



CMS Update



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**CLIAC
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Disclaimer

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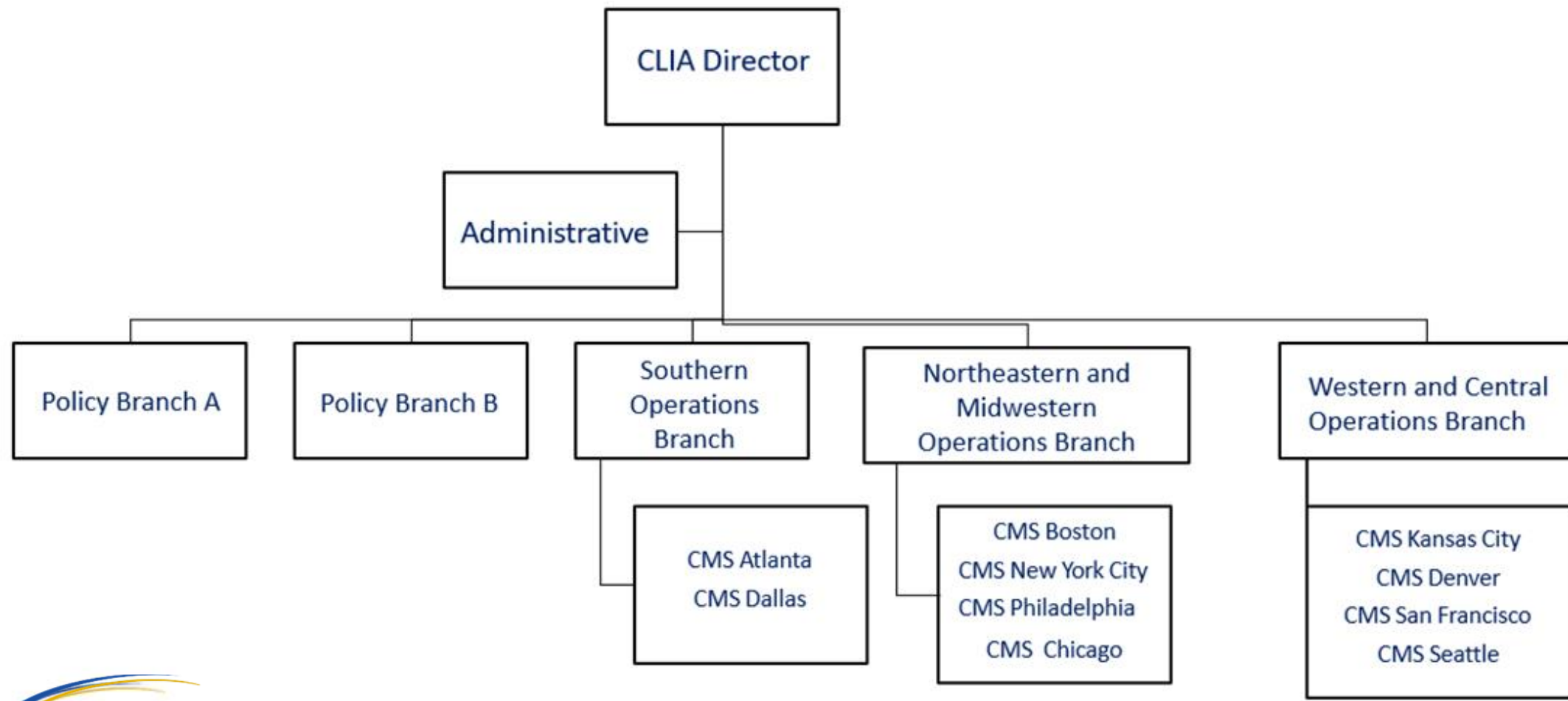
This publication is a general summary that explains certain aspects of the Clinical Laboratory Improvement Amendments (CLIA) Program, but is not a legal document. The official CLIA Program provisions are contained in the relevant laws, regulations, and rulings. Links to the source documents have been provided within the document for your reference.

The Centers for Medicare & Medicaid Services (CMS) employees, agents, and staff make no representation, warranty, or guarantee that this compilation of CLIA information is error-free and will bear no responsibility or liability for the results or consequences of the use of this guide.

