

**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><b>TEST KITS</b>  <b>Molecular tests</b> 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"> <li>Perform testing as per <a href="#">Manufacturer's Instruction (MI)</a></li> <li>Perform Quality Control as per MI</li> <li>No personnel requirements</li> </ul>	
	 <p><b>Serology tests</b> 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"> <li>Certificate of Compliance</li> <li>Certificate of Accreditation</li> </ul>	Must meet requirements for <b>Moderate</b> or <b>High Complexity Testing</b> , depending upon test complexity or setting, as authorized in EUA
	 <p><b>Antigen tests</b> detect SARS-CoV-2 antigens present in the blood</p> <p>Required certificate type depends on authorized settings included in <a href="#">Emergency Use Authorization (EUA)</a></p>	FDA <a href="#">notified</a> ,** but test is not FDA authorized under EUA	<ul style="list-style-type: none"> <li>Certificate of Compliance</li> <li>Certificate of Accreditation</li> </ul>	Must meet requirements for <b>High Complexity Testing (regardless of whether manufacturer intends for test to be point-of-care/waived)</b>
 <p><b>LABORATORY DEVELOPED TESTS (LDTs)</b>            In vitro diagnostic test that is designed, manufactured and used within a single laboratory; can be a molecular, serology, or antigen test</p>	LDT authorized under EUA	<ul style="list-style-type: none"> <li>Certificate of Compliance</li> <li>Certificate of Accreditation</li> </ul>	Must meet requirements for <b>High Complexity Testing</b>	
	FDA <a href="#">notified</a> , ** but LDT not authorized under EUA	<ul style="list-style-type: none"> <li>Certificate of Compliance</li> <li>Certificate of Accreditation</li> </ul>	Must meet requirements for <b>High Complexity Testing</b>	
	LDT authorized by State Authority through a <a href="#">State Approved Program</a>	<ul style="list-style-type: none"> <li>Certificate of Compliance</li> <li>Certificate of Accreditation</li> </ul>	Must meet requirements for <b>High Complexity Testing</b>	
	LDT not authorized under EUA or State Authority and <b>FDA NOT NOTIFIED</b>	<b>Email: <a href="mailto:FDA-COVID-19-Fraudulent-Products@fda.hhs.gov">FDA-COVID-19-Fraudulent-Products@fda.hhs.gov</a></b>		
 <p><b>AT-HOME</b></p>	At-Home Specimen Collection and Testing	<b>Home specimen collection or home testing is not permitted unless explicitly authorized under EUA</b>		

\*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	<b>Approx. \$36</b>	HCPCS code U0001
Non- CDC Lab Test that uses any technique, multiple types or subtypes (includes all targets)	<b>Approx. \$51</b>	HCPCS code U0002
Non CDC Lab Test using RNA based technique	<b>Approx. \$51</b>	CPT code 87635
Serology (antibody) test	<b>TBD</b>	CPT code 86328 CPT code 86769
Lab Test Using High Through-Put Technology	<b>\$100</b> <i>(effective 4/14)</i>	HCPCS code U0003; HCPCS code U0004
Lab Specimen Collection from a Patient	<b>Approx \$23-\$25</b>	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