



May 29, 2020

**MEMORANDUM**

**TO:** Healthcare Facilities and Testing Sites

**FROM:** Gwen C. Thompson, Director of Healthcare Quality

**SUBJECT:** CLIA Certification and COVID-19 Testing

At present, the Clinical Laboratory Improvement Amendments (CLIA) Program and the Centers for Medicare and Medicaid Services (CMS) have not waived any requirements for COVID-19 testing. **All facilities and testing sites wanting to perform COVID-19 testing must have an active CLIA certificate.**

Prior to conducting COVID-19 testing, the Department of Health and Environmental Control (DHEC) urges healthcare facilities and testing sites to make sure that COVID-19 testing being performed matches the correct complexity type (e.g., waived, moderate, or high complexity) specified on their respective CLIA certificates. Facilities and testing sites that have any questions regarding test complexity standards can review the Food and Drug Administration's (FDA) Evaluation available [here](#).

Instructions on how to apply for CLIA certification to conduct COVID-19 testing is available [here](#). Completed CLIA applications for COVID-19 testing will be processed by the next business day. To ensure successful processing, applicants should indicate the manufacturer of the COVID-19 test that they are using. All tests categorized as moderate or high complexity must still follow CLIA regulatory requirements for compliance available [here](#).

Facilities wanting to perform COVID-19 testing that currently do not have an active CLIA certificate and are unsure if they meet regulatory requirements to obtain one should contact DHEC's CLIA Office at (803) 545-4291 or [SC\\_CLIA@dhec.sc.gov](mailto:SC_CLIA@dhec.sc.gov) for more information.