(b)(2)**: MD, DO, or DPM licensed to practice medicine in the State in which the laboratory is located **AND** Have at least 1 year directing or supervising non-waived testing **AND** Have at least 20 continuing education (CE) credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1407

    * **493.1405(b)(3)**: Hold an earned doctoral degree with additional requirements (*refer to CLIA Corner First Quarter 2025 for additional details about the doctoral degree pathways*)

2. **Be a doctor of medicine (MD), doctor of osteopathy (DO) or doctor of podiatric medicine (DPM) and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.**

High Complexity Clinical Consultant Qualifications

Again, the regulations for high complexity clinical consultant qualifications did not change with the CLIA personnel updates, but the regulatory reference changed to reflect the updates made to the laboratory director qualifications for high complexity testing. There is no grandfather clause. To qualify as a high complexity clinical consultant, individuals must meet one of the following:

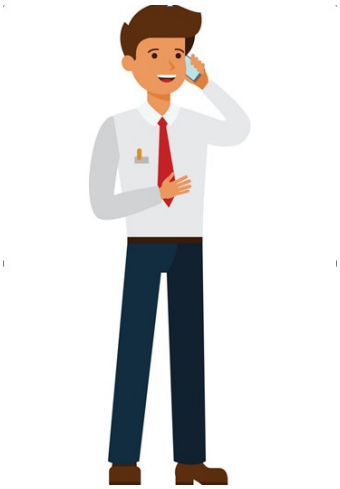
1. **Be qualified as a laboratory director under *493.1443(b)(1), (2), or (3) or, for the subspecialty of oral pathology, 493.1443(b)(5); OR**

    - **493.1443(b)(1)**: MD or DO licensed to practice medicine in the State in which the laboratory is located **AND** Board certification in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology
    - **493.1443(b)(2)**: MD, DO, or DPM licensed to practice medicine in the State in which the laboratory is located **AND** Have at least 2 years of experience directing or supervising high complexity testing **AND** Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1445
    - **493.1443(b)(3)**: Hold an earned doctoral degree with additional requirements (*refer to **CLIA Corner First Quarter 2025** for additional details about the doctoral degree pathways)*
    - **493.1443(b)(5)**: For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology.

2. **Be a MD, DO or DPM and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.**

Moderate and High Complexity Clinical Consultant Responsibilities

The responsibilities are the same for both moderate and high complexity clinical consultants and include:



1. Consultation regarding the appropriateness of the testing ordered and interpretation of test results;
2. Availability to provide clinical consultation to the laboratory's clients;
3. Availability to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;
4. Ensuring that reports of test results include pertinent information required for specific patient interpretation; and
5. Ensuring that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

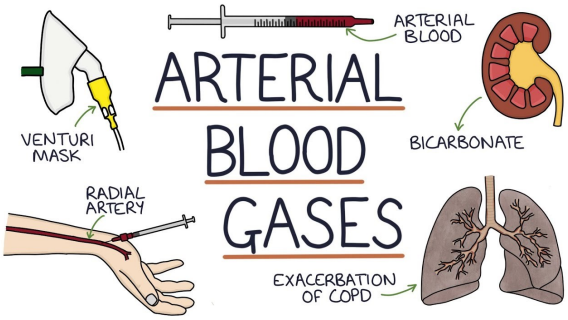
General Supervisor Qualifications

Laboratories performing high complexity testing must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provide day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. To qualify as a general supervisor, individuals must meet one of the following:

1. **Laboratory director under *493.1443; OR**
    - *Refer to **CLIA Corner First Quarter 2025** for high complexity laboratory director qualifications*
2. **Technical supervisor under *493.1449; OR**
    - *Technical supervisor qualifications will be discussed in a later issue of the CLIA Corner; refer to pages 333-341 of the CMS memo **QSO-25-10-CLIA**.*
3. **Be a MD, DO, or 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 high complexity testing; OR**
4. **Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; AND**
    - **Have at least 1 year of laboratory training or experience, or both, in high complexity testing; OR**
5. **Qualify as testing personnel under *493.1489(b)(3); AND**
    - *Testing personnel qualifications will be discussed in a later issue of the CLIA Corner; refer to pages 359-362 of the CMS memo **QSO-25-10-CLIA**.*
    - **Have at least 2 years of laboratory training or experience, or both, in high complexity testing; OR**
6. **Meet the requirements at *493.1443(b)(3) or *493.1449(c)(4) or (5); OR**
    - *Refer to **CLIA Corner First Quarter 2025** for high complexity laboratory director qualifications and pages 333-341 of the CMS memo **QSO-25-10-CLIA** for technical supervisor qualifications.*
7. **Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.**