Overview

- CLIA Division organization
- CLIA Priorities
- CLIA Statistics
- Flexibilities
- Additional Updates
- Specific Guidance/Tools

DCLIQ Organization Chart



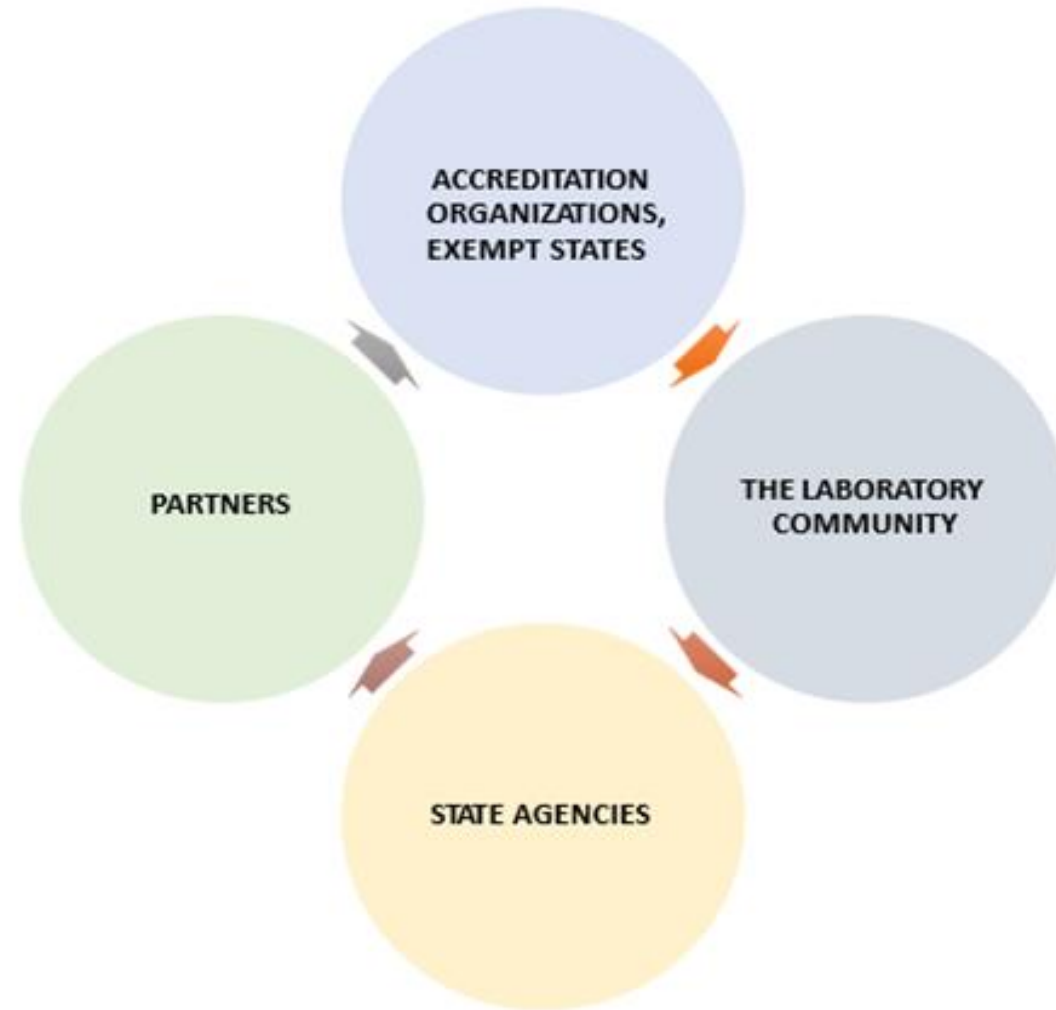
Survey Consistency

- Maintain a strong and effective survey program
- Maximize operational efficiencies across the nation
- Collaborate with our State Agencies, Accreditation Organizations, and Exempt States

Stakeholder Engagement

- Increase outreach activities with stakeholders
- Strengthen stakeholder engagement and program accountability
- Improving awareness and compliance with CLIA regulations and guidance

