CLINICAL PATHOLOGY LABORATORIES
A Sonic Healthcare Company

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 March 25th, 2020, at least 455,000 confirmed cases and more than 20,500 deaths in over 180 countries are reported. In the US, 840 deaths and at least 61,000 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: **https://www.cdc.gov/coronavirus/2019-nCoV/index.html**. The current CDC criteria for laboratory testing includes:

> "Clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Decisions on which patients receive testing should be based on the local epidemiology of COVID-19, as well as the clinical course of illness. Most patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). Clinicians are strongly encouraged to test for other causes of respiratory illness, including infections such as influenza.
>
> Epidemiologic factors that may help guide decisions on whether to test include: any persons, including healthcare workers, who have had close contact with a laboratory-confirmed COVID-19 patient within 14 days of symptom onset, or a history of travel from affected geographic areas within 14 days of symptom onset."

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: **https://www.fda.gov/media/134920/download**

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

Please contact your Account Representative should you have any questions regarding testing details.

See page 2 for test information and specimen requirements

Thank you for supporting Clinical Pathology Laboratories

Testing for COVID-19

TEST INFORMATION:	
Test Code / Name:	7305 **SARS-COV-2 BY RT-PCR**
Important Information:	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: (**https://www.cdc.gov/coronavirus/2019-ncov/downloads/pui-form.pdf**). **The source must be clearly indicated on the specimen and test requisition.** Test Code 7305 should be utilized for patients who are symptomatic with respiratory symptoms (cough, fever, dyspnea or sore throat) AND have traveled to a COVID-19 endemic area, have been in close contact with a known COVID-19 patient, have chronic medical conditions, are immunocompromised, or are otherwise considered High Risk from an epidemiological perspective.
SPECIMEN REQUIREMENTS (*Please refer to our test catalog at* ***cpllabs.com*** *for up-to-date information on acceptable specimen requirements*)**:**	
Preferred Sample:	• Upper Respiratory Tract: Nasopharyngeal Swab
Acceptable Sample:	• Sputum • Lower Respiratory Tract: Bronchoalveolar Lavage OR Tracheal Aspirate
Container Type:	Nasopharyngeal swabs: Viral or Universal Transport Media (VTM-M4, VTM-M4RT, UTM-RT or BD UTV) or eSwab (white, blue or green top) with Swab(s) in collection container. Ensure cap is properly sealed. Sputum: Sterile cup. Bronchoalveolar lavage/tracheal aspirate: Sterile cup. *For initial diagnostic testing for COVID-19, CDC recommends collecting and testing an upper respiratory nasopharyngeal swab (NP)*
Collection Instructions:	**Nasopharyngeal Swab:** 1. Tilt patient's head back 70 degrees. 2. 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. 3. Slowly remove swab while rotating it. 4. Place tip of swab into VTM/UTM and snap off the applicator stick. 5. Ensure cap is properly sealed. 6. Refrigerate (critical). **NOTE:** Use only synthetic fiber swabs with plastic shafts. 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 48 hours of collection, freeze and ship on dry ice. **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. **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.
Transport Temperature:	Critical Refrigerate
Specimen Stability:	Refrigerated: 48 Hours 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 OR 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 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.