



Guidelines for Emergency Testing Authorization For Oregon CLIA certified Laboratories 04/09/2020

Guidelines are subject to change as the testing capacity and the public health emergency evolves or if the State Agency receives any updates from CMS Seattle and CMS Baltimore.

Background: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing authority to promulgate standards for certain laboratory testing to ensure the accuracy, reliability and timeliness of test results regardless of where or by whom the test was performed. CLIA requires all facilities that perform a test on “Materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of disease or impairment of or the assessment of the health of, human beings” to meet certain Federal requirements. If a facility performs tests for these purposes, it is considered a laboratory.

The 1864 agreement is the formal agreement between the Secretary of the Department of Health and Human Services and individual states to carry out specific survey and certification-related provisions of the Social Security Act. The Laboratory Compliance Section within the Oregon State Public Health Laboratory (OSPHL), coordinates the Centers for Medicare and Medicaid Services (CMS) CLIA activities within the state as the CMS CLIA State Agency (to be referred to hereafter as the State Agency). The State Agency CLIA program is responsible for the certifications of clinical laboratories, and ensuring certifications are fully documented and consistent with applicable law, regulations and general instructions. The State Agency CLIA program is in alignment with the current Oregon statute and rules, for the purpose of ensuring the quality of medical laboratory work in order to protect the health and welfare of the people of the State of Oregon.

The potential public health threat posed by COVID-19 is high, not only for Oregon or the United States, but globally as well. Recognizing the urgency of the public health emergency and the need to achieve more rapid testing capacity for COVID-19, the CMS CLIA State Agency has prepared these guidelines for emergency testing based on the most recent Food and Drug Administration (FDA) guidance and directive from Centers for Medicare and Medicaid Services (CMS) Baltimore.

Be advised, these guidelines are subject to change considering future update directives from CMS Baltimore, FDA guidelines or Centers for Disease Control and Prevention (CDC) guidelines. In the event of the termination of the Emergency Use Authorization (EUA) for test systems and kits, the CLIA State Agency will follow through with the CLIA certified laboratories testing COVID-19 to ensure compliance to the CLIA certificate types.

Intent: It is the intent of the State Agency CLIA program to maintain a structure consistent to the CLIA regulations and Oregon rules and regulations to ensure all clinical laboratories provide quality and accurate testing during this time of unprecedented use of test systems or test kits that are:

- Not FDA approved with Emergency Use Authorization (EUA), or
- Not FDA approved without Emergency Use Authorization

Scope: All laboratories need a CLIA certificate to perform COVID-19 testing of human specimens. The CLIA CMS 116 application will be used for tracking the names of new and existing CLIA certified laboratories to perform COVID-19 testing and the test systems specified in use during this emergency testing event. The submitted CMS 116 will be tracked within the state system for reporting to CMS Seattle (formerly CMS CLIA Region X) and the applications will be scanned and uploaded into the federal database.

The tracking of the laboratories with the designated test systems or test kits in use during the emergency testing event will be reviewed by the State Agency CLIA Program upon the termination of the EUA. Based on the final FDA approval process and categorization of the test systems, the CLIA certificate type for a laboratory may need to change to the appropriate certificate type, if testing is to be continued. The laboratory is responsible to submit a new CMS CLIA application to change accordingly, if needed. The State Agency will follow-up with the laboratories that have not requested a change to their CLIA certificates, if necessary.

Expedited Review of CLIA Applications:

Based on the CLIA memo dated March 26, 2020, Oregon laboratories seeking to perform COVID-19 testing that are applying for a CLIA certificate can begin testing as quickly as possible during the public health emergency. No requirements are being waived, however, once the laboratory has identified a qualified laboratory director and has provided all required information on the CMS 116 application, a CLIA number will be assigned. We are allowing for testing once a CLIA number has been assigned. Laboratories do not need to wait for a hard copy paper CLIA certificate to arrive in the mail. Once the CLIA number has been assigned, the laboratory can begin testing if applicable CLIA requirements have been met (e.g. establishing performance specifications).

Guidelines for submitting CLIA CMS 116 to perform COVID-19 testing

All laboratories need a CLIA certificate to perform COVID-19 testing. To become CLIA-certified, laboratories must comply with the accuracy, quality and reliability requirements as dictated by the statute. All CLIA applications will be prioritized for processing to allow the laboratory to begin testing as quickly as possible during this public health emergency provided all CLIA requirements are fulfilled and based on the test system specified.

Instructions and guidelines for CLIA certification for COVID-19 testing:

All facilities that intend to perform COVID-19 tests are requested to complete the CLIA CMS 116 application. The application is available at:

<https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>

- The completed CMS 116 application (hereafter to be referred to as CMS 116) is to include supporting EUA Letter of Authorization and the package insert(s) for the testing system(s). This application will serve to add new facilities and provide official documentation that COVID-19 testing will be added to existing certificates' test menus.
- The CMS 116 form must specify the effective date and include EUA:
 - Section I: Tracking effective date- Enter the effective date and specify COVID-19 (page 1).
 - Section VIII: Tracking test system- Identify what test system will be in use. (page 4) The following will help you verify the CLIA certificate type needed for the testing performed.
 - FDA non-approved with EUA test system- Laboratory Developed Test (LDT). CLIA certificate type: moderate or high complexity.
 - FDA non-approved with EUA-manufacturer test kit. CLIA certificate type: moderate or high complexity.
 - FDA non-approved with no EUA-manufacturer test kit. CLIA certificate type: high complexity.
- The State Agency will reference the FDA website to determine the authorization status and intended use of the COVID-19 test system.
 - A test system may be performed under a Certificate of Waiver, PPMP, Compliance or Accreditation if the EUA or package insert states, "Testing is authorized for laboratories certified under CLIA to perform moderate complexity/high complexity tests. The [name of assay] is also authorized to be distributed and used in patient care settings outside of the clinical laboratory environment."