Stakeholder and Partner Engagement



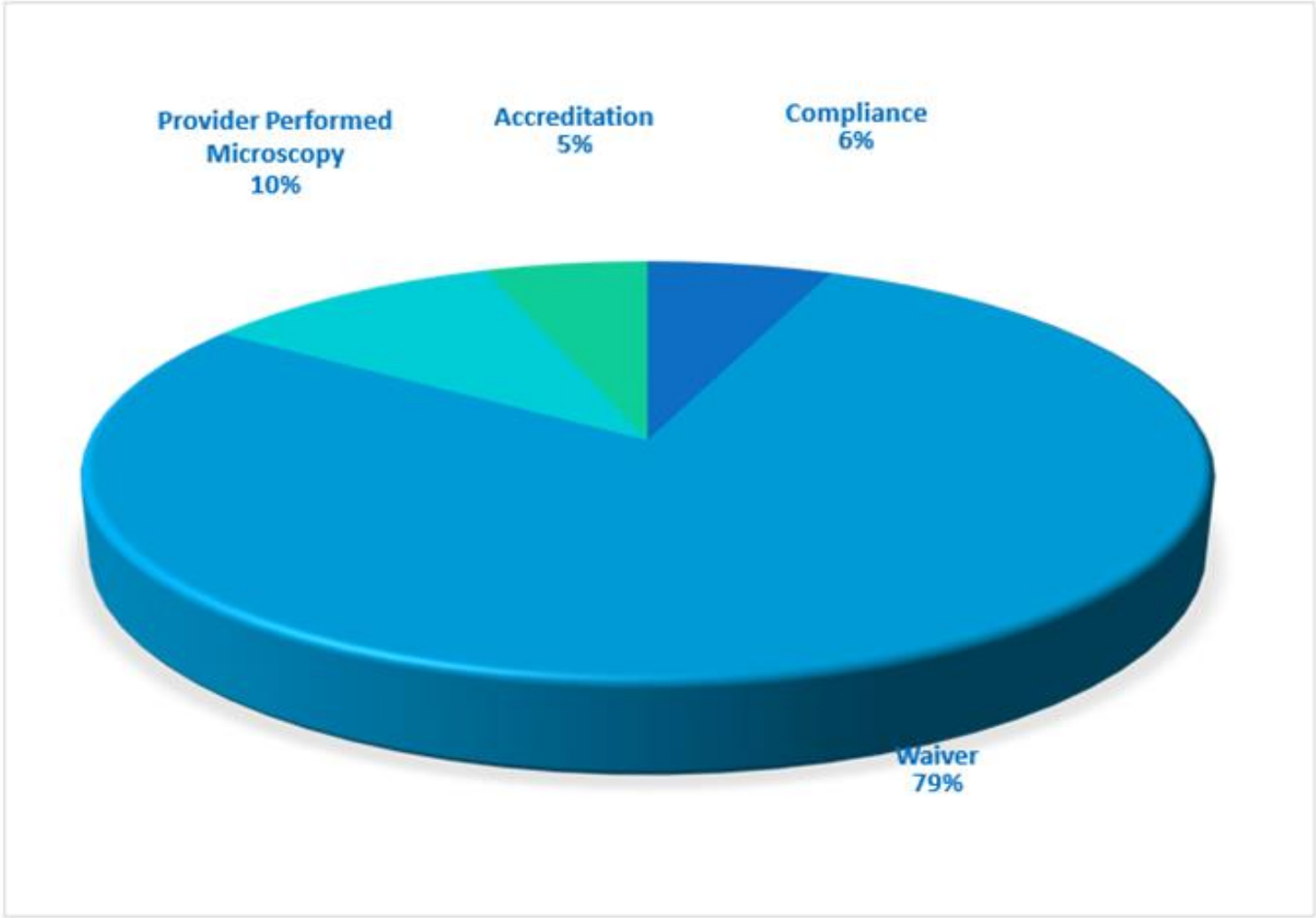
Current Statistics – Enrollment

Total Number of CLIA Laboratories	323,086
Total Exempt States (NY & WA)	12,956
Total Non-Exempt	310,130
• Certificate of Waiver	246,358
• Provider Performed Microscopy	29,759
• Certificate of Compliance	18,060
• Certificate of Accreditation	15,953

