# 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.

Fact sheets for this assay can be found at the following links:
For healthcare providers: https://www.fda.gov/media/136154/download
For patients: https://www.fda.gov/media/136155/download

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

### NY State Available
Yes

## Specimen

### Specimen Type
Varies

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

### 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)
-Mid Turbinate (MT) Swab (FLOQSwab/COPAN) (T864)
-Swab, Sterile Polyester (T507)
**Container/Tube:** Sterile container with transport media
**Specimen Volume: Entire specimen with a minimum of 1.5 mL (maximum 3 mL) of transport media.**
**Preferred:** BBL Culture Swab, COPAN Mid-turbinate Swab
**Acceptable:** Dacron-tipped swab with plastic handle
**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<br>Calcium alginate-tipped swab<br>Wooden shaft swab<br>Dry swab Glass transport media tubes<br>Transport swab containing gel | Reject |

| | |
|---|---|
| or charcoal additive Sample tubes containing guanidine isothiocyanate, guanidine thiocyanate, or guanidine hydrochloride | |

### 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 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.

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 June 25, 2024. Accessed August 22, 2024. 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 22, 2024. Available at www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2

## Performance

### Method Description

Specimens are transferred first to a specimen lysis tube, which lyses the cells, releases target nucleic acid, and protects them from degradation during storage. The internal control-S (IC-S) is added to each test specimen and control via the working Panther Fusion capture reagent-S. The IC-S in the reagent monitors all aspects of the testing process, including nucleic acid capture, elution, amplification, and detection. Capture oligonucleotides hybridize to nucleic acid in the test specimen. Hybridized nucleic acid is then separated from the specimen in a magnetic field. Wash steps purify the hybridized nucleic acid by removing extraneous components from the reaction tube. The resulting purified nucleic acid is

then isolated during the elution step.

During the elution transfer step, purified nucleic acid is transferred to a Panther Fusion reaction tube already containing reconstituted master mix overlaid with oil reagent. Amplification of the target sequences occurs via real-time reverse transcription polymerase chain reaction. A reverse transcriptase generates a DNA copy of the target sequences. Target-specific forward and reverse primers and probes amplify and detect 2 regions of the *orf1ab* gene of SARS-CoV-2 in conjunction with the internal control. The amplified *orf1ab* target products are detected on the ROX channel, while the internal control is detected on RED677. The assay software compares the viral target and internal control fluorescence signals to predetermined cut-off values to produce a qualitative result for the presence or absence of the virus.(Instruction manual: SARS-CoV-2 Assay [Panther Fusion System]. AW-21159-001. Hologic, Inc; Rev. 006, 05/2022)

### 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 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 Definition: HPCOV

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| 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 |