MAYO CLINIC LABORATORIES

Test Definition: COFLU

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) RNA and Influenza Virus Type A and Type B RNA Detection, PCR, Varies

Overview

Useful For

Detection and differentiation of COVID-19 illness (due to SARS-CoV-2) and influenza A and B viral infection in a single test using upper respiratory tract specimens

See following websites on indications and recommendations for testing:
www.cdc.gov/coronavirus/2019-ncov/index.html
www.cdc.gov/flu/symptoms/testing.htm

Special Instructions

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

Highlights

This test provides simultaneous, qualitative detection and differentiation of SARS-CoV-2 RNA, influenza A RNA, and influenza B RNA in upper respiratory tract specimens from patients with flu-like illness that may be due to COVID-19 and/or influenza.

Fact sheets for this FDA emergency use authorized assay can be found at the following:
For healthcare providers: www.fda.gov/media/141885/download
For patients: www.fda.gov/media/141886/download

Method Name

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

NY State Available

Yes

Specimen

Specimen Type

Varies

Ordering Guidance

Due to the nonspecific clinical presentation of COVID-19