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- **Note-** the FDA has authorized use in “patient care settings outside of the clinical laboratory environment” referring to settings that are equipped with the instrumentation and appropriately trained personnel in performing and interpreting the results and for the **period of emergency use only**.
 - A test system may be performed under a Certificate of Compliance or Accreditation if applicable CLIA personnel requirements have been met to perform moderate or high complexity if the EUA or package insert states, “Authorized laboratories to perform moderate and high complexity tests.”
 - If there is no EUA for the test system, this test system may be performed under a Certificate of Compliance or Accreditation to perform high complexity tests **only**.
- Laboratory director must be qualified based on the CLIA certificate type. Laboratory Director must meet all required qualifications for the CLIA certificate type requested. The Laboratory Director for any certificate type is NOT “waived” from his/her full overall operation and administration of the laboratory -even at the patient care setting. The Laboratory Director Qualification Appraisal form must be submitted with the CMS 116 application if CLIA certificate needs to be changed based on the complexity of the test.
<https://www.oregon.gov/oha/PH/LABORATORYSERVICES/CLINICALLABORATORYREGULATION/Documents/dir.pdf>
- **Applications may be submitted to the email address lc.info@state.or.us or faxed to 503-693-5602.**
- For a new CMS 116 application, the Laboratory Director will receive a letter of notification of the unique CLIA number assigned to the laboratory. Once a CLIA number has been assigned the laboratory can begin testing if applicable CLIA requirements have been met. Requirements include, but are not limited to:
 - Verification of Performance Specifications
 - <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/6064bk.pdf>
 - Personnel Competency
 - https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf
 - Director Responsibilities
 - <https://www.oregon.gov/oha/PH/LABORATORYSERVICES/CLINICALLABORATORYREGULATION/Documents/respons.pdf>
 - <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/brochure7.pdf>

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- For the existing CLIA certified laboratory, the Laboratory Director will receive a letter of notification confirming the COVID-19 testing activity has been included into the state and federal database. All applicable CLIA requirements must be met as specified above.

COVID-19 testing Guidelines: Laboratory Director Responsibilities

Laboratory Directors are strongly encouraged to be more diligent in this emergency testing event using non-approved FDA test systems and kits, to assure every laboratory test result performed within the clinical laboratory environment or in the patient care setting provides quality, accurate test results. Laboratory Directors are encouraged to establish robust policies stating how the overall oversight of the EUA for the COVID-19 test system will be administered within the clinical laboratory environment and patient care setting. This should include, but is not limited to:

- Ensure all Laboratory tests have an order from a medical doctor (MD), doctor of osteopathy (DO) or other “Authorized” individual. A resource tool is available here:
<https://www.oregon.gov/oha/PH/LABORATORYSERVICES/CLINICALLABORATORYREGULATION/Documents/order.pdf>
- Establish robust policy to follow the package insert and manufacturer’s EUA.
- Establishing a training/competency assessment process for all testing personnel.
- Maintain a list of all testing personnel throughout the emergency testing event.
- Establishing a QA policy specific for the oversight of the preanalytic, analytic and postanalytic phase of testing of the COVID-19 test system
- Report of Results- Laboratories and healthcare providers must include information in the patient test report as required by FDA policy “This test is not yet approved or cleared by the FDA” statement with additional information per package insert.
- How the testing will be handled once the EUA has been terminated

Notification of positive or negative results:

Please visit: www.healthoregon.org/diseasereporting

The top of the page includes information about COVID-19 reporting for positive and negative test results. For questions regarding reporting, please contact the State Acute and Communicable Disease Prevention section at 971-673-1111, option 1 then option 3.

Records:

All documents of validation or verification of performance specifications must be retained and be easily retrievable for review during compliance surveys, investigation of patient complaints or issues regarding manufacturer’s performance.

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Additional References:

Federal CLIA Guidance During COVID-19 Public Health Emergency:

<https://www.cms.gov/files/document/qso-20-21-clia.pdf-0>

Ready Set Test Patient Testing is Important booklet (CDC)

<https://www.cdc.gov/clia/docs/waived-tests/ready-set-test-booklet.pdf>

Email Questions about the CLIA program to:

- Oregon CLIA State Agency Lc.info@dhsosha.state.or.us
- Federal CMS CLIA LabExcellence@cms.hhs.gov.

OSPH/Lab Compliance Section: www.healthoregon.org/

- See Oregon Rules and Regulation website:
<https://www.oregon.gov/oha/PH/LABORATORYSERVICES/CLINICALLABORATORYREGULATION/Pages/rules.aspx>

Federal CLIA Webpage <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index>

FDA COVID-19 EUA Assays: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019>

FDA FAQs that includes the list the serology tests: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#5e7cb840e33ed>

FDA Coronavirus Daily Roundup: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup>