MAYO CLINIC LABORATORIES

Test Definition: CVOOA

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) RNA Detection, Varies

Overview

Useful For

Diagnosis of coronavirus disease 2019 (COVID-19) illness due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

Recommended only for patients who meet current clinical and/or epidemiologic criteria defined by federal, state, or local public health directives

Testing Algorithm

See Coronavirus Disease 2019 (COVID-19), Influenza, and Respiratory Syncytial Virus Testing Algorithm in Special Instructions.

Special Instructions

- COVID-19 Oropharyngeal Collection Instructions
- Coronavirus Disease 2019 (COVID-19), Influenza, and Respiratory Syncytial Virus Testing Algorithm

Highlights

This test provides qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA from select upper respiratory tract specimens from patients under investigation (PUI) for coronavirus disease 2019 (COVID-19).

This test ID combines 2 molecular assays designed for detection of SARS-CoV-2 into 1 orderable test. All of the assays used for testing have received emergency use authorization (EUA) from the FDA. Testing will be performed with 1 of the following assays:
-Abbott m2000rt RealTime SARS-CoV-2 assay (Abbott Molecular Inc.)
-Abbott Alinity m SARS-CoV-2 AMP assay (Abbott Molecular Inc.)

URL links to the fact sheets for each of these EUA assays are provided in the Method Description section.

Method Name

Real-Time Reverse Transcription Polymerase Chain Reaction (RT-PCR)

NY State Available

No

Specimen

Specimen Type

Varies

Ordering Guidance

Due to the non-specific clinical presentation of coronavirus disease 2019 (COVID-19) during the early stages of illness, testing for other respiratory tract infections (eg, influenza) may be warranted.

For the most up-to-date COVID-19 epidemiology and testing recommendations, visit https://www.cdc.gov/coronavirus/2019-ncov/index.html

Shipping Instructions

Ship specimens refrigerated (if less than 72 hours from collection to arrive at MCL) or frozen (if 72 hours or more from collection to arrive at MCL).

Specimen Required

Specimen Type: Nasopharyngeal (NP), oropharyngeal (OP; ie, throat).
Supplies: Swab, Sterile Polyester (T507)
Container/Tube: Universal transport media, viral transport media, or equivalent (eg, Copan UTM-RT, BD VTM, MicroTest M4, M4-RT, M5)
Media should not contain guanidine thiocyanate (GTC).
For more information on acceptable transport media, see https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2
Specimen Volume: Entire specimen with a minimum of 1.5 mL (maximum 3 mL) of transport media.
Collection Instructions:
1. Collect specimen by swabbing back and forth over nasal or pharyngeal mucosa surface to maximize recovery of cells. For more information on OP swab specimen collection, see COVID-19 Oropharyngeal Collection Instructions in Special Instructions.
2. NP and OP swab specimens may be combined at collection into a single vial of transport media but only one swab is required for analysis.
3. Swab must be placed into transport medium. Swab shaft should be broken or cut so that there is no obstruction to the sample or pressure on the media container cap.
4. Do **not** send in glass tubes, vacutainer tubes, or tubes with push caps**.**
5. **Do not overfill** with more than 3 mL total volume of media.

Specimen Type: Lower respiratory tract
Sources: Bronchoalveolar lavage (BAL) fluid, bronchial washings, endotracheal aspirate, sputum
Container/Tube: Sterile container
Specimen Volume: Minimum of 2.2 mL
Additional Information: Do not aliquot into viral transport media glass tubes, vacutainer tubes, or tubes with push caps.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Calcium alginate-tipped swab, wood shaft swab, or transport swab containing gel or charcoal additive	Reject
Transport media tubes containing the entire swab (shaft and knob attached)	Reject
Glass transport media tubes	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated	72 hours	
	Frozen (preferred)	14 days	

Clinical & Interpretive

Clinical Information

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a positive-sense, single-stranded RNA virus that causes coronavirus disease 2019 (COVID-19). Like other coronaviruses that infect humans, SARS-CoV-2 can cause both upper and lower respiratory tract infection. Symptoms can range from mild (ie, common cold) to severe (ie, pneumonia) in both healthy and immunocompromised patients. SARS-CoV-2 transmission occurs primarily via respiratory droplets. During the early stages of COVID-19, symptoms maybe nonspecific and resemble other common respiratory tract infections, such as influenza. If testing for other respiratory tract pathogens is negative, specific testing for SARS-CoV-2 may be warranted.

SARS-CoV-2 is likely to be at the highest concentrations in the nasopharynx during the first 3 to 5 days of symptomatic illness. As the disease progresses, the viral load tends to decrease in the upper respiratory tract, at which point lower respiratory tract specimens (eg, sputum, tracheal aspirate, bronchoalveolar fluid) would be more likely to have detectable SARS-CoV-2.

Reference Values

Undetected

Interpretation

A "Detected" result indicates that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA is present and suggests the diagnosis of coronavirus disease 2019 (COVID-19). Test result should always be considered in the context of patient's clinical history, physical examination, and epidemiologic exposures when making the final diagnosis.

