

***Instructions for Laboratories Seeking a  
Certificate of Accreditation with COLA***

## •Introduction•

Any laboratory that performs testing on human specimens for the purpose of diagnosis, prevention, or treatment of any disease or for the overall health assessment of an individual is required to have a CLIA identification number. The CLIA Form CMS-116 is utilized to apply for a CLIA identification number. Within thirty (30) days of enrollment in COLA's Laboratory Accreditation Program, a laboratory is required to notify their state CLIA agency, in writing, that they are seeking accreditation with COLA. After payment of accreditation fees to COLA, the laboratory will receive a Verification of Enrollment (VOE) letter. A copy of this letter may be forwarded to your state CLIA agency.

## •Various Scenarios for COLA Laboratories Seeking a Certificate of Accreditation•

If you are opening a new laboratory, send a copy of your completed CMS 116 form requesting a CLIA Certificate of Accreditation, along with the Verification of Enrollment letter to your state CLIA agency.

If you are switching from another accrediting organization to COLA and already have a certificate of accreditation, send a copy of the Verification of Enrollment letter along with your request to switch to COLA accreditation to your state CLIA agency. Submit an updated CMS 116 form indicating COLA as your accrediting organization.

If you are switching from the state CLIA agency to COLA, complete a new CMS 116 form, requesting a change in CLIA certificate type to a Certificate of Accreditation, with COLA marked as your accrediting organization. Include a copy of the Verification of Enrollment letter.

## •Step-by-Step Instructions to Complete the CLIA Form CMS-116•

### • Section I General Information

- If this is an initial application to obtain a CLIA ID check the box for Initial Application. Indicate the anticipated start date. The CLIA Identification number will be left blank.
- If you already have a CLIA ID and wish to change the type of the certificate, check the box for Change in Certificate Type. Indicate the effective date of the change. Enter your CLIA Identification number.
- If you already have a CLIA ID and wish to make changes to the Laboratory Director, check the box for Change in Laboratory Director. Indicate the effective date of the change. Enter your CLIA Identification number.

- If you already have a CLIA ID and wish to make changes to other information regarding the laboratory, check the box for other changes and specify the change. Indicate the effective date of the change. Enter your CLIA Identification number.
  - Enter the facility name as you would like it to appear on your CLIA certificate.
  - Enter a valid email address to be used for communications with CLIA. It is also advisable to check the box to receive notifications including electronic certificates.
  - Enter the physical address of the laboratory. This must reflect the physical location where laboratory testing is performed. Include any specifics such as building, floor or suite number if applicable. If the laboratory has a separate mailing or corporate address, please also complete the applicable sections of the form.
  - Select which address the laboratory would like the fee coupon to be sent. Select the address the laboratory would like their certificate to be sent. The choices for each of these will be either the physical, mailing or corporate address.
  - Indicate the Federal Tax Identification Number
  - Indicate the telephone number and fax number of the laboratory (if applicable). Please include the area code for each number.
  - To complete section I of the application, include the full name of the Laboratory Director, a phone number for the Laboratory Director and any credentials.
- **Section II Type of Certificate Requested**
    - Select your certificate type based on the highest level of testing complexity that is performed by the laboratory.
    - For laboratories performing only waived testing select a certificate of waiver and complete sections one through six and nine through ten of the CLIA Form CMS-116.  
 \*A laboratory with a certificate of waiver can only perform waived testing.
    - For laboratories in which only providers perform microscopic examinations select the certificate for Provider Performed Microscopy Procedures (PPM) and complete sections one through seven and nine through ten of the CLIA Form CMS-116.  
 \*A laboratory with a certificate for provider performed microscopy procedures (PPM) can perform PPM or waived testing.
    - For laboratories performing moderate complexity testing (other than PPM testing) and/or high complexity testing select the box for certificate of accreditation and select COLA in the box below to indicate COLA as your accrediting organization. Remember to also include your Verification of Enrollment letter with your application.  
 \*A laboratory with a certificate of accreditation can perform testing for any level of complexity (high, moderate and waived).

- **Section III Type of Laboratory**

- Select the type of laboratory that best describes the facility where testing is being performed.

\*If mobile laboratory (code 19) is selected, include on a separate sheet of paper the vehicle identification numbers of all vehicles used for mobile testing.

\*\*Select practitioner other (code 22) for practitioners such as dentists, chiropractors, etc.

- **Section IV Hours of Operation**

- Enter only the hours and days when laboratory testing is performed. Use the format HH: MM. Do not use military time. If the facility is open continuously (24 hours a day 7 days a week) select the box indicating testing 24/7.

- **Section V Multiple Sites**

- A laboratory may only apply for a single cite CLIA certificate to cover multiple testing locations if they meet one of the three exceptions listed on the form. Select no if not applying for this option and proceed to section 6 of the application. If the laboratory is applying for a single cite CLIA certificate to cover multiple testing locations, then select yes and complete the remaining questions in this section.

- **Section VI Waived Testing**

- If waived testing is performed, list any waived testing that is performed by indicating each analyte/test, test name or test system and manufacturer. If additional space is needed, check the appropriate box and attach additional information using the same format. Indicate an estimated annual test volume for all waived testing.

- If no waived testing is being performed, check the box for no waived tests are performed.

- **Section VII PPM Testing**

- If PPM testing is performed, select the box next to any PPM testing that is performed in the laboratory. If additional space is needed, check the appropriate box and attach additional information using the same format. Indicate an estimated annual test volume for all PPM testing.

- If no PPM testing is being performed, check the box for no PPM tests are performed.

- **Section VIII Non-Waived Testing**

- Complete this section if applying for a Certificate of Accreditation. Include PPM testing if applicable. List any non-waived testing that is performed by indicating each analyte/test, test name or test system, manufacture and complexity of test using either M for moderate complexity or H for high complexity. If additional space is needed, check the appropriate box and attach additional information using the same format. On the chart that follows, for each specialty or subspecialty that the laboratory performs testing put a checkmark and indicate the annual test menu for each. For any of these specialties/subspecialties that you elect COLA to accredit please indicate COLA under the column for accrediting organization. Include in the last box of this section the total estimated annual test volume for all non-waived testing.

- **Section IX Type of Control**

- Select the type of control that describes the facility.

- **Section X Director Affiliation with Other Laboratories**

- If applicable, list all other laboratories that the Laboratory Director directs. This includes any waived, PPM, certificate of compliance or certificate of accreditation laboratories. Indicate the CLIA number and the name of each laboratory.
- Once the information in the ten sections has been completed, carefully read the statement on the form before signing the application.
- To sign the application:
  - Print the name of the Laboratory Director.
  - Print the name of the owner of the laboratory.
  - Indicate the signature of the owner/Laboratory Director. Sign either in ink or using a secure electronic signature. Include the date of the signature.
  - For applications of laboratories that perform non-waived testing, include documentation to demonstrate Laboratory Director qualification.
  - Send the completed form CMS-116 to your appropriate state agency.

## •What to Expect After Submission of CMS-116 Form •

Once the form CMS-116 has been processed by the applicable state agency, a fee remittance coupon will be issued. This coupon will indicate your CLIA identification number and the amount due for the certificate. If you are applying for a certificate of accreditation, you will initially pay for and receive a certificate of registration. This certificate of registration permits the laboratory to perform testing until an onsite survey is performed and verification of accreditation is received by CMS.

## •Valuable Websites•

The CLIA form CMS-116 can be found by visiting: <https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms116.pdf>

The CLIA state agency list can be found by visiting: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>