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.

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.

This test ID combines various molecular assays designed for detection of SARS-CoV-2 into one orderable test. All of the assays used for testing have received emergency use authorization (EUA) from the FDA. Testing will be performed with 1 of the following assays:
- cobas SARS-CoV-2 (Roche Molecular Systems)
- PerkinElmer New Coronavirus Nucleic Acid Detection Kit (PerkinElmer, Inc.)
- ThermoFisher TaqPath COVID-19 Combo Kit (ThermoFisher Scientific, Inc.)

URL links to the fact sheets for each of these EUA assays are provided in the Method Description.

Reflex Tests

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<th>Test ID</th>
<th>Reporting Name</th>
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<th>Always Performed</th>
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<td>No, (Bill Only)</td>
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</tbody>
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Testing Algorithm

See Coronavirus Disease 2019 (COVID-19), Influenza, and Respiratory Syncytial Virus Testing Algorithm in Special Instructions.

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 turnaround-time requirement. For additional information refer to www.cms.gov/newsroom/press-releases/cms-changes-medicare-payment-support-faster-covid-19-diagnostic-testing.

Special Instructions
- COVID-19 Oropharyngeal Collection Instructions
- Coronavirus Disease 2019 (COVID-19), Influenza, and Respiratory Syncytial Virus Testing Algorithm

Method Name
Real-Time Reverse Transcription Polymerase Chain Reaction (RT-PCR)
NY State Available
Yes

Specimen

Specimen Type
Varies

Ordering Guidance
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 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 72 hours or more from collection to arrive at MCL).

Specimen Required
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, MicroTest M4, M4-RT, M5)

Media should not contain guanidine thiocyanate (GTC).

For more information on acceptable transport media, see 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 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.
Test Definition: COVOO
SARS Coronavirus 2 RNA, PCR, V

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.

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

Specimen Minimum Volume
See Specimen Required

Reject Due To

<table>
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<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Calcium alginate-tipped swab, wooden shaft swab, or</td>
<td>Frozen (preferred)</td>
<td>14 days</td>
<td>Rejected</td>
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<td>swab collection tubes containing gel or charcoal additive.</td>
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<tr>
<td>Transport media tubes containing the entire swab (shaft and knob attached)</td>
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<tr>
<td>Glass transport media tubes</td>
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<td>Bloody specimen</td>
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<tr>
<td>Thawed</td>
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Specimen Stability Information

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<td></td>
<td>Refrigerated</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, 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**

Based on sequence analysis, this assay is predicted to 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.

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. A summary of available treatment options for COVID-19 can be found at the U.S. Department of Health and Human Services website: https://combatcovid.hhs.gov/i-have-covid-19-now/available-covid-19-treatment-options

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, 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 "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 and/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 these assays for testing human nasopharyngeal and oropharyngeal swab specimens.

The sensitivity of the assays is dependent on the timing of the specimen collection (in relation to symptom onset), as well as the 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 patient's history and clinical presentation.

**Clinical Reference**


Performance

Method Description

cobas Severe Acute Respiratory Syndrome Coronavirus-2 Assay:

The assay is a TaqMan probe-based, real-time reverse transcription polymerase chain reaction (RT-PCR) assay designed for qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA from human upper respiratory tract specimens processed on the fully automated cobas 6800 or 8800 system. Viral target-specific primers and probes are used to amplify and detect 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. 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. (Package insert: cobas SARS-CoV-2: Qualitative assay for use on the cobas 6800/8800 Systems. Roche Molecular Systems, Inc; Doc Rev. 3.0, 05/2020)

Fact sheets for this EUA assay can be found at the following URL:

For health care providers: [www.fda.gov/media/136047/download](http://www.fda.gov/media/136047/download)

For patients: [www.fda.gov/media/136048/download](http://www.fda.gov/media/136048/download)

PerkinElmer New Coronavirus Nucleic Acid Detection Kit:

This assay is a TaqMan probe-based, RT-PCR assay designed for detection of SARS-CoV-2 in human upper respiratory tract specimens, and it amplifies and detects the ORF1ab (ROX) and N gene (FAM) sequences of SARS-CoV-2, with the bacteriophage MS2 as the internal control (VIC) for extraction and amplification/detection. An automated liquid handing workstation is used to prepare the 96-well sample extraction plates, and the samples undergo nucleic acid extraction and purification. Post-elution 96-well RT-PCR plates are prepared on another workstation prior to loading onto the RT-PCR thermocyclers. (Package insert: Instructions for PerkinElmer New Coronavirus Nucleic Acid Detection Kit. PerkinElmer, Inc; Doc Rev. 4.0, 07/28/2020)

Fact sheets for this assay can be found at the following URL:

For healthcare providers: [www.fda.gov/media/136408/download](http://www.fda.gov/media/136408/download)

For patients: [www.fda.gov/media/136409/download](http://www.fda.gov/media/136409/download)

TaqPath COVID-19 Combo Kit:

This assay is a TaqMan probe-based, RT-PCR assay designed for detection of SARS-CoV-2 in human upper respiratory tract specimens, and it amplifies and detects the ORF1ab, N, and S gene sequences of SARS-CoV-2, with the bacteriophage MS2 as the internal control for extraction and amplification/detection. An automated liquid
handing workstation is used to prepare the 96-well sample extraction plates, and the samples undergo nucleic acid extraction and purification. Post-elution 96-well RT-PCR plates are prepared on another workstation prior to loading onto the RT-PCR thermocyclers. (Package insert: TaqPath COVID-19 Combo Kit. Life Technologies Corp; Doc Rev. D.0, 05/2020)

Fact sheets for this assay can be found at the following URL:

For healthcare providers: www.fda.gov/media/136111/download

For patients: www.fda.gov/media/136114/download

**PDF Report**

No

**Day(s) Performed**

Monday through Sunday

**Report Available**

1 to 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. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

U0003

U0005-(If applicable)

**LOINC® Information**

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