Source: CMS database – January 2022

Certificate Type by Percent of Total

CLIA LABORATORIES BY CLIA CERTIFICATE TYPE



Current Laboratory Enrollment Since March 2020

Laboratory Types	Number of Laboratories Enrolled Since March 2020
Total Number of Laboratories Enrolled	62,110
Certificate of Waiver	57,525
Physician Office Laboratories	15,233
Pharmacy Laboratories	9,628
Assisted Living facilities	6,079
Nursing Facilities/Skilled Nursing Facilities	603
Home Health Agencies	1,946
CMS Database January 2022	

Flexibilities during the Public Health Emergency (PHE)

- Remote review of clinical laboratory data, results and pathology slides
- Expedited review of CLIA applications
- Pooled Sample Testing
- Surveillance Testing
- Expired Reagents

Link: [CMS Emergencies Page](#)

CLIA Workgroups

- Regulatory Assessment Workgroup - total testing process
- Certificate of Waiver/Provider Performed Microscopy
- NGS

Regulatory, *Federal Register* Notice Update

- **1/19/2022** – Extension published in *Federal Register* to allow CMS to publish the PT final rule after 2/4/2022
- **3/7/2022** – *Federal Register* notice published adding the specialty of pathology for COLA

Resource for upcoming rules:

- Unified Agenda of Regulatory and Deregulatory Actions
- Select Agency: Department of Health and Human Services
- Organization: CMS
- <https://resources.regulations.gov/public/custom/jsp/navigation/main.jsp>

CLIA SARS-CoV-2 Test Result Reporting Requirement

- Only assessing if a laboratory has reported, or attempted to report, the test results
- Laboratory needs to have documentation of reporting or attempting to report the results
- Compliance with The HHS Secretary's Guidance and CDC guidance does not fall under CLIA oversight
- CLIA surveyor guidance being updated

COVID-19 Inquiries

- Team that triages and responds to all COVID-19 inquiries
- Received > 4900 inquiries since January 2020
 - ✓ CLIA applicability/applications
 - ✓ Travel
- Average turnaround time 24-48 hours

Survey Prioritization, Certificate Extensions

- Guidance to surveyors
 - ✓ Fully resume and prioritize CLIA survey activities to include on-site surveys
 - ✓ Enforcement actions
 - ✓ Proficiency testing review
- Continue to evaluate the need to extend expiration dates of certificates on a case-by-case basis
- Survey Prioritization Policy Memo, 3/22/2022: [QSO-22-14-CLIA](#)

Temporary Testing Sites Guidance and Tools

- Policy Memo, CLIA Guidance for Temporary Testing Sites under the Multiple Site Exception, 2/28/2022: [QSO-22-13-CLIA](#)
- [Consumer Complaints FAQ](#)
- [Temporary COVID-19 Testing Sites Infographic](#)

Consumer Complaints FAQ

- What is CLIA?
- What can a CLIA complaint include?
- Who can file a complaint?
- How do I file a complaint?
- What information should I give when filing a complaint?
- Do I have to give my contact information?
- Can I stay anonymous if i give my contact information?
- What happens after I file a complaint?
- Where can I find additional information about CLIA?

Consumer Complaints FAQ, Screenshot

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA): CONSUMER COMPLAINTS FAQ

WHAT IS CLIA?

The Centers for Medicare & Medicaid Services (CMS) regulates all clinical laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). Congress passed CLIA in 1988 to establish quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results no matter where the test is performed.

WHAT CAN A CLIA COMPLAINT INCLUDE?

CLIA requirements apply specifically to laboratory testing. You can submit a complaint if you have concerns about the quality of laboratory testing.

A CLIA complaint can include any concern about a laboratory's operation, such as:

- Unlabeled specimens
- Record falsification
- Confidentiality of patient information
- Unqualified staff
- Missing or incorrect test results

This is not a comprehensive list and only includes examples of some of the most common types of complaints.

