Test Definition: HPCOV

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

Overview

Useful For
Diagnosis of COVID-19 illness due to SARS-CoV-2

Testing Algorithm
For information see Coronavirus Disease 2019 (COVID-19), Influenza, and Respiratory Syncytial Virus Testing Algorithm.

Highlights
This test qualitatively detects SARS-CoV-2 RNA present in select upper and lower respiratory specimens from patients under investigation for COVID-19.

Method Name
Reverse Transcription, Real-Time Polymerase Chain Reaction (RT-qPCR)

NY State Available
Yes

Specimen

Specimen Type
Varies

Ordering Guidance
Due to the nonspecific clinical presentation of COVID-19 during the early stages of the illness, testing for other respiratory infections (eg, influenza) may be warranted. If this test is ordered with HPFLU / Influenza Virus Type A and Type B and Respiratory Syncytial Virus (RSV) RNA, Molecular Detection, PCR, Varies, then both tests will be canceled and automatically reordered by the laboratory as SCOF4 / Severe Acute Respiratory Syndrome Coronavirus 2 (SARS CoV-2), Influenza Virus Type A and Type B RNA, and Respiratory Syncytial Virus (RSV) Molecular Detection, PCR, Varies.

Specimen Required
Preferred:
Specimen Type: Nasopharyngeal swab
Container/Tube: Sterile container with viral transport media
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 mucosa surface to maximize recovery of cells.
2. Swab must be placed into viral transport media (eg, M4-RT, M4 or M5), saline, or phosphate buffered saline (PBS). Media **should not** contain guanidine thiocyanate (GTC).

Specimen Type: Bronchoalveolar lavage fluid
Container/Tube: Sterile container
Specimen Volume: 0.6 mL
Additional Information: **Do not aliquot into viral transport media.**

Acceptable:
Specimen Type: Oropharyngeal (throat) swab, nasal mid-turbinate, or nares/nasal swab
Supplies:
-Culturette (BBL Culture Swab) (T092)
-Swab, Sterile Polyester (T507)
Collection Container/Tube:
Preferred: BBL Culture Swab or COPAN Mid-turbinate Swab
Acceptable: Dacron-tipped swab with plastic handle
Submission Container/Tube: Swab in sterile container with transport media
Specimen Volume: Entire specimen with a minimum of 1.5 mL (maximum 3 mL) of transport media.
Collection Instructions: Swab must be placed into viral transport media (eg, M4-RT, M4, or M5), saline, or PBS. Media **should not** contain guanidine thiocyanate (GTC).

Specimen Type: Bronchial washings, endotracheal aspirate, sputum
Container/Tube: Sterile container
Specimen Volume: 0.6 mL
Additional Information: Do not aliquot into viral transport media.

Specimen Minimum Volume

Upper respiratory tract swab: See Specimen Required; lower respiratory specimens: 0.3 mL

Reject Due To

Bloody specimen	Reject
Calcium alginate-tipped swab	Reject
Wooden shaft swab	Reject
Dry swab	Reject
Glass transport media tubes	Reject
Transport swab containing gel or charcoal	Reject

additive	
Sample tubes containing guanidine isothiocyanate, guanidine thiocyanate, or guanidine hydrochloride	Reject

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) 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 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 may be 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.

Severe acute respiratory syndrome coronavirus 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) may be more likely to have detectable SARS-CoV-2.

Reference Values

Undetected

Interpretation

A "Detected" (positive) result indicates that SARS-CoV-2 RNA is present and suggests the diagnosis of COVID-19. The 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" (negative) 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 inhibition. Submission of a new specimen for testing is recommended.

Cautions

The sensitivity of the assay is dependent on the stage of the illness when the sample is collected, the quality of the specimen submitted, and the test's performance characteristics. SARS-CoV-2 is likely at higher viral loads in the upper respiratory tract (eg, nasopharyngeal swab) during the first 3 to 5 days post onset of symptoms. At later stages of the disease, the virus may be more readily detected in lower respiratory samples (eg, sputum, bronchoalveolar lavage fluid).

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

An undetected (ie, negative) result does not preclude infection with SARS-CoV-2 and should not be used as the sole basis for treatment or other patient management decisions.

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;59:102903. doi:10.1016/j.ebiom.2020.102903
4. Centers for Disease Control and Prevention. Testing for COVID-19. CDC; Updated March 10, 2025. Accessed August 29, 2026. Available at www.cdc.gov/covid/testing/index.html
5. US Food and Drug Administration. FAQs on diagnostic testing for SARS-CoV-2. Updated November 8, 2023. Accessed August 29, 2026. Available at www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2

Performance

Method Description

The SARS-CoV-2/Flu A/B/RSV assay (Panther Fusion System, Hologic, Inc) is a fully automated, multiplexed, real-time polymerase chain reaction (PCR) in vitro diagnostic assay cleared by the US Food and Drug Administration (FDA) for qualitative detection and differentiation of SARS-CoV-2, influenza A virus, influenza B virus, and respiratory syncytial virus in nasopharyngeal specimens (ie, upper respiratory tract [URT] specimens) obtained from individuals exhibiting signs and symptoms of a respiratory tract infection. In addition to testing URT specimens, this assay is being used to test lower respiratory tract (LRT) specimens, which are not cleared by FDA for testing with this assay. In the testing

laboratory, 0.5 mL of the viral transport medium with URT swab is transferred to the Hologic Specimen Lysis Tube (SLT) to be loaded onto the Panther Fusion system. For LRT specimens, 0.25 mL of the specimen from the transport container and 0.25 mL of sterile Gibco 1x phosphate buffered saline, pH 7.4, are transferred into the SLT for loading onto the instrument system.

This assay involves the following steps: sample lysis, nucleic acid capture and elution transfer, and multiplex reverse transcription (RT)-PCR in which analytes are simultaneously amplified, detected, and differentiated. Nucleic acid capture and elution take place in a single tube on the Panther Fusion system. The internal control-S (IC-S) is added to each test specimen and positive and negative assay controls via the working Panther Fusion Capture Reagent-S. The IC-S reagent monitors specimen processing, amplification, and detection. The eluate is transferred to the Panther Fusion system reaction tube containing the assay reagents, and multiplex RT-PCR is then performed on the eluted nucleic acid.

Viral target-specific forward and reverse primers and probes simultaneously amplify, detect, and discriminate among the viral target sequences with various fluorescence channels. The assay software compares the fluorescence signals generated to predetermined cutoff values to produce a qualitative result for the presence or absence of each virus.(Instruction manual:SARS-CoV-2/Flu A/B/RSV assay [Panther Fusion System], AW-32326-001. Hologic, Inc; Rev. 003, 03/2026)

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
Same day/1 to 2 days

Specimen Retention Time
4 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

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 been modified from the manufacturer's instructions. Its performance characteristics were determined by

Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

87635

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HPCOV	SARS CoV-2 RNA, PCR, Varies	94559-2

Result ID	Test Result Name	Result LOINC® Value
614021	SARS CoV-2 RNA, PCR	94559-2
HPCVS	SARS CoV-2 RNA, PCR, Source	31208-2