AGD Guidance on
Clinical Laboratory Improvement Amendments (CLIA) Certification

Overview

The Clinical Laboratory Improvement Amendments (CLIA) was passed by Congress in 1988 to establish consistent testing and requirements standards for laboratories who perform tests. CLIA requires all entities that perform even one test, including waived tests on "materials derived from the human body 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, human beings" to meet certain Federal requirements. If an entity performs tests for these purposes, it is considered under CLIA to be a laboratory and must register with the CLIA program.

This outline provides recommendations for dental practices looking to obtain a CLIA certificate, specifically for the purposes of performing COVID-19 tests. In addition to these recommendations, we strongly encourage you to view the Center for Medicare & Medicaid Services (CMS) Guidance on Obtaining CLIA Certificates, which provides in-depth information on testing, requirements for laboratories, FAQs and more, so you are aware of all options and can assess what is best for your practice.

To apply for a CLIA certificate, you must fill out the following form:
https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf

Once you have completed the form, submit it to your CLIA State Agency which may be found through the link below. Be sure to check with your CLIA State Agency as well as your State Dental Board for any additional requirements that may be specific to your state/territory.

- List of CLIA State Agency Contacts
- List of State Dental Board Contacts

Please read on for more information, including guidance on completing the CLIA Certificate application.

Types of CLIA Certification

- **Certificate of Waiver (COW):** Issued to a laboratory that performs only waived tests.
- **Certificate for Provider-performed Microscopy (PPM) procedures**: Issued to a laboratory in which a physician, midlevel practitioner or dentist performs specific microscopy procedures during the course of a patient's visit. A limited list of provider-performed microscopy procedures is included under this certificate type, which are categorized as moderate complexity testing.

- **Certificate of Registration:** Issued to a laboratory to allow the laboratory to conduct non-waived (moderate and/or high complexity) testing until the laboratory is surveyed (inspected) to determine its compliance with the CLIA regulations. Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a certificate of registration.
- **Certificate of Compliance (COC):** Issued to a laboratory once the State Agency or CMS surveyors conduct a survey (inspection) and determine that the laboratory is compliant with the applicable CLIA requirements. This type of certificate is issued to a laboratory that performs non-waived (moderate and/or high complexity) testing.
- **Certificate of Accreditation (COA):** Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS. This type of certificate is issued to a laboratory that performs non-waived (moderate and/or high complexity) testing.

*Any application to perform non-waived testing (including PPM) must meet specific education, training and experience requirements per CLIA regulations. Due to this, our guidance focuses on the **Certificate of Waiver (COW)**, as its requirements are suitable for the majority of AGD members. As stated before, it is encouraged that you explore all testing and certification options and assess what is best for your practice.*

<u>Laboratories</u>

Definition

The Clinical Laboratory Improvement Amendments of 1988 defines ''laboratory'' or ''clinical laboratory'' as:

"…a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, bio-physical, cytological, pathological, or other ex-amination of materials derived from the human body 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, human beings." (42 U.S.C. §263a, Certification of Laboratories)

Choosing Your Laboratory – Dentists

For the purposes of completing the application for a CLIA Certificate, most dentists should choose 'Practitioner Other' (code 22) under Section III., which asks you to define your type of laboratory.

Depending on where you are applying to perform testing, it is possible that you may be a 'Mobile Laboratory' (code 19), which 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.

Types of Tests

The complexity of tests that may be performed correlate with the type of CLIA Certificate a laboratory is issued. The Certificate of Waiver allows a laboratory to only perform waived tests, which as defined by CLIA are simple tests with a low risk for an incorrect result. They include:

- Certain tests listed in the CLIA regulations
- Tests cleared by the FDA for home use
- Tests that the manufacturer applies to the FDA for waived status by providing scientific data that verifies that the CLIA waiver criteria have been met

PPM tests are certain moderate complexity microscopy tests commonly performed by health care providers during patient office visits, and non-waived testing is the term used to refer collectively to moderate and high complexity testing. Both moderate and high complexity testing are only allowed for those who have completed specific education, training and other requirements, and who hold an advanced CLIA Certificate to perform these tests.

For the purposes of completing an application to obtain a CLIA Certificate of Waiver, you must define the waived tests you wish to perform (Section VI.) There are currently eight waived tests for COVID-19, meaning they have received Emergency Use Authorization (EUA) by the FDA to be performed in a laboratory that has received a CLIA Certificate of Waiver. These include:

Molecular Technology

Cue COVID-19 Test
- Authorized June 10, 2020
- FDA Letter of Authorization: https://www.fda.gov/media/138823/download

ID NOW COVID-19
- Authorized March 27, 2020
- FDA Letter of Authorization: https://www.fda.gov/media/136522/download

Accula SARS-Cov-2 Test
- Authorized March 23, 2020
- FDA Letter of Authorization: https://www.fda.gov/media/136345/download

Xpert Xpress SARS-CoV-2 Test
- Authorized March 20, 2020
- FDA Letter of Authorization: https://www.fda.gov/media/136316/download

Antigen Technology

BinaxNOW COVID-19 Ag Card
- Authorized August 26, 2020
- FDA Letter of Authorization: https://www.fda.gov/media/141567/download

LumiraDx SARS-CoV-2 Ag Test

- Authorized August 18, 2020
- FDA Letter of Authorization: https://www.fda.gov/media/141301/download

BD Veritor System for Rapid Detection of SARS-CoV-2

- Authorized July 2, 2020
- FDA Letter of Authorization: https://www.fda.gov/media/139752/download

Sofia 2 SARS Antigen FIA

- Authorized May 8, 2020
- FDA Letter of Authorization: https://www.fda.gov/media/137886/download

Due to the limited availability of COVID-19 tests, it is suggested to list all waived tests under this section of the application. This portion of the application calls for specificity when describing each test, and can be achieved by including the name of the test, the type of technology, the analyte system/device(s) required, and anything else you may feel is valuable. This information and more can be found by viewing the FDA Letter of Authorization for each test listed above. Please see the following example:

> *Accula SARS-Cov-2 Test, Molecular Technology, throat swab and nasal swab specimens combined*

It is strongly suggested that you read the Letters of Authorization in full, where you can find in-depth information regarding each test.

You may also view a list of all authorized in vitro COVID-19 tests here, which are separated in tables by technology. "The Authorized Settings" category describes test complexity, where **H= High Complexity**, **M= Moderate Complexity**, and **W= Waived**. It is important to check this resource regularly as more tests become authorized.