MAYO CLINIC LABORATORIES

Test Definition: COVOO

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

Overview

Useful For

Diagnosing COVID-19 illness due to SARS-CoV-2

Recommended only for patients who meet current clinical and/or epidemiologic criteria defined by federal, state, or local public health directives.

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
TATCH	TAT <=2 days additional charge	No, (Bill Only)	No

Testing Algorithm

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

In response to the new Centers for Medicare and Medicaid Services (CMS) payment strategy for 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.

Special Instructions

- Coronavirus Disease 2019 (COVID-19), Influenza, and Respiratory Syncytial Virus Testing Algorithm
- Respiratory Virus Testing Algorithm Coronavirus Disease 2019 (COVID-19), Influenza, Respiratory Syncytial Virus in Nasopharyngeal Specimens

Highlights

This test provides qualitative detection of SARS-CoV-2 RNA from select upper respiratory tract specimens from patients under investigation for 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.

The assay used for testing has received emergency use authorization (EUA) from the US Food and Drug Administration. Testing will be performed using the cobas SARS-CoV-2 (Roche Molecular Systems) kit.

URL links to the fact sheets this EUA assay is provided in the Method Description.

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 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 Mayo Clinic Laboratories [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.
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 Minimum Volume

See Specimen Required

Reject Due To

Calcium alginate-tipped swab, wooden shaft swab, or swab collection tubes containing gel or charcoal additive. Transport media tubes containing the entire swab (shaft and knob attached) Glass transport media tubes Bloody specimen	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 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 US 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 SARS-CoV-2 RNA is present and suggests the diagnosis of 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 US 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 US Food and Drug Administration has provided emergency use authorization 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 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

1. Zhu N, Zhang D, Wang W, et al: A novel coronavirus from patients with pneumonia in China, 2019. N Engl J Med. 2020 Feb 20;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 Dec;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 (CDC). Overview of testing for SARS-CoV-2. CDC; Updated March 17, 2021. Accessed March 18, 2021. Available at www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html
5. US Food and Drug Administration (FDA). FAQs on testing for SARS-CoV-2. FDA; Updated November 15, 2021. Accessed November 16, 2021. Available at www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2

Performance

Method Description

The assay is a TaqMan probe-based, real-time reverse transcription polymerase chain reaction (RT-PCR) assay designed for qualitative detection of 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. 8.0, 02/2022)

Fact sheets for this EUA assay can be found at the following URL:
For health care providers: www.fda.gov/media/136047/download
For patients: www.fda.gov/media/136048/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 & 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
U0003
U0005-(If applicable)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
COVOO	SARS Coronavirus 2 RNA, PCR, V	94500-6

Result ID	Test Result Name	Result LOINC® Value
CVOOS	SARS-CoV-2 Specimen Source	31208-2
610013	SARS-CoV-2 RNA	94500-6
CRACE	Patient Race	72826-1
CETHN	Patient Ethnicity	69490-1
610016	Method Summary	62364-5