Other General Supervisor Qualifications

For blood gas analysis, individuals must meet one of the following:



1. **Be qualified as a general supervisor as previously detailed; OR**
2. **Have earned a bachelor's degree in respiratory therapy or cardio-vascular technology from an accredited institution; AND**
    - **Have at least one year of laboratory training or experience, or both, in blood gas analysis; OR**
3. **Have earned an associate degree related to pulmonary function from an accredited institution; AND**
    - **Have at least two years of training or experience, or both in blood gas analysis**

For histopathology, dermatopathology, ophthalmic pathology, and oral pathology, individuals must meet the following:

Histopathology- an individual qualified as a technical supervisor under ***493.1449(b) or (f)(1);

Dermatopathology- an individual qualified as a technical supervisor under ***493.1449(b) or (f)(2);

Ophthalmic pathology- an individual qualified as a technical supervisor under ***493.1449(b) (f)(3);

Oral pathology- an individual qualified as a technical supervisor under ***493.1449(b) or (g).

* *Technical supervisor qualifications will be discussed in a later issue of the CLIA Corner; refer to pages 333-341 of the CMS memo **QSO-25-10-CLIA**.*

General Supervisor Responsibilities

Individuals fulfilling the general supervisor role are responsible for the following:

1. Must be 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;
2. Is responsible for providing day-to-day supervision of high complexity test performance by testing personnel;
3. Must be onsite to provide direct supervision when high complexity testing is performed by any individuals qualified under the grandfather clause for high complexity testing personnel; and
4. Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

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

Delegation of Responsibilities to the General Supervisor

The director or technical supervisor may delegate to the general supervisor, ***in writing***, the following responsibilities:

1. Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

2. Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;

3. Providing orientation to all testing personnel; and

4. Evaluating and documenting the competency of all testing personnel, including semi-annual and annual competency assessment on high complexity testing personnel.

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. If 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. 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.

Changes to CLIA Fees & Certificates

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.

Laboratories have until March 1, 2026, to receive:

- Email notifications from CMS
- Electronic Fee Coupons
- Electronic CLIA certificates

Certificates will be sent to your laboratory's email address.

Timeline

May 2025 – February 2026
All laboratories should update their email address with their State Agency

March 1, 2026
CMS will no longer mail paper fee coupons or issue paper certificates

March–May 2026
CMS and State Agencies will work with laboratories who missed the deadline

Reach out to your State Agency for assistance.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Changes to CLIA Fees & Certificates

What's Changing with CLIA Fees & Certificates

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. Laboratories have until **March 1, 2026**, to switch to CMS email notifications and begin receiving electronic CLIA fee coupons and certificates. After this date, paper fee coupons and CLIA certificates will no longer be available.

Benefits to Going Paperless

When your laboratory switches to electronic notifications, you will receive:

- **Email notifications from CMS** - including important CLIA updates.
- **Electronic Fee Coupons*** - your laboratory will no longer receive paper coupons. In addition, you can pay your CLIA certification fees via Pay.gov, a secure online platform. Your payment gets processed overnight – a faster way to pay!
- **Electronic CLIA Certificates*** - no need to wait for it to come in the mail. Certificates will be sent to your laboratory's email address.

**This does not apply to CLIA exempt states or state licensure.*

How to Switch

To switch to electronic notifications or to update your email address, you must:

- Provide written notification to your State Agency by email.

-OR-

- Fill out the CMS-116 application form. To switch, check the box, "Receive notifications including electronic certificates via email."

Tip: Make sure CMS has your laboratory's **most up-to-date email address** on file so you get important CLIA updates and information. CMS recommends using a business email address, or one that many staffers can access and use.

Timeline

May 2025 – February 2026

All laboratories should update their email address with their State Agency and switch to electronic notifications to receive:

- email notifications from CMS
- electronic fee coupons
- electronic CLIA certificates

March 1, 2026

CMS will no longer mail paper fee coupons or issue paper certificates

March–May 2026

CMS and State Agencies will work with laboratories who missed the deadline

Resources

- Reach out to your State Agency for help switching to paperless
- Fact sheet on paying CLIA fees on Pay.gov
- Visit CMS.gov to learn more

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