



## **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.

For more specific information from CMS please see here:

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