



Testing for COVID-19

Offering our clients state-of-the-art testing is part of CPL's ongoing commitment to excellence.

On **March 11th, 2020**, Clinical Pathology Laboratories began offering testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19).

Clinical Information:

Coronaviruses (CoVs) are a family of enveloped positive-strand RNA viruses that can infect humans and many different species of birds and mammals, including camels, cattle, cats, and bats. The family of viruses can cause respiratory illness ranging from the common cold to more severe respiratory diseases such as Middle East Respiratory Syndrome and Severe Acute Respiratory Syndrome. The most recently identified severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the causative agent of Coronavirus Disease 2019 (COVID-19). Since its emergence at the end of 2019 in Wuhan City, China, the virus has caused an ongoing global outbreak of COVID-19 and a major global public health emergency. The number of patients infected globally by the SARS-CoV-2 virus are increasing rapidly. As of May 12th, 2020, at least 4.18 million confirmed cases and more than 286,000 deaths in over 210 countries are reported. In the US, 81,500 deaths and at least 1.38 million confirmed and presumptive cases of COVID-19 have been reported.

Characteristics of the COVID-19:

- Transmitted via respiratory droplets similar to influenza virus.
- Has an incubation period of 2-14 days following exposure with most showing symptoms in 5 days.
- Manifestations range from mild disease with fever, dry cough, shortness of breath, and pulmonary infiltrates to critical illness with respiratory failure, shock, or multi-organ failure.

The SARS-CoV-2 (COVID-19) test offered by CPL uses the FDA Emergency Use Authorization (EUA) approved CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel and is intended for the presumptive qualitative detection of 2019-nCoV in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) from individuals who meet CDC or public health criteria for COVID-19 testing.

CDC's clinical criteria for COVID-19 testing is frequently updated as additional information becomes available. The most recent information on COVID-19 can be found at: www.cdc.gov/coronavirus/2019-ncov/downloads/priority-testing-patients.pdf. The current CDC criteria for laboratory testing includes:

Priority 1: Symptomatic hospitalized patients or healthcare workers (to ensure optimal care for hospitalized patients, lessen the risk of hospital infections, and maintain the healthcare system).

Priority 2: Symptomatic long-term care residents, patients 65 years of age and older, patients with underlying conditions or first responders (to ensure that those at highest risk of complications are rapidly identified and triaged).

Priority 3: Symptomatic critical infrastructure workers, asymptomatic health care workers, and individuals with mild symptoms in communities with high COVID-19 hospitalizations (to test individuals in the community around increasing hospital cases to decrease community spread and ensure health of essential workers).

With limited test capacity, CPL is requesting that clinics submit priority 1 and 2 specimens as defined above for testing. There is limited capacity for lower priority testing. Please contact your Account Representative should you have any questions regarding testing details.

Test results from SARS-CoV-2 by RT-PCR test must be accompanied by the following information pertaining to the EUA, which is required to be made available to healthcare providers and patients.

