



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Admin Info: 20-06-CLIA

DATE: **May 21, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: CMS SARS-CoV-2 Laboratory Testing Comparison

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. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

David R. Wright

cc: Survey & Operations Group (SOG) Management

Attachments: CMS COVID-19 Testing Infographic

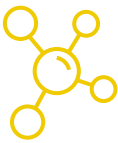
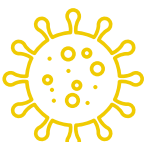
CMS CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA):

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

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

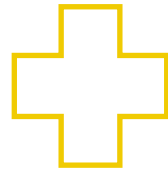
*Laboratories and facilities such as academic laboratories, research laboratories, pharmacies, and veterinary laboratories would need CLIA certification to perform SARS-CoV-2 testing

**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



DOCTOR'S OFFICE, HOSPITAL

- Medicare is separately paying hospitals and practitioners to assess patients and collect laboratory samples for COVID-19 testing even when that is the only service the patient receives. This approach supports both hospitals and physician practices to operate testing sites.
- To ensure that Medicare beneficiaries have broad access to testing, for Medicare payment purposes, Medicare no longer requires an order from the treating physician or other practitioner for beneficiaries to get both COVID-19 testing and laboratory tests for influenza and respiratory syncytial virus that may be part of a COVID-19 diagnosis. COVID-19 tests may be covered when ordered by any healthcare professional authorized to do so under state law.
- Medicare is covering serology (or antibody) tests, which may be helpful for patients, practitioners, and communities in making decisions on medical treatment and responsible social distancing policies.



HOME (INCLUDING NURSING HOMES)

- For beneficiaries who are homebound and unable to travel, Medicare pays labs to send technicians to a beneficiary's home, including a nursing home when a beneficiary is not in a Part A skilled nursing stay, to collect a lab sample.
- A home health nurse could collect a lab sample as part of a normal visit for beneficiaries receiving home health services.
- A visiting nurse working for a Rural Health Clinic or Federally Qualified Health Center and making a home visit can collect a lab sample under certain conditions.



PHARMACY

- Medicare will pay for COVID-19 tests performed by pharmacists as part of a Medicare-enrolled laboratory.
- A pharmacist also may furnish basic clinical services, such as collect lab samples, under contract with a doctor or practitioner, in accordance with a pharmacist's scope of practice and state law.
- Beneficiaries can get tested at "parking lot" test sites operated by pharmacies consistent with state requirements.



DRIVE-THROUGH TESTING OR ALTERNATIVE SITES

- Healthcare facilities like hospitals, doctor's offices, labs can set up off-site locations like drive-through testing to collect samples. Medicare pays these healthcare providers as they normally would.

// MEDICARE
PAYMENT FOR
LAB SERVICES

MEDICARE PAYMENT FOR LAB SERVICES

LAB SERVICE	MEDICARE PAYMENT	BILLING CODE
CDC RNA Based Lab Test	Approx. \$36	HCPCS code U0001
Non- CDC Lab Test that uses any technique, multiple types or subtypes (includes all targets)	Approx. \$51	HCPCS code U0002
Non CDC Lab Test using RNA based technique	Approx. \$51	CPT code 87635
Serology (antibody) test	Approx \$45	CPT code 86328
	Approx \$42	CPT code 86769
Lab Test Using High Through-Put Technology	\$100 <i>(effective 4/14)</i>	HCPCS code U0003; HCPCS code U0004
Lab Specimen Collection from a Patient	Approx \$23-\$25	HCPCS code C9803 billed by hospital outpatient department
		HCPCS code 99211 billed by a physician office
		HCPCS code G2023/G2024 for home/nursing home collection by a lab or on behalf of a home health agency