Temporary COVID-19 Testing Sites Infographic

- Provides consumers information about laboratory quality and safety
 - ✓ Personal, medical, financial information
 - ✓ Personnel
 - ✓ Complaints
 - ✓ Fraud
- Collaboration of several CMS areas, including CLIA

Temporary COVID-19 Testing Sites Infographic, Screenshot

TEMPORARY COVID-19 TESTING SITES: ASSURING LABORATORY QUALITY & SAFETY



BE MINDFUL WHEN VISITING COVID-19 TESTING SITES. Fraudsters are attempting to obtain your personal and medical information, including your Medicare number. The personal information collected can be used to fraudulently bill federal health care programs and commit medical identity theft. Visit hhs.gov/coronavirus/testing/index.html for a list of available testing sites.



WHEN VISITING A TESTING SITE, be observant and make sure testing personnel are wearing appropriate protective equipment (i.e., gloves, masks).



IF THIS IS A RAPID TEST, results of the test must be evaluated within the timeframe stated in the manufacturer's instructions. You can ask the testing personnel how long it will take to read the test results.



PATIENT TEST RESULTS NEED TO BE DOCUMENTED AND REPORTED. Ask the testing personnel how your results will be documented and reported.

CLIA Quick Start Guide for Schools

QUICK START GUIDE TO CLIA CERTIFICATION FOR COVID-19 TESTING IN SCHOOLS

MAY 2021



Facility Quick Start Guide to CMS CLIA Certification

The Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) regulates the quality and safety of U.S. clinical laboratories. This guide helps schools and other non-healthcare entities apply for a CLIA Certificate of Waiver to conduct COVID-19 testing. Items that schools must complete are highlighted in yellow, accompanied by directions specific to school COVID-19 testing.



STEP 1: Download and Complete Form CMS-116

- The CLIA application (Form CMS-116) collects information about your facility's (e.g. school) operation to issue a CLIA number.
- Include information based on the date of form completion.
- All applicable highlighted sections/fields must be completed. Incomplete applications cannot be processed.
- Print legibly or type.
- Waived tests are not exempt from CLIA. Facilities that perform only those tests categorized or authorized as waived must apply for a CLIA Certificate of Waiver.



Complete General Information in section I.

If you do not have a CLIA certificate and this is the first time you are applying for a certificate, check "Initial Application."

For all other changes, check "other changes" and provide the effective date of the change. Some examples of "other changes" are address, phone number, or laboratory director.

Facility Name should be specific. NOTE: The information you provide will appear on your certificate. The Facility Name should be specific to the school, school district, county or other controlling organization.

Providing an **Email Address** to receive notifications is optional.

Facility Address is the physical location of a school where the lab testing is performed. It may also be the address of a school district or state responsible for the testing. The address may include a floor, suite, and/or room location, but cannot be a Post Office box or Mail Stop.

For **Name Of Director**, enter the name of the individual responsible for overall operation of the facility, including testing ("Facility Director"). For a Certificate of Waiver, this does not have to be a physician or medical professional.

"Check Certificate of Waiver" for Type of Certificate.

Disclaimer: This guide is a restatement of the law intended to assist people in understanding the basics about the CLIA program, and that the reader should consult the relevant statutes and regulations for the full scope of the CLIA requirements.

COVID – School Testing Fact Sheet

HOW TO GET CERTIFICATION FOR IN-SCHOOL COVID-19 TESTING



WHAT IS CLIA? WHY WOULD MY SCHOOL NEED A CLIA CERTIFICATE?

The [Clinical Laboratory Improvement Amendments](#) (CLIA) of 1988 are federal regulatory standards that ensure patient laboratory test results are accurate, reliable, and timely. CLIA applies to testing performed on humans, including testing performed in schools.

A school, school district, county or state needs a CLIA certificate to perform on-site COVID-19 testing. This certificate shows that a school meets CLIA quality and safety requirements to follow test manufacturers' instructions and provide accurate results.

