

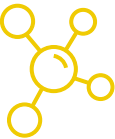

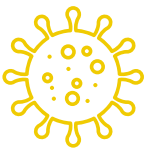


CMS CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA):

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	
 <p>TEST KITS Molecular tests detect nucleic acid from SARS-CoV-2</p>	Test authorized under EUA for point-of-care (deemed Waived)	May be performed under all certificate types	<ul style="list-style-type: none"> Perform testing as per Manufacturer's Instruction (MI) Perform Quality Control as per MI No personnel requirements 	
	 <p>Serology tests detect SARS-CoV-2 antibodies present in the blood</p>	Test authorized under EUA for high and/or moderate complexity	<ul style="list-style-type: none"> <input type="radio"/> Certificate of Compliance <input type="radio"/> Certificate of Accreditation 	Must meet requirements for Moderate or High Complexity Testing , depending upon test complexity or setting, as authorized in EUA
	 <p>Antigen tests detect SARS-CoV-2 antigens present in the blood</p> <p>Required certificate type depends on authorized settings included in Emergency Use Authorization (EUA)</p>	FDA notified ,** but test is not FDA authorized under EUA	<ul style="list-style-type: none"> <input type="radio"/> Certificate of Compliance <input type="radio"/> Certificate of Accreditation 	Must meet requirements for High Complexity Testing (regardless of whether manufacturer intends for test to be point-of-care/waived)
 <p>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</p>	Test not authorized under EUA and FDA NOT notified	Email: FDA-COVID-19-Fraudulent-Products@fda.hhs.gov		
	LDT authorized under EUA	<ul style="list-style-type: none"> <input type="radio"/> Certificate of Compliance <input type="radio"/> Certificate of Accreditation 	Must meet requirements for High Complexity Testing	
	FDA notified , ** but LDT not authorized under EUA	<ul style="list-style-type: none"> <input type="radio"/> Certificate of Compliance <input type="radio"/> Certificate of Accreditation 	Must meet requirements for High Complexity Testing	
	LDT authorized by State Authority through a State Approved Program	<ul style="list-style-type: none"> <input type="radio"/> Certificate of Compliance <input type="radio"/> 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			
 <p>AT-HOME</p>	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](#)

