MAYO CLINIC LABORATORIES

Test Definition: SCOVH

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) RNA, 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: https://www.cdc.gov/coronavirus/2019-ncov/index.html

Testing Algorithm

In response to the new Centers for Medicare and Medicaid Services (CMS) payment strategy for coronavirus disease 2019 (COVID-19) diagnostic testing, a bill-only code will be added for orders that meet the new CMS turn-around-time requirement. For additional information refer to www.cms.gov/newsroom/press-releases/cms-changes-medicare-payment-support-faster-covid-19-diagnostic-testing.

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). Based on sequence analysis, it is predicted that this test will detect the United Kingdom (B.1.1.7), South Africa (B.1.351), and Brazil (P.1) variants.

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/138095/download
For patients: https://www.fda.gov/media/138098/download

Method Name

Transcription-Mediated Amplification

NY State Available

Yes

Specimen

Specimen Type

Varies

Ordering Guidance

This test should be used for symptomatic patients under investigation for coronavirus disease 2019 (COVID-19).

Shipping Instructions

Ship specimens refrigerated (if <72 hours from collection to arrive at MCL) or frozen (if > or =72 hours from collection to arrive at MCL).

Necessary Information

Specimen source, race and ethnicity are required.

Specimen Required

Preferred

Specimen Type: Nasopharyngeal (NP), oropharyngeal (OP; ie, throat), nasal mid-turbinate, or nares/nasal swab
Supplies: Swab, Sterile Polyester (T507)
Container/Tube: Universal transport media, viral transport media, or equivalent (eg, Copan UTM-RT, BD VTM, M4, M4-RT, M5, phosphate buffered saline: PBS)
Media should not contain guanidine thiocyanate (GTC), such as Abbott Multi-Collect Specimen Collection Kit, Copan eNAT, PrimeStore MTM.
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 1.5 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 tubes, vacutainer tubes, or tubes with push caps.
5. **Do not overfill** with more than 3 mL total volume of media.

Acceptable

Specimen Type: Nasopharyngeal (NP) aspirate, nasal washing
Container/Tube: Sterile container
Specimen Volume: Minimum of 1.5 mL
Additional Information: Do not aliquot into viral transport media, **glass tubes, vacutainer tubes, or tubes with push caps.**

Forms

If not ordering electronically, complete, print, and send General Test Request (T239) with the specimen.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Calcium alginate-tipped swab	Reject

wood shaft swab transport swab containing gel or charcoal additive	

Specimen Stability Information

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

Clinical & 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 necessary.

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 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 RT-PCR inhibition. Submission of a new specimen for testing is recommended.

Based on sequence analysis, it is predicted that this assay will detect the circulating variants reported by the U.S. Centers

for Disease Control and Prevention (www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html), such as the United Kingdom (B.1.1.7), South Africa (B.1.351), and Brazil (P.1) variants.

Cautions

The FDA has issued emergency use authorization (EUA) of this assay to test human nasopharyngeal, oropharyngeal (throat), nasal mid-turbinate, and nasal swab specimens.

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 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 Feb;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 Mar 5;382(10):929-936. doi: 10.1056/NEJMoa2001191
3. Loeffelholz MJ, Tang YW: Laboratory diagnosis of emerging human coronavirus infections-State of the art. Emerg Microbes Infect. 2020 Dec;9(1):747-756. doi: 10.1080/22221751.2020.1745095
4. Mohammadi A, Esmaeilzadeh E, Li Y, Bosch RJ, Li JZ: SARS-CoV-2 detection in different respiratory sites: a systematic review and meta-analysis. [published online ahead of print, 2020 Jul 18]. EBioMedicine. 2020;102903. doi: 10.1016/j.ebiom.2020.102903
5. Centers for Disease Control and Prevention. Overview of testing for SARS-CoV-2. Available at https://www.cdc.gov/coronavirus/2019-ncov/index.html
6. 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

This test is performed using the Aptima SARS-CoV-2 Assay on the Panther System. It is a viral nucleic acid sequence-amplification assay combining the principles of target capture, transcription-mediated amplification, and dual kinetic assay. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral RNA is isolated and purified from specimens using an automated magnetic microparticle method, while artificial RNA sequences are added as internal control (IC) during this process. Sequence-specific oligonucleotide probes are added to capture and bind to 2 different sequences in the ORF1ab region of the viral genome and to the internal control sequences. Both the captured

probe-RNA target and probe-IC complexes undergo replication involving reverse transcriptase and RNase enzymes to generate viral RNA amplicon and IC amplicon products, both of which are then bound to different chemiluminescent nucleic acid probes. Light emitted from the labeled hybrids of probe-amplicon is detected and recorded as relative light units (RLU). Presence of viral RNA and IC amplicons is distinguished on the basis of differences in kinetics of the chemiluminescent signals generated from the 2 types of amplicon-probe hybrids. Assay results are then determined by a cut-off based on the total RLU and the kinetic curve type.(Package insert: Aptima SARS-CoV-2 Assay [Panther System]. Hologic, Inc; Doc. AW-21492-001 Rev. 002, 05/2020)

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
Same day/1 to 3 days

Specimen Retention Time
5 days

Performing Laboratory Location
Rochester

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 Regional Manager. 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
U0003
U0005-(if applicable)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
SCOVH	SARS Coronavirus-2 RNA, V	94559-2

Result ID	Test Result Name	Result LOINC® Value
SCOVS	SARS CoV-2 Specimen Source	31208-2
609471	SARS CoV-2 RNA, TMA	94559-2
CRACE	Patient Race	72826-1
CETHN	Patient Ethnicity	69490-1