DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: Admin Info: 20-06-CLIA EXPIRED

DATE: **December 4, 2025**

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group

SUBJECT: **EXPIRED:** CMS SARS-CoV-2 Laboratory Testing Comparison

Memo Information:
Memo expiration date: **2025-12-04**
Original release date: **2020-05-21**

Memorandum Summary

- **CMS is committed to taking critical steps to ensure America's clinical laboratories can respond to the threat of the 2019 Novel Coronavirus (COVID-19) and other respiratory illnesses to ensure patient health and safety.**
- **Laboratories need a Clinical Laboratory Improvement Amendments (CLIA) certificate to perform severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) testing. Under CLIA, laboratories are prohibited from testing human specimens for the purpose of diagnosis, prevention, treatment, or health assessment without a valid CLIA certificate. This also applies to facilities not typically considered to be laboratories that are performing SARS-CoV-2 testing.**
- **This guidance is a part of the Centers for Medicare & Medicaid Services (CMS) effort to clarify:**
  - **The types of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) testing and whether the tests are being offered under an Emergency Use A20-Xuthorization (EUA) issued by FDA or as described in FDA's COVID-19 Test Guidance**
  - **The CLIA certifications under which each test can be performed**
  - **An explanation of requirements under each testing scenario**
  - **Updated information for Medicare beneficiaries on testing services and coverage**

Background:
CMS is committed to taking critical steps to ensure America's clinical laboratories can respond to the threat of COVID-19 and other respiratory illnesses to protect patient health and safety. The intent of the CLIA program is to ensure that test results provided to individuals and their health care providers are accurate and reliable.

Laboratories need a CLIA certificate to perform SARS-CoV-2 testing. Under CLIA, laboratories are prohibited from testing human specimens for the purpose of diagnosis, prevention, treatment,

or health assessment without a valid CLIA certificate. Clinical laboratories and facilities such as academic laboratories, research laboratories, pharmacies, physician offices, urgent care clinics, and veterinary laboratories need CLIA certification to perform SARS-CoV-2 testing on human specimens. This guidance is part of the CMS effort to clarify the types of SARS-CoV-2 testing, whether the tests are being offered under an EUA issued by FDA or as described in FDA's COVID-19 Test Guidance, the CLIA certifications and requirements under which testing can be performed, and information for Medicare beneficiaries on testing services and coverage.

Guidance:
This guidance is intended to clarify the different types of testing available for laboratories, whether the tests are being offered under an EUA issued by FDA or as described in FDA's COVID-19 Test Guidance for these tests systems, and the CLIA certificates under which testing can be performed. As of today, there are two different types of SARS-CoV-2 testing. One type is molecular, which detects nucleic acid from SARS-CoV-2. The other type is serology, or antibody testing, which measures SARS-CoV-2 antibodies present in the blood. There is a third type of SARS-CoV-2 test which detect antigens present in the blood. As of today, no antigen tests for SARS-CoV-2 have been authorized by FDA. Such tests will be added to the FDA website when authorized.

Currently, COVID-19 tests are being offered that have been FDA authorized under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (these are listed on the FDA website here.) or under the policies outlined in the FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019 ("COVID-19 Test Guidance"). This document discusses policies applicable to testing for COVID-19, including Laboratory Developed Tests (LDTs). "FDA notification" means that the laboratory or manufacturer has provided FDA with notification that it has validated its test as described in the policies outlined in FDA's COVID-19 Test Guidance and is now listed on the FDA website here.

Further, an explanation of covered testing services for beneficiaries and payment rates for SARS-CoV-2 tests under Medicare is included with this information.

CMS has received many questions about which assays can be performed under which type of CLIA certificate. This document delineates which assays offered can be performed by laboratories under each of the CLIA Certificate types. CLIA has four different certificate types, which are Certificate of Waiver, Certificate of Provider-Performed Microscopy, Certificate of Compliance, and Certificate of Accreditation. The required certificate type depends on whether the test was issued an EUA, and if so, the authorized settings included in the Emergency Use Authorization (EUA).

For information about CMS' response to the COVID-19 public health emergency, please refer to our CMS QSO 20-21-CLIA guidance document and CMS CLIA COVID-19 FAQs

Contact: For questions or concerns relating to this memorandum, please contact LabExcellence@cms.hhs.gov

Effective Date: Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Attachments: CMS COVID-19 Testing Infographic

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

Receive email notification for memos:

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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 **Serology tests** detect SARS-CoV-2 antibodies present in the blood **Antigen tests** detect SARS-CoV-2 antigens present in the blood Required certificate type depends on authorized settings included in Emergency Use Authorization (EUA)	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
	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
	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)**
	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**	

CMS CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA):

TESTING REQUIREMENTS FOR SARS-CoV-2

Last updated May 20, 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

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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*

// CMS ACTIONS TO EXPAND **SARS-CoV-2 TESTING**

WHERE MEDICARE BENEFICIARIES CAN GET TESTED

ALTERNATIVE SITES

// MEDICARE PAYMENT FOR **LAB SERVICES**

MEDICARE PAYMENT FOR LAB SERVICES