Fact Sheet for Healthcare Providers: www.fda.gov/media/134920/download

Fact Sheet for Patients: www.fda.gov/media/134921/download

See page 2 for test information and specimen requirements

Thank you for supporting Clinical Pathology Laboratories

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TEST INFORMATION:	
Test Code / Name:	7305 SARS-COV-2 BY RT-PCR
Important Information:	<p>When possible, please include the official Human Infection With 2019 Novel Coronavirus Person Under Investigation (PUI) and Case Report Form with test sample. PUI Form can be accessed here: (www.cdc.gov/coronavirus/2019-ncov/downloads/pui-form.pdf).</p> <p>The source must be clearly indicated on the specimen and test requisition.</p> <p>See front for information on test priority.</p>
SPECIMEN REQUIREMENTS (Please refer to our test catalog at cpllabs.com for up-to-date information on acceptable specimen requirements):	
Preferred Sample:	<ul style="list-style-type: none">Upper Respiratory Tract: Nasopharyngeal Swab
Acceptable Sample:	<ul style="list-style-type: none">SputumLower Respiratory Tract: Bronchoalveolar Lavage OR Tracheal Aspirate
Container Type:	<p>Nasopharyngeal swabs: Viral or Universal Transport Media (VTM-M4, VTM-M4RT, UTM-RT, BD UTV, Puritan UniTranz-RT (UT-100), Sonic VTM), ESwab (white, blue or green top), OneSwab or glass sterile saline tube inside U50 with swab(s) in collection container.</p> <p>Sputum: Sterile cup.</p> <p>Bronchoalveolar lavage/tracheal aspirate: Sterile cup.</p> <p><i>For initial diagnostic testing for COVID-19, CDC recommends collecting and testing an upper respiratory nasopharyngeal swab (NP).</i></p>
Collection Instructions:	<p>Nasopharyngeal Swab: Tilt patient's head back 70 degrees and insert swab into nostril parallel to palate. (Swab should reach depth equal to distance from nostrils to outer opening of the ear). Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Place tip of swab into the transport media and snap off the applicator stick. Ensure cap is properly sealed and refrigerate (critical).</p> <p>NOTE: Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. Refrigerate specimen at 2-8°C and ship overnight on ice pack. If specimen will not reach the laboratory within 72 hours of collection (48 hours for ESwab collection devices), freeze and ship on dry ice.</p> <p>Instruction for Saline Collection Media: We prefer that you use our collection supplies and we will get them to you as quickly as possible. If you have to urgently sample a patient, you should use: 1) 0.9% commercially prepared sterile, preservative free saline. 2) Sterile clean plastic transport tubes, no larger than 15 mL capacity; 15 mL polypropylene tubes (Falcon, Fisher, others) are acceptable. 3) At least 2 mL and no more than 3 mL fill volume; under-filling prevents retesting and overfilling will be rejected as this decreases test sensitivity. 4) Use of an approved flocced or foam swab (see laboratory COVID-19 Specimen Transport Media and Swab announcement for acceptable swab types). All saline swabs are critical refrigerated, ship refrigerated unless testing cannot be conducted within 72 hours in which case these should be frozen -20°C. Glass tubes cannot be frozen. If using plastic saline tube, there is no need to transport inside of the U50.</p> <p>Other specimens:</p> <p>Oropharyngeal (OP) swab: collected by a healthcare professional</p> <p>Nasal mid-turbinate swab: collected by healthcare professional or onsite self-collection</p> <p>Anterior nare swab: collected by healthcare professional or onsite self-collection</p> <p>Sputum: Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Do not induce sputum. Refrigerate specimen at 2-8°C. If specimen will not reach the laboratory within 48 hours of collection, freeze and ship on dry ice.</p> <p>Bronchoalveolar Lavage, Tracheal Aspirate: Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C and ship overnight on ice pack. If specimen will not reach the laboratory within 48 hours of collection, freeze and ship on dry ice.</p>
Transport Temperature:	Critical Refrigerate
Specimen Stability:	Refrigerated: 72 Hours (48 Hours for ESwab collection systems) Frozen (-20°C or below): 1 Week
Rejection Criteria:	Room temperature specimens, swabs not in viral transport media, calcium alginate swabs and swabs with wooden shafts WILL NOT be accepted.
TESTING:	
Expected Turn Around:	1 - 3 Days (NOTE: High Risk testing takes priority and may impact TAT accordingly)
Testing Frequency:	Daily
CPT:	87635 <u>OR</u> U0001/U0002 for Medicare patients and testing performed prior to 3/13/20
Methodology:	Real-Time Polymerase Chain Reaction (RT-PCR)

COMPLIANCE STATEMENT: This test has not been Food and Drug Administration (FDA) cleared or approved and has been authorized by FDA under an Emergency Use Authorization (EUA). The test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of SARS-CoV-2 under Section 564(b)(1) of the Act, 21 U.S.C. section 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. Sonic Reference Laboratory and Clinical Pathology Laboratories are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. section 263a, to perform high complexity tests.