An "Undetected" result indicates that SARS-CoV-2 is not present in the patient's specimen. However, this result may be influenced by the stage of the infection, as well as the quality and type of the specimen collected for testing. Result should be correlated with patient's history and clinical presentation.

An "Inconclusive" result indicates that the presence or absence of SARS-CoV-2 RNA in the specimen could not be determined with certainty after repeat testing in the laboratory, possibly due to real-time reverse transcription polymerase chain reaction (RT-PCR) inhibition. Submission of a new specimen for testing is recommended.

Cautions

The FDA has provided emergency use authorization (EUA) of these assays for testing human nasopharyngeal and oropharyngeal swab specimens. Bronchoalveolar lavage fluid specimens were validated in a manner consistent with CLIA requirements.

The sensitivity of the assays is dependent on the timing of the specimen collection (in relation to symptom onset), as well as the quality and type of the specimen submitted for testing.

The test is specific for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and positive test results do not exclude the possibility of concurrent infection with other respiratory viruses.

Undetected (ie, negative) results do not rule out coronavirus disease 2019 (COVID-19) in patients and should not be used as the sole basis for treatment or other patient management decisions. Result should be correlated with patient's history and clinical presentation.

Clinical Reference

1. Zhu N, Zhang D, Wang W, et al: A novel coronavirus from patients with pneumonia in China, 2019. N Engl J Med. 2020;382(8):727-733 doi: 10.1056/NEJMoa2001017
2. Loeffelholz MJ, Tang YW: Laboratory diagnosis of emerging human coronavirus infections-the state of the art. Emerg Microbes Infect. 2020;9(1):747-756 doi: 10.1080/22221751.2020.1745095
3. Mohammadi A, Esmaeilzadeh E, Li Y, Bosch RJ, Li JZ: SARS-CoV-2 detection in different respiratory sites: a systematic review and meta-analysis. EBioMedicine. 2020 Sep;59:102903. doi: 10.1016/j.ebiom.2020.102903
4. Centers for Disease Control and Prevention. Overview of testing for SARS-CoV-2. Available at www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html
5. Food and Drug Administration. FAQs on diagnostic testing for SARS-CoV-2. Available at www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

Performance

Method Description

Abbott m2000rt assay:

The Abbott m2000 Sample Preparation System kit is used with the automated Abbott m2000sp sample preparation system to extract and purify viral RNA from human nasopharyngeal specimens, based on magnetic particle technology. Amplification and detection of target sequence is performed on the Abbott m2000rt instrument. This kit contains primers and probes targeting the N and RdRp genes specific for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). An internal RNA control is also added to the extraction reagents and carried through the entire process in each specimen to ensure adequate extraction has occurred free of inhibitory substances.(Package insert: Abbott RealTime SARS-CoV-2. Abbott Molecular Inc; 03/2020)

Fact sheets for this EUA assay can be found at the following URL:
For health care providers: https://www.fda.gov/media/136256/download
For patients: https://www.fda.gov/media/136257/download

Abbott Alinity m assay:
The Alinity m SARS-CoV-2 assay is a dual target assay for the RdRp and N genes.

An RNA sequence that is unrelated to the SARS-CoV-2 sequence is introduced into each specimen at the beginning of sample preparation. This unrelated RNA sequence is simultaneously amplified by real-time reverse transcription polymerase chain reaction (RT-PCR) and serves as an internal control (IC) to demonstrate that the process has proceeded correctly for each sample.

The Alinity m SARS-CoV-2 assay detects the SARS-CoV-2 virus and IC target sequences through the use of target-specific fluorescent-labeled oligonucleotide probes. The probes do not generate a signal unless they are specifically bound to the amplified product. The 2 SARS-CoV-2-specific probes are labeled with the same fluorophore and the IC-specific probe is labeled with a different fluorophore, thus allowing for simultaneous detection of both SARS-CoV-2 and IC amplified products in the same reaction vessel.(Package insert: Abbot SARS-CoV-2 AMP Procedure. Abbott Molecular Inc; 05/2020)

Fact sheets for this assay can be found at the following URL:
For healthcare providers: https://www.fda.gov/media/137978/download
For patients: https://www.fda.gov/media/137981/download

PDF Report

No

Day(s) Performed

Monday through Sunday

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Report Available
1 to 3 days

Specimen Retention Time
3 days

Performing Laboratory Location
Phoenix

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test has received Emergency Use Authorization (EUA) by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
87635

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CVOOA	SARS Coronavirus 2 RNA, PCR, V	94500-6

Result ID	Test Result Name	Result LOINC® Value
CVOAS	SARS-CoV-2 Spec. Source	31208-2
610438	SARS-CoV-2 RNA	94500-6
610439	Method Summary	62364-5
CAETH	Patient Ethnicity	69490-1
CARAC	Patient Race	72826-1