MAYO CLINIC LABORATORIES

Test Definition: RSARS

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

Overview

Useful For

Rapid diagnostic test for detection of COVID-19 illness due to SARS-CoV-2

This test **should be requested only on** patients meeting current clinical and/or epidemiologic criteria defined by federal, state, or local public health directives: www.cdc.gov/coronavirus/2019-ncov/index.html

Highlights

This test provides qualitative detection of SARS-CoV-2 RNA from select upper respiratory tract specimens from patients under investigation for COVID-19.

This test is approved for testing human nasopharyngeal specimens under US Food and Drug Administration emergency use authorization (EUA). Fact sheets for this EUA assay can be found at the following links:
For health care providers: www.fda.gov/media/158404/download
For patients: www.fda.gov/media/158405/download

Method Name

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

NY State Available

No

Specimen

Specimen Type

Varies

Necessary Information

Patient's race and ethnicity, as well as collection date, are required.

Reject Due To

Calcium alginate-tipped swab Wooden shaft swab Dry swab	Reject

Swab collection tubes containing gel or charcoal additive	

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated	72 hours	

Clinical & Interpretive

Clinical Information
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a positive-sense, single-stranded RNA virus that causes 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, 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, 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.

Reference Values
Negative

Interpretation
A "Detected" result indicates that SARS-CoV-2 RNA is present and suggests the diagnosis of 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 and the quality of the specimen collected for testing. Result should be correlated with patient's history and clinical presentation.

An "Indeterminate" result suggests that the patient may be infected with a variant SARS-CoV-2 or SARS-related coronavirus. Additional testing with an alternative molecular method is recommended on a newly collection specimen.

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 inhibition. Submission of a new specimen for testing is recommended.

Cautions

The US Food and Drug Administration has provided emergency use authorization of this test for testing human nasopharyngeal swab specimens.

The sensitivity of the assay is dependent on the quality of the specimen collected for testing.

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

Negative results do not preclude infection with SARS-CoV-2 and should not be used as the sole basis for decisions on treatment or other patient care management.

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. Patel A, Jernigan DB: Initial public health response and Interim Clinical Guidance for the 2019 Novel Coronavirus Outbreak United States, December 31, 2019 - February 4, 2020. Morb Mortal Wkly Rep. 2020;69(5):140-146. doi:10.15585/mmwr.mm6905e1
3. Holshue M, DeBolt C, Lindquist S, et al: First case of 2019 novel coronavirus in the United States. N Engl J Med. 2020;382(10):929-936. doi:10.1056/NEJMoa2001191

Performance

Method Description

The Xpert Xpress SARS-CoV-2 plus test is an automated in vitro diagnostic test for qualitative detection of nucleic acid from SARS-CoV-2. The Xpert Xpress SARS-CoV-2 plus test is performed on GeneXpert Instrument Systems.

The GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real-time polymerase chain reaction (RT-PCR) assays. The systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable cartridges that hold the RT-PCR reagents and host the RT-PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. The specimen is briefly mixed by rapidly inverting the collection tube 5 times. Using the supplied transfer pipette, the sample is transferred to the sample chamber of the Xpert Xpress SARS-CoV-2 plus cartridge. The GeneXpert cartridge is loaded onto the GeneXpert Instrument System platform, which performs hands-off, automated sample processing and real-time RT-PCR for detection of viral RNA.(Package insert: Xpert Xpress SARS-CoV-2 plus. Cepheid; 302-7070, Rev A 05/2022)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available
Same day/1 to 3 days

Specimen Retention Time
7 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
RSARS	SARS Coronavirus 2 PCR, V	94500-6

Result ID	Test Result Name	Result LOINC® Value
RSAR1	SARS Coronavirus 2, PCR	94500-6
RSAR2	SARS Coronavirus 2, Source	31208-2
SRACE	Patient's Race	72826-1
SETHN	Patient's Ethnicity	69490-1