Overview

Useful For
Detection 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/hcp/clinical-criteria.html

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

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

For health care providers: https://www.fda.gov/media/136047/download

For patients: https://www.fda.gov/media/136048/download

Special Instructions

COVID-19 Oropharyngeal Collection Instructions

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

NY State Available
Yes

Specimen

Specimen Type
Varies

Advisory Information
Due to the non-specific clinical presentation of coronavirus disease (COVID-19) during the early stages of illness, testing for other respiratory tract infections (eg, influenza) may be warranted.

For the most up-to-date COVID-19 epidemiology and testing recommendations, visit https://www.cdc.gov/coronavirus/2019-ncov/index.html

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).

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

Supplies:
Test Definition: COVID
SARS Coronavirus 2 RNA Detection, V

-Swab, Sterile Polyester, 10 per package (T507)

-Dacron-tipped swab with plastic shaft is acceptable

**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 acceptable transport media, see [https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2](https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2)

**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 nasal or pharyngeal mucosa surface to maximize recovery of cells. For more information on OP swab specimen collection, see [COVID-19 Oropharyngeal Collection Instructions](https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2) 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.

**Specimen Type:** Nasopharyngeal aspirate or nasal washings

**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.

**Specimen Type:** Lower respiratory tract:

**Sources:** Bronchoalveolar lavage (BAL) fluid, bronchial washings, endotracheal aspirate, sputum

**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 a [General Request](https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2) (T239) with the specimen.
**Specimen Minimum Volume**
See Specimen Required

**Reject Due To**

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Rejection Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium alginate-tipped swab, wooden shaft swab, or swab collection tubes containing gel or charcoal additive.</td>
<td>Reject</td>
</tr>
<tr>
<td>Thawed</td>
<td>Cold OK; Warm reject</td>
</tr>
<tr>
<td>Transport media tubes containing the entire swab (shaft and knob attached)</td>
<td>Reject</td>
</tr>
<tr>
<td>Glass transport media tubes</td>
<td>Reject</td>
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</table>

**Specimen Stability Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varies</td>
<td>Frozen (preferred)</td>
<td>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>72 hours</td>
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**Clinical and Interpretive**

**Clinical Information**
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) 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 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.

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 the specimen collected for testing. Result should be correlated with patientâ€™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 may be considered if the patient does not have signs or symptoms of COVID-19.

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 and oropharyngeal 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 the specimen submitted for testing.

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

Undetected (ie, negative) results do not rule out 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 the patient's history and clinical presentation.

Clinical Reference


Performance

Method Description

The cobas SARS-CoV-2 (Roche Molecular Systems, Inc.) is a TaqMan probe-based, real-time, reverse transcription PCR assay designed for qualitative detection of 2019 novel coronavirus (SARS-CoV-2) RNA from human nasopharyngeal and oropharyngeal swabs processed on the fully automated cobas 6800 system. Clinical samples undergo automated sample preparation (nucleic acid extraction and purification), during which viral nucleic acid in patient samples and added internal control RNA (RNA IC) molecules are simultaneously extracted. Nucleic acid is released by the addition of proteinase and lysis reagent to the sample. The released nucleic acid binds to the silica surface of the added magnetic glass particles. Unbound substances and impurities, such as denatured protein, cellular debris and potential PCR inhibitors, are removed with subsequent wash steps and purified nucleic acid is
eluted from the magnetic glass particles with elution buffer at elevated temperature. External controls (positive and negative) are processed in the same way in each assay run.

Using target-specific primers and probes, this assay amplifies and detects both the ORF1ab (nonstructural protein) sequence of SARS-CoV-2 and the E gene (structural envelope protein) sequence of Sarbecovirus group. Samples containing SARS-CoV-2 should generate positive results for both targets by this assay. (Package insert: cobas SARS-CoV-2 - Qualitative assay for use on the cobas 6800 / 8800 Systems. Roche Diagnostics; Doc Rev. 2.0 04/2020)

**Test Definition: COVID**

SARS Coronavirus 2 RNA Detection, V

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

Monday through Sunday, Varies

**Analytic Time**

Same day/1 day

**Maximum Laboratory Time**

3 days

**Specimen Retention Time**

4 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**

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<th>Test Order Name</th>
<th>Order LOINC Value</th>
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