SARS-CoV-2 (COVID-19) by NAAT

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

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 June 24th, 2020, at least 9.24 million confirmed cases and more than 477,000 deaths in over 210 countries are reported. In the US, 123,000 deaths and at least 2.39 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.

Methodologies:

Roche COBAS Real-Time RT-PCR: This assay uses the FDA Emergency Use Authorization (EUA) authorized Roche COBAS 2019 Novel Coronavirus (SARS-CoV-2) Real-Time Reverse Transcriptase (RT)-PCR assay intended for the qualitative detection of nucleic acids from SARS-CoV-2 in clinician-instructed self-collected nasal swab specimens (collected on site), and clinician-collected nasal, nasopharyngeal, and oropharyngeal swab specimens from individuals who meet COVID-19 clinical and/or epidemiological criteria. For more information, see:
Fact Sheet for Healthcare Providers: ***www.fda.gov/media/136047/download***
Fact Sheet for Patients: ***www.fda.gov/media/136048/download***

Roche COBAS Real-Time RT-PCR with specimen pooling: This assay uses the FDA Emergency Use Authorization (EUA) authorized Roche COBAS 2019 Novel Coronavirus (SARS-CoV-2) Real-Time Reverse Transcriptase (RT)-PCR assay. For specimen pooling, the assay is submitted for authorization by FDA under an Emergency Use Authorization (EUA). Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, pooled samples should be tested individually. Negative results do not preclude SARS-CoV-2 infection and must not be used as the sole basis for patient management decisions. Negative results must be considered in the context of a patient's recent exposures, history, presence of clinical signs and symptoms consistent with COVID-19. For more information, see:
Fact Sheet for Healthcare Providers: ***www.fda.gov/media/136047/download***
Fact Sheet for Patients: ***www.fda.gov/media/136048/download***

Thermo-Fisher Real-Time RT-PCR: This assay uses the FDA Emergency Use Authorization (EUA) authorized Thermo Fisher TaqPath COVID-19 Real-Time Reverse Transcriptase (RT)-PCR Diagnostic intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (such as nasopharyngeal, oropharyngeal, nasal, and mid-turbinate swabs, and nasopharyngeal aspirate) and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider. For more information, see:
Fact Sheet for Healthcare Providers: ***www.fda.gov/media/136111/download***
Fact Sheet for Patients: ***www.fda.gov/media/136114/download***

Transcription-Mediated Amplification (TMA): This assay uses the FDA Emergency Use Authorization (EUA) authorized Hologic Aptima SARS-CoV-2 Transcription Mediated Amplification and Dual Kinetic Assay. It is a nucleic acid amplification test intended for the qualitative detection of RNA from SARS-CoV-2 isolated and purified from nasopharyngeal (NP), nasal, mid-turbinate and oropharyngeal (OP) swab specimens, nasopharyngeal wash/aspirate or nasal aspirates obtained from individuals meeting COVID-19 clinical and/or epidemiological criteria. intended for the qualitative detection of nucleic acids from SARS-CoV-2 in clinician-instructed self-collected nasal swab specimens (collected on site), and clinician-collected nasal, nasopharyngeal, and oropharyngeal swab specimens from individuals who meet COVID-19 clinical and/or epidemiological criteria. For more information, see:
Fact Sheet for Healthcare Providers: ***www.fda.gov/media/138095/download***
Fact Sheet for Patients: ***www.fda.gov/media/138098/download***

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***. CDC currently provides guidance for testing in five categories with the most recent information found here:

- Testing individuals with signs or symptoms consistent with COVID-19.
- Testing asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2 to control transmission.
- Testing asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings.
- Testing to determine resolution of infection (i.e., test-based strategy for Discontinuation of Transmission-based Precautions, HCP Return to Work, and Discontinuation of Home Isolation).
- Public health surveillance for SARS-CoV-2.

Thank you for supporting Clinical Pathology Laboratories

TEST INFORMATION:	
Test Code / Name:	***7305 SARS-COV-2 BY NUCLEIC ACID AMPLIFICATION (NAAT)***
Important Information:	All specimens must be accompanied by demographic information to include address with zip code, race and ethnicity. This is required by the CARES Act and federal regulation and is requested by state and local health authorities for public health and contact tracing purposes. In addition, limited clinical data are requested for testing. The clinical data are used for epidemiology and public health purposes. These may be used by the laboratory to determine testing priority and suitability for pooled analysis. Contact your account representative for further information on prioritization of testing. COVID-19 Requisition: ***www.cpllabs.com/COVID19_Req*** COVID-19 History Form: ***www.cpllabs.com/COVID19_History_Form*** ***The source must be clearly indicated on the specimen and test requisition***.
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, oropharyngeal, nasal mid-turbinate or anterior nares swabs
Acceptable Sample:	• Nasopharyngeal wash/aspirate • Lower Respiratory Tract - Sputum - Bronchoalveolar Lavage OR Tracheal Aspirate
Container Type:	***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), nuclease free water or 0.9% saline and phosphate buffered saline (PBS). ***Sputum:*** Sterile cup. ***Bronchoalveolar lavage/tracheal aspirate:*** Sterile cup. *For initial diagnostic testing for COVID-19, CDC recommends collecting an upper respiratory tract specimen.*
Collection Instructions:	***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). ***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. For further instructions with graphics, see URL: ***www.cpllabs.com/COVID19_Nasal_Collection*** ***Other specimens:*** ***Oropharyngeal (OP) swab:*** collected by a healthcare professional ***Nasal mid-turbinate swab:*** collected by healthcare professional or onsite self-collection ***Anterior nare swab:*** collected by healthcare professional or onsite self-collection ***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***. ***Bronchoalveolar Lavage, Tracheal Aspirate:*** Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. All specimens should be refrigerated at 2-8°C and shipped 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.
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 - 5 Days (NOTE: High Risk testing takes priority and may impact TAT accordingly)
Testing Frequency:	Daily
CPT:	87635 (NOTE: CPT for Medicare is U0003)
Methodology:	Real-Time Polymerase Chain Reaction (RT-PCR) OR Real-Time Polymerase Chain Reaction (RT-PCR) with specimen pooling OR Transcription Mediated Amplification (TMA). See report for method.

COMPLIANCE STATEMENT: The SARS-CoV-2 test is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal and oropharyngeal swab samples from patients who meet COVID-19 clinical and/or epidemiological criteria. For lower respiratory tract specimens using the Roche COBAS assay, the assay is submitted for authorization by FDA under an Emergency Use Authorization (EUA). Testing methodology is nucleic acid amplification technology (NAAT) by real-time RT-PCR or transcription mediated amplification (TMA). The methodology employed is noted in the analysis report. If received as separate collection devices, nasopharyngeal and oropharyngeal specimens are combined for analysis. Additional specimens may be split to a separate accession for analysis and reporting as this test includes a single unit of service.

Test results must be correlated with clinical presentation and evaluated in the context of other laboratory and epidemiologic data. Test performance can be affected because the epidemiology and clinical spectrum of infection caused by SARS-CoV-2 is not fully known. For example, the optimum types of specimens to collect and when during the course of infection these specimens are most likely to contain detectable viral RNA may not be known.

The real-time RT-PCR and TMA tests have not been Food and Drug Administration (FDA) cleared but have been authorized by FDA under an Emergency Use Authorization (EUA). The tests are 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. 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.