MAYO CLINIC LABORATORIES

Test Definition: COVID

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

Overview

Useful For

Detection of 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: www.cdc.gov/covid/hcp/clinical-care/overview-testing-sars-cov-2.html

Testing Algorithm

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

Special Instructions

- 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 upper respiratory tract specimens from patients under investigation for COVID-19.

Method Name

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

NY State Available

No

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/covid/hcp/clinical-care/overview-testing-sars-cov-2.html

Shipping Instructions

1. If less than 72 hours from collection to arrival at MCL, ship specimens refrigerated.

2. If greater than or equal to 72 hours from collection to arrival at MCL, ship specimens frozen.

Specimen Required

Specimen Type: Nasopharyngeal (NP), oropharyngeal (OP ie, throat), nasal mid-turbinate, or nares/nasal swab (Endotracheal aspirate and sputum specimens **are not acceptable**)
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).
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 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.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Calcium alginate-tipped swab Wooden shaft	Reject

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

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Frozen (preferred)	14 days	
	Refrigerated	72 hours	

Clinical & Interpretive

Clinical Information

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, 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 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.

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 real-time, reverse transcription polymerase chain inhibition. Submission of a new specimen for testing is recommended.

Cautions

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 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;59:102903. doi:10.1016/j.ebiom.2020.102903
4. Centers for Disease Control and Prevention. Overview of testing for SARS-CoV-2. Accessed November 14, 2024 Available at www.cdc.gov/covid/hcp/clinical-care/overview-testing-sars-cov-2.html#cdc_generic_section_2-diagnostic-testing
5. United States Food and Drug Administration. COVID-19 Test Uses: FAQs on Testing for SARS-CoV-2. Updated September 29, 2023. Accessed January 27, 2025. Available at www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-uses-faqs-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 ORF1a (nonstructural protein) sequence of SARS-CoV-2 and the E gene (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

Day(s) Performed

Monday through Sunday

Report Available

Same day/1 to 3 days

Specimen Retention Time

5 days

Performing Laboratory Location

Mayo Clinic Jacksonville Clinical Lab

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 been cleared, approved, or is exempt 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

87635

LOINC® Information

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

Result ID	Test Result Name	Result LOINC® Value
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