Test Definition: COVOO

SARS Coronavirus 2 RNA, PCR, V

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.

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 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

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)

-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

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

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.

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.

Forms

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

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 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, 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 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 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 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

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 Jul 18;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. 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

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 sever 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. 5.0, 12/2020)

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

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. K.0, 10/2021)

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

Specimen Retention Time
4 days

Performing Laboratory Location
Rochester

Fees & Codes

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	Reporting Name	LOINC®
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