A school district, county, or state can apply for a single CLIA certificate for multiple schools. Multiple schools can be listed as separate temporary testing sites under one CLIA certificate. The person listed as "laboratory director" on the CLIA certificate is responsible for all testing administered at each school under the certificate. There is no limit on the number of temporary testing sites that can be listed under one certificate. You will need to check with the [state agency](#) where the school is located to see if there are any state requirements for "laboratory directors."



WHICH CLIA CERTIFICATE DOES MY SCHOOL NEED?

On-site COVID-19 tests generally require schools to [get a Certificate of Waiver](#). These tests are generally of low complexity and therefore most schools would only need a Certificate of Waiver.

A Certificate of Waiver costs \$180. If a school continues to perform testing and pays the certificate fee, the certificate will be automatically renewed every 2 years. CMS recommends keeping a copy of the CLIA certificate on file at each school nurse's office or on-site testing location.



HOW QUICKLY CAN A SCHOOL START TESTING?

Once any applicable state requirements are met, testing can begin as soon as the Certificate of Waiver application is submitted to CLIA.

Requirements can vary by state, so check with your [state agency](#) before you begin testing if you don't have a CLIA certificate yet.



DOES THE GOVERNMENT INSPECT SCHOOLS FOR CLIA COMPLIANCE?

A facility that holds a CLIA Certificate of Waiver is not usually inspected, but it can be if a complaint is received. CLIA inspectors can make in-person visits to schools and other facilities to make sure they meet CLIA requirements. Please refer to the [How To Obtain A Certificate of Waiver](#) brochure for additional information.

During the COVID-19 public health emergency, inspectors will also ensure schools and other facilities are reporting COVID-19 test results as required. Generally, CMS is recommending that the inspections related to test reporting be done remotely, if possible.



HOW DOES A SCHOOL APPLY FOR A CLIA CERTIFICATE?

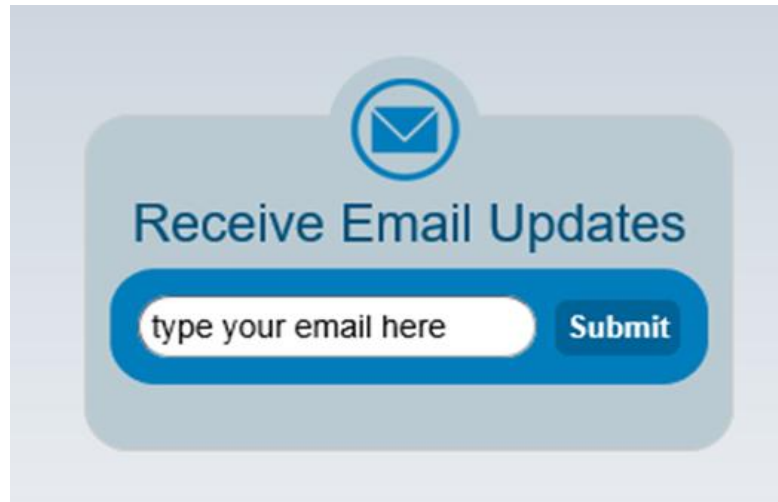
A school can follow the [quick start guide](#) and complete the [CMS-116 Application](#) to get a CLIA certification. Completed forms should be sent to the State [survey agency](#) for the school's state.

For questions related to COVID-19 testing in schools, please email LabExcellence@cms.hhs.gov.



CLIA Communications Listserv

- **GOAL:** CMS to disseminate information to laboratories and laboratory professionals
- We have created a listserv that the public can subscribe to in order to get updates directly from CLIA



- <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA>

CLIA Contact Information

CMS Baltimore: 410-786-3531

CLIA Questions: CMS LabExcellence@cms.hhs.gov

Sarah Bennett: sarah.bennett1@cms.hhs.gov

Resource Information

- CLIA Website: [Clinical Laboratory Improvement Amendments \(CLIA\)](#)
- [CMS Emergencies Page](#)
- [Frequently Asked Questions \(FAQs\), CLIA Guidance During the COVID-19 Emergency \(PDF\) UPDATED \(12/17/20\)](#)
- Revised HHS Secretary SARS-CoV-2 Test Reporting Guidance, 3/8/2022, effective 4/4/2022: [HHS-Laboratory-Reporting-Guidance](#)