**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 employers and other non-healthcare entities apply for a CLIA Certificate of Waiver to conduct COVID-19 testing. Items that employers must complete are highlighted in yellow, accompanied by directions specific to workplace 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., workplace) 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.

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**Form CMS-116**

<table>
<thead>
<tr>
<th><strong>GENERAL INFORMATION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial Application</strong></td>
</tr>
<tr>
<td><strong>Date of Signature</strong></td>
</tr>
<tr>
<td><strong>Other Changes (Specify)</strong></td>
</tr>
</tbody>
</table>

**CREDENTIALS**

- **Name of Director** (Last, First, Middle Initial)
- **Laboratory Director’s Phone Number**
- **Corporate Address**
- **Mailing Address**
- **Physical Address**

**RECEIVE FUTURE NOTIFICATIONS VIA EMAIL**

**SEND FEE COUPON TO THIS ADDRESS**

**SEND CERTIFICATE TO THIS ADDRESS**

**CERTIFICATE OF COMPLIANCE**

- **Type of Certificate Requested** (Check only one)
  - Certificate of Waiver (Complete Sections I – VI and IX – X)
  - Certificate of Accreditation (Complete Sections I – X)

**NOTICE:** Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

**FOR ALL OTHER CHANGES, CHECK “OTHER”**

- **Other Changes (Specify)**
  - **Effective Date**
  - **Type of Certificate**
  - **Reason for Change**

**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.

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**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.
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 Hospice
14 Hospital
15 Industrial
16 Insurance
17 Intermediate Care Facility for Individuals with Intellectual Disabilities
18 Mobile Laboratory
19 Physician Office
20 Pharmacy
21 Public Health Laboratories
22 Rural Health Clinic
23 School/Student Health Service
24 Skilled Nursing Facility/Nursing Facility
25 Tissue Bank/Repositories
26 Other

IV. HOURS OF LABORATORY TESTING
(List times during which laboratory testing is performed in HH:MM format)
If testing 24/7 Check Here
SUNDAY MONDAY TUESDAY WEDNESDAY THURSDAY FRIDAY SATURDAY
FROM: TO:

(VII. 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 VII. Yes. If yes, complete remainder of this section.
Indicate which of the following regulatory exceptions applies to your facility’s operation.
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, address and test performed at each site below.
If additional space is needed, check here and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT
ADDRESS/LOCATION (Number, Street, Location if applicable)
CITY, STATE, ZIP CODE
TELEPHONE NO. (Include area code)
NAME OF LABORATORY OR HOSPITAL DEPARTMENT
ADDRESS/LOCATION (Number, Street, Location if applicable)
CITY, STATE, ZIP CODE
TELEPHONE NO. (Include area code)

Complete Type of Laboratory in section III.
In section III, select the Type of Laboratory that is most descriptive of the location where the laboratory testing is performed. Check 29 “Other.” If you have questions, contact your State Agency.

Complete Multiple Sites in section V
If you are applying for multiple locations for a single employer, please attach a list of the sites, including each site’s name, address, and tests performed. Please also answer questions 1 – 3 under Section V.
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 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>Strep A antigen</td>
<td>Acute Rapid Strip Test</td>
<td>Acute Corporation</td>
</tr>
<tr>
<td></td>
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</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
- Worm examinations
- Fecal specimens
- Yeast and candida direct, qualitative examinations of vaginal or cervical mucus
- Urine sediment examinations
- Fecal leukocyte examinations
- 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**

If also performing waived complexity tests, complete Section VI. For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the “total estimated annual test volume” in Section VIII.

Check if no PPM tests are performed

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

Complete Waived Testing in section VI

As an example:

<table>
<thead>
<tr>
<th>TEST</th>
<th>TEST NAME</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 workplace locations 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

IX. TYPE OF CONTROL (CHECK THE ONE MOST DESCRIPTIVE OF OWNERSHIP TYPE)

<table>
<thead>
<tr>
<th>VOLUNTARY NONPROFIT</th>
<th>FOR PROFIT</th>
<th>GOVERNMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 Religious Affiliation</td>
<td>04 Proprietary</td>
<td>05 City</td>
</tr>
<tr>
<td>02 Private Nonprofit</td>
<td></td>
<td>06 County</td>
</tr>
<tr>
<td>03 Other Nonprofit</td>
<td></td>
<td>07 State</td>
</tr>
</tbody>
</table>

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

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?

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>
<tr>
<td></td>
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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 OWNER/DIRECTOR OF LABORATORY (DRAWN IN INK OR A FACSIMILE OF A WRITTEN SIGNATURE) 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:

Page 4
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: Apply to State Agency (SA) for a Certificate of Waiver and begin COVID-19 testing*

*If permitted by local/state laws