

## 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: [www.cdc.gov/coronavirus/2019-ncov/index.html](http://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](http://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 upper respiratory tract specimens from patients under investigation (PUI) for coronavirus disease 2019 (COVID-19).

Sequence analyses have 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 authorized (EUA) assay can be found at the following links:

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)

### Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
TATCH	TAT <=2 days additional charge	No	No

### Method Name

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

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**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](http://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:**

-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

[www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2](http://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.

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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.

### Reject Due To

Calcium alginate-tipped swab, wooden shaft swab, or swab collection tubes containing gel or charcoal additive.	Reject
Transport media tubes containing the entire swab (shaft and knob attached)	
Glass transport media tubes	
Bloody specimen	
Thawed	Cold OK; Warm reject

### Specimen Minimum Volume

See Specimen Required

**Specimen Stability Information**

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

**Clinical & 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 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 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.

Sequence analyses have 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](http://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 provided emergency use authorization \(EUA\) of this test for testing human nasopharyngeal and oropharyngeal 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 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**

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 Sep;59:102903. doi: 10.1016/j.ebiom.2020.102903
4. Centers for Disease Control and Prevention. Overview of testing for SARS-CoV-2. Available at [www.cdc.gov/coronavirus/2019-ncov/index.html](http://www.cdc.gov/coronavirus/2019-ncov/index.html)

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5. 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](http://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2)

## Performance

### Method Description

The cobas SARS-CoV-2 assay is a TaqMan probe-based, real-time, reverse transcription polymerase chain reaction (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)

### PDF Report

No

### Specimen Retention Time

4 days

### Performing Laboratory Location

Rochester

## Fees & Codes

### Test Classification

This test has received Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration and is modified from the manufacturer's instructions with a bridging study. Performance characteristics were verified by Mayo Clinic in a

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manner consistent with CLIA requirements.

**CPT Code Information**

U0003

U0005-(If applicable)

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
COVID	SARS Coronavirus 2 PCR Detect, V	94500-6

Result ID	Reporting Name	LOINC®
CVDS	SARS-CoV-2 Specimen Source	31208-2
608827	SARS-CoV-2 RNA by PCR	94500-6
CRACE	Patient Race	72826-1
CETHN	Patient Ethnicity	69490-1