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.

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.
### III. TYPE OF LABORATORY

(Check the one most descriptive of facility type)

- 01 Ambulance
- 02 Ambulatory Surgery Center
- 03 Ancillary Testing Site in Health Care Facility
- 04 Assisted Living Facility
- 05 Blood Bank
- 06 Community Clinic
- 07 Comp. Outpatient Rehab Facility
- 08 End Stage Renal Disease Dialysis Facility
- 09 Federally Qualified Health Center
- 10 Health Fair
- 11 Health Main. Organization
- 12 Home Health Agency
- 13 Hospital
- 14 Hospital Outpatient
- 15 Industrial
- 16 Insurance
- 17 Intermediate Care Facilities for Individuals with Intellectual Disabilities
- 18 Mobile Laboratory
- 19 Pharmacy
- 20 Physician Office
- 21 Physician Office (Specify)
- 22 Practitioner Other (Specify)
- 23 Prison
- 24 Public Health Laboratories
- 25 Rural Health Clinic
- 26 School/Student Health Service
- 27 Skilled Nursing Facility/Nursing Facility
- 28 Tissue Bank/Repositories
- 29 Other
- 30 Other (Specify)

### IV. HOURS OF LABORATORY TESTING

(List times during which laboratory testing is performed in HH:MM format)

<table>
<thead>
<tr>
<th>Day of Week</th>
<th>From</th>
<th>To</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUNDAY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MONDAY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TUESDAY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WEDNESDAY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>THURSDAY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FRIDAY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SATURDAY</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If testing 24/7, check here.

(For multiple sites, attach the additional information using the same format.)

### V. MULTIPLE SITES

(Must meet one of the regulatory exceptions to apply for this provision in 1-3 below)

Are you applying for a single site CLIA certificate to cover multiple testing locations?

- No. If no, go to section VI.
- Yes. If yes, complete remainder of this section.

1. Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?
   - Yes
   - No

   If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?
   - Yes
   - No

   If yes, provide the number of sites under the certificate and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?
   - Yes
   - No

   If yes, provide the number of sites under this certificate and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

   If additional space is needed, check here and attach the additional information using the same format.

**NAME AND ADDRESS/LLOCATION**

- NAME OF LABORATORY OR HOSPITAL DEPARTMENT
- STREET ADDRESS (including street number)
- CITY, STATE, ZIP CODE
- TELEPHONE NO.

**TESTS PERFORMED/SPECIALTY/SUBSPECIALTY**

- NAME OF LABORATORY OR HOSPITAL DEPARTMENT
- STREET ADDRESS (including street number)
- CITY, STATE, ZIP CODE
- TELEPHONE NO.
In the next three sections, indicate testing performed and estimated annual test volume.

**VI. WAIVED TESTING** If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-Waived Testing).

Identify the waived testing (if any) to be performed by completing the table below. Include each analyte, test system, or device used in the laboratory.

<table>
<thead>
<tr>
<th>ANALYTE / TEST</th>
<th>TEST NAME</th>
<th>MANUFACTURER</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. pneumoniae</td>
<td>Rapid Strips Test</td>
<td>Acme Corporation</td>
</tr>
<tr>
<td>S. suis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S. pyogenes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S. aureus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S. flexneri</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M. tuberculosis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed.

Check if no waived tests are performed.

If additional space is needed, check here and attach additional information using the same format.

**VII. PPM TESTING** If only applying for a Certificate for PPM, complete this section and skip Section VIII (Non-Waived Testing).

Listed below are the only PPM tests that can be performed by a facility having a Certificate for PPM. Mark the checkbox by each PPM procedure(s) to be performed:

- Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- Potassium hydroxide (KOH) preparations
- Fernald preparations
- Fecal leukocyte examinations
- Parasite examinations
- Direct examination of specimens
- Post-coital direct, qualitative examinations of vaginal or cervical mucus
- Urine sediment examinations
- Feces examination
- Post-coital direct examination of vaginal or cervical mucus
- Intracellular staining examination
- Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed.

Check if no PPM tests are performed.

If additional space is needed, check here and attach additional information using the same format.

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**Complete Waived Testing in section VI**

As an example:

<table>
<thead>
<tr>
<th>TEST</th>
<th>TEST KIT</th>
<th>MANUFACTURER</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19</td>
<td>BINAXNOW COVID-19 Ag 2 CARD</td>
<td>ABBOTT</td>
</tr>
</tbody>
</table>

**Complete Estimated Total Annual Test**

Please add the total number of tests that you think will be performed by all the schools under this CLIA certificate in a year. This number is used to know how many tests you are performing each year.
Complete Type of Control in section IX and sign application

<table>
<thead>
<tr>
<th>IX. TYPE OF CONTROL (CHECK THE ONE MOST DESCRIPTIVE OF OWNERSHIP TYPE)</th>
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</thead>
<tbody>
<tr>
<td>VOLUNTARY NONPROFIT</td>
</tr>
<tr>
<td>☐ 01 Religious Affiliation</td>
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<tr>
<td>☐ 02 Private Nonprofit</td>
</tr>
<tr>
<td>☐ 03 Other Nonprofit (Specify)</td>
</tr>
<tr>
<td>FOR PROFIT</td>
</tr>
<tr>
<td>☐ 04 Proprietary</td>
</tr>
<tr>
<td>GOVERNMENT</td>
</tr>
<tr>
<td>☐ 05 City</td>
</tr>
<tr>
<td>☐ 06 County</td>
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<tr>
<td>☐ 07 State</td>
</tr>
<tr>
<td>☐ 08 Federal</td>
</tr>
<tr>
<td>☐ 09 Other Government (If 09 is selected, please specify the</td>
</tr>
<tr>
<td>country or the province.)</td>
</tr>
</tbody>
</table>

Does this facility have partial or full ownership by a foreign entity or foreign government?  
☐ Yes ☐ No

If Yes, what is the country of origin for the foreign entity?

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X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

<table>
<thead>
<tr>
<th>CLIA NUMBER</th>
<th>NAME OF LABORATORY</th>
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</tbody>
</table>

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory’s eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

PRINT NAME OF DIRECTOR OF LABORATORY

PRINT NAME OF OWNER OF LABORATORY

SIGNATURE OF DIRECTOR OF LABORATORY (Include date or official seal if applicable)  DATE

NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.

STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:  

Form CMS-116 (04/20)
STEP 2: Send Completed CMS-Form 116 to the appropriate State Agency

- Send via mail or email
- Include state-specific paperwork. As your local CLIA contact, the State Agency can answer your questions on CLIA certificates. They can also advise about any state requirements that apply.

STEP 3: Receive Fee Coupon (i.e., invoice);
See coupon image below

- You will receive a 10-digit alphanumeric CLIA identification number, with the “D” in the third position identifying the provider/supplier as a laboratory certified under CLIA.
- Amount due will be included on Fee Coupon as the Total Payment Due

STEP 4: Pay Applicable Fees

Pay CLIA certification fees by:

- Using the U.S. Treasury online platform—include the CLIA Identification Number and charge to a debit or credit card; this secure federal government platform applies payments nightly to outstanding fees
- Writing a check—include the provider number and allow 10 business days for outstanding fees to be applied

STEP 5: Receive Certificate and Begin Testing