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

TYPE OF SARS-CoV-2 TESTING	FDA AUTHORIZATION/ NOTIFICATION	CLIA CERTIFICATES UNDER WHICH TESTING CAN BE PERFORMED	REQUIREMENTS
TEST KITS **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)	Test not authorized under EUA and **FDA NOT notified**	**Email: FDA-COVID-19-Fraudulent-Products@fda.hhs.gov**	
LABORATORY DEVELOPED TESTS (LDTs) 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	At-Home Specimen Collection and Testing	**Home specimen collection or home testing is not permitted unless explicitly authorized under EUA**	

**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*