Test Definition: SARS2

SARS Coronavirus 2 RNA, V

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: www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html

Highlights

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

Fact sheets for this emergency use authorization (EUA) assay can be found at the following links:

For health care providers: https://www.fda.gov/media/136256/download

For patients: https://www.fda.gov/media/136257/download

Special Instructions

- COVID-19 Oropharyngeal Collection Instructions

Method Name

Real-Time Polymerase Chain Reaction (RT-PCR)

NY State Available

Yes

Specimen

Specimen Type

Varies

Advisory Information

This test should be used for symptomatic patients under investigation for coronavirus disease 2019 (COVID-19). It is not to be used for screening asymptomatic patients.

Shipping Instructions

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

Necessary Information

Specimen source is required.

Specimen Required

Specimen Type: Nasopharyngeal (NP), oropharyngeal (OP; ie, throat), or nares/nasal swab

Supplies:

-Nasopharyngeal Swab (Rayon Mini-Tip Swab) (T515)

-Swab, Sterile Polyester swab (T507)

-Dacron-tipped swab with plastic shaft is acceptable

-M4-RT (T605)

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 alternative transport media, see www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

Specimen Volume: Entire collection with a minimum of 2.2 mL (maximum 3 mL) of transport medium

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 tube, and **do not overfill** with more than 3 mL total volume of media.

Specimen Type: Nasopharyngeal aspirate, nasal washing

Container/Tube: Sterile container

Specimen Volume: Minimum of 1.5 mL

Additional Information: Do not aliquot into viral transport 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.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Calcium alginate-tipped swab, wooden shaft swab, or swab collection tubes containing gel or charcoal additive. Transport media tubes containing the entire swab (shaft and knob attached) Glass transport media tubes	Reject
Thawed	Cold OK; Warm reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Frozen (preferred)	7 days	
	Refrigerated	72 hours	

Clinical and Interpretive

Clinical Information

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus 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 illness. Symptoms can range from mild (ie, the 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 disease, the symptoms maybe nonspecific and resemble other common respiratory infections, such as influenza. If testing for other respiratory infections is negative, specific testing for SARS-CoV-2 (COVID-19) 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, quality and type of specimen collected for testing. Result should be correlated with patientâ€™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 RT-PCR inhibition. Submission of a new specimen for testing is recommended.

Cautions

The FDA has provided emergency use authorization (EUA) of this test for testing human nasopharyngeal, oropharyngeal (throat), and nasal swab specimens. The assay is adapted to test lower respiratory tract specimens, such as bronchial washing, bronchoalveolar lavage (BAL) fluid.

The sensitivity of the assay is dependent on the timing of the specimen collection (in relation to symptom onset), quality and type of specimen submitted.

The test is specific for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2); therefore, the results do not exclude the possibility of 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 patientâ€™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. Holshue M, DeBolt C, Lindquist S, et al: First Case of 2019 Novel Coronavirus in the United States. N Engl J Med 2020 Jan 31 doi: 10.1056/NEJMoa2001191

3. Loeffelholz MJ, Tang YW: Laboratory diagnosis of emerging human coronavirus infections-State of the art. Emerg Microbes Infect. 2020 (published ahead of print) doi.org/10.1080/22221751.2020.1745095

4. Centers for Disease Control and Prevention. Evaluating and testing persons for Coronavirus Disease 2019 (COVID-19). 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

The Abbott RealTi*m*e SARS-CoV-2 assay is performed using the FDA-approved, semi-automated Abbott *m*2000 system, which comprises the Abbott *m*2000*sp* sample preparation instrument and the Abbott *m*2000*rt* real-time PCR thermocycler. The Abbott*m*Sample Preparation System kit is used on the Abbott*m*2000*sp*instrument, based on magnetic microparticle technology, to extract and purify viral RNA from clinical upper respiratory tract swab specimens and assay controls (negative and positive) placed in 96-well microtiter plate format. An internal control is also added to the extraction reagents and carried through the entire process in each specimen to ensure adequate extraction and subsequent target amplification have occurred free of inhibitory substances.

The PCR assay mastermix contains 3 sets of primers and TaqMan probes targeting sequences in the *RdRp* and *N* genomic regions of SARS-CoV-2 and the internal control armored RNA. Amplification and detection of target sequences are performed on the Abbott*m*2000*rt*thermocycler. Clinical samples containing SARS-CoV-2 would yield detectable signals for the *RdRp* and *N* sequences.(FAM-labeled fluorescent probes) as well as the internal control gene sequence (VIC-labeled fluorescent probe) (Package insert: Abbott RealTi*m*e SARS-CoV-2. Abbott Molecular, Inc., Doc. 51-608445/R1, 03/2020)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Sunday

Analytic Time

Same day/1 day

Maximum Laboratory Time

3 days

Specimen Retention Time

5 days

Performing Laboratory Location

Rochester

Fees and 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 Regional Manager. For assistance, contact Customer Service.

Test Classification

This test has received Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration and is used per manufacturer's instructions in testing upper respiratory tract specimens, but it is modified from the manufacturer's instructions with a bridging study in testing lower respiratory tract specimens. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

U0003

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
SARS2	SARS Coronavirus 2 RNA, V	94500-6

Result ID	Test Result Name	Result LOINC Value
CVDS2	SARS-CoV-2 Spec. Source	31208-2
608933	SARS-CoV-2 RNA PCR	94500-6