

A CLIA certificate is required in order to perform any lab test, including the COVID test. It has come to our attention that there is not a clear understanding of the application process, as evidence of the many incomplete CMS 116 applications we receive daily in our office. The incomplete applications delay the processing/uploading activity to the federal database. For us to better serve you, please read all three pages to understand the application process. This guideline is to ensure you complete your application so that we may issue your CLIA ID as soon as it can be uploaded without delays, i.e. the follow-up emails with request of the missing information(s) .

There are ten (10) sections to the CMS 116 application that comes with the **Instructions for Completion**. Key components of the instructions are high light in yellow for your review and must be completed. We will not be able to process your application if you leave blanks, and we cannot make decisions for you to advance in the data entry mode to generate a CLIA ID number for you.

Please see the **Instructions for Completion** for further guidance, however, first take note, the following sections have special instructions for COVID testing.

Section I. General Information

I. GENERAL INFORMATION

- Initial Application Survey
- Change in Certificate Type
- Other Changes (Specify) _____

Effective Date _____

Two options:

1. if new laboratory with no CLIA certificate:
 - check box - Initial Application
 - check box- Other Changes (Specify) write in space COVID testing
 - Effective date- estimate date of testing Patients
2. if laboratory already has current valid CLIA certificate-
 - call our office 503-693-4126 for a prepopulated CMS 116
 - Check box- Other Changes (Specify) Add COVID testing and/or add temporary test sites
 - Effective date- estimate date of testing Patients

Section VI. Waived Testing

1. Identify the waived testing (to be) performed , Be as specific as possible. This includes analyte test system. For examples: Device: BinaxNOW COVID-19 Ag Card
2. Estimated annual test volume - Required

Section X. Laboratory Director

1. Laboratory Director must print name and sign name on the appropriate line and date the completed CMS 116

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION (FORM CMS-116)

INSTRUCTIONS FOR COMPLETION

CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service are not considered laboratories. CLIA does not apply to a facility that only performs forensic testing. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory's operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion.

NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M (42 CFR PART 493) of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application. Information to be submitted with the application include:

- Verification of State Licensure, as applicable
- Documentation of qualifications:
 - Education (copy of Diploma, transcript from accredited institution, CMEs),
 - Credentials, and
 - Laboratory experience.

Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States. Failure to submit this information will delay the processing of your application.

ALL APPLICABLE SECTIONS MUST BE COMPLETED. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED AND WILL BE RETURNED TO THE FACILITY. PRINT LEGIBLY OR TYPE INFORMATION.

I. GENERAL INFORMATION

For an initial applicant, check "initial application". For an initial survey or for a recertification, check "survey". For a request to change the type of certificate, check "change in certificate type" and provide the effective

date of the change. For all other changes, including change in location, director, lab closure, etc., check "other changes" and provide the effective date of the change.

CLIA Identification Number: For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. For all other applicants, enter the 10 digit CLIA identification number already assigned and listed on your CLIA certificate.

Facility Name: Be specific when indicating the name of your facility, particularly when it is a component of a larger entity, e.g., respiratory therapy department in XYZ Hospital. For a physician's office, this may be the name of the physician. **NOTE: the information provided is what will appear on your certificate.**

Physical Facility Address: This address is mandatory and must reflect the physical location where the laboratory testing is performed. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.

If the laboratory has a separate mailing and/or corporate address (from the Facility Address), please complete the appropriate sections on the form.

Mailing Address: This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to an alternate location, such as an accounts payable office. A Post Office box number or Mail Stop number may be used as part of the Mailing Address for this section.

Corporate Address: This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to another location, such as, the main headquarters or home office for the laboratory. A Post Office box number or Mail Stop number may be used as part of the Corporate Address for this section.

Form Mailing: Select the address (Physical, Mailing, Corporate) where the CLIA fee coupon and CLIA certificate are to be mailed.

For Office Use Only: The date received is the date the form is received by the state agency or CMS regional office for processing.

II. TYPE OF CERTIFICATE REQUESTED

Select your certificate type based on the highest level of test complexity performed by your laboratory. A laboratory performing non-waived tests can choose Certificate of Compliance or Certificate of Accreditation based on the agency you wish to survey your laboratory.

When completing this section, please remember that a facility holding a: **Certificate of Waiver can only perform tests categorized as waived;***

- **Certificate for Provider Performed Microscopy Procedures (PPM) can only perform tests categorized as PPM, or tests categorized as PPM and waived tests;***

- **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the applicable CLIA quality standards are met following a CLIA survey; and
- **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/or high complexity non-waived tests provided the laboratory is currently accredited by an approved accreditation organization. (If your CMS-approved accreditation organization is not listed, contact your local State Agency for further instructions.)

*A current list of waived and PPM tests may be obtained from your State agency. Specific test system categorizations can also be found on the Internet at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm>.

III. TYPE OF LABORATORY

Select the type that is most descriptive of the location where the laboratory testing is performed.

If selecting 'mobile laboratory' (code 19), a mobile laboratory is defined as a movable, self-contained operational laboratory with its own personnel, equipment, and records. For record keeping purposes, include, on a separate sheet of paper, the vehicle identification numbers (VINS) of all vehicles used for mobile laboratory testing.

If selecting 'Practitioner Other' (code 22), this type includes practitioners such as, dentists, chiropractors, etc.

IV. HOURS OF ROUTINE OPERATION

Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM format and check box marked '24/7' if laboratory testing is performed continuously, e.g., 24 hours a day, 7 days a week. Do not use military time.

V. MULTIPLE SITES

You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493.493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3). Hospice and HHA could qualify for an exception.

VI. WAIVED TESTING

Indicate the estimated total annual test volume for all waived tests performed. List can be found at: <http://www.cms.gov/CLIA/downloads/waivetbl.pdf>

VII. PPM TESTING

Indicate the estimated total annual test volume for all PPM tests performed. List can be found at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ppmplist.pdf>

VIII. NON-WAIVED TESTING (INCLUDING PPM)

The total Estimated Annual Test volume in this section includes all non-waived testing, including PPM tests previously counted in section VII. Follow the specific instructions on page 3 of the Form CMS-116 when completing this section for test counting information. (Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.).

IX. TYPE OF CONTROL

Select the type of ownership or control which most appropriately describes your facility.

X. DIRECTOR OF ADDITIONAL LABORATORIES

List all other facilities for which the director is responsible and that are under different certificates. Note that for a Certificate of PPM, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.

Reminders - Before submitting the Form CMS-116:

1. Include the current or estimated annual test volume.
2. For Certificate for PPM, Certificate of Compliance, or Certificate of Accreditation, include the laboratory director qualifications.
3. Do not send any money with your application.
4. Send the completed Form CMS-116 to the appropriate State Agency (<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>).

Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until verification of accreditation by an approved accreditation organization is received by CMS.

If you need additional information concerning CLIA, or if you have questions about completion of this form, please contact your State agency. State agency contact information can be found at: <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>