## CMS Clinical Laboratory Improvement Amendments (CLIA):
### Testing Requirements for SARS-CoV-2

**Last updated April 29, 2020; information subject to change based on FDA authorizations and updates.**

Laboratories performing testing must be CLIA certified.*

To apply for CLIA certification, refer to our brochure.

See pages 2 and 3 for more on expansion of testing and specimen collection sites and Medicare payment updates.

### Test Kits

<table>
<thead>
<tr>
<th><strong>TYPE OF SARS-CoV-2 TESTING</strong></th>
<th><strong>FDA AUTHORIZATION/NOTIFICATION</strong></th>
<th><strong>CLIA CERTIFICATES UNDER WHICH TESTING CAN BE PERFORMED</strong></th>
<th><strong>REQUIREMENTS</strong></th>
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| Molecular tests detect nucleic acid from SARS-CoV-2 | Test authorized under EUA for point-of-care (deemed Waived) | May be performed under all certificate types | • Perform testing as per Manufacturer’s Instruction (MI)  
• Perform Quality Control as per MI  
• No personnel requirements |
| Serology tests detect SARS-CoV-2 antibodies present in the blood | Test authorized under EUA for high and/or moderate complexity | ○ Certificate of Compliance  
○ Certificate of Accreditation | Must meet requirements for Moderate or High Complexity Testing, depending upon test complexity or setting, as authorized in EUA |
| Antigen tests detect SARS-CoV-2 antigens present in the blood | FDA notified,** but test is not FDA authorized under EUA | ○ Certificate of Compliance  
○ Certificate of Accreditation | Must meet requirements for High Complexity Testing (regardless of whether manufacturer intends for test to be point-of-care/waived) |

Required certificate type depends on authorized settings included in Emergency Use Authorization (EUA).

### Laboratory Developed Tests (LDTs)

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<td><strong>LABORATORY DEVELOPED TESTS (LDTs)</strong></td>
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| In vitro diagnostic test that is designed, manufactured and used within a single laboratory; can be a molecular, serology, or antigen test | LDT authorized under EUA | ○ Certificate of Compliance  
○ Certificate of Accreditation | Must meet requirements for High Complexity Testing |
| FDA notified,** but LDT not authorized under EUA | | ○ Certificate of Compliance  
○ Certificate of Accreditation | Must meet requirements for High Complexity Testing |
| LDT authorized by State Authority through a State Approved Program | | ○ Certificate of Compliance  
○ Certificate of Accreditation | Must meet requirements for High Complexity Testing |
| LDT not authorized under EUA or State Authority and FDA NOT NOTIFIED | | | Email: FDA-COVID-19-Fraudulent-Products@fda.hhs.gov |

### AT-HOME

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<td>Email: <a href="mailto:FDA-COVID-19-Fraudulent-Products@fda.hhs.gov">FDA-COVID-19-Fraudulent-Products@fda.hhs.gov</a></td>
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| • Perform testing as per Manufacturer’s Instruction (MI)  
• Perform Quality Control as per MI  
• No personnel requirements | Test authorized under EUA for point-of-care (deemed Waived) |
| ○ Certificate of Compliance  
○ Certificate of Accreditation | Test authorized under EUA for high and/or moderate complexity |
| ○ Certificate of Compliance  
○ Certificate of Accreditation | FDA notified,** but test is not FDA authorized under EUA |
| ○ Certificate of Compliance  
○ Certificate of Accreditation | LDT authorized by State Authority through a State Approved Program |

Email: FDA-COVID-19-Fraudulent-Products@fda.hhs.gov

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*Laboratories and facilities such as academic laboratories, research laboratories, pharmacies, and veterinary laboratories would need CLIA certification to perform SARS-CoV-2 testing.

**FDA notified means that the laboratory or manufacturer has notified FDA as described in FDA’s COVID-19 Test Guidance and is now listed on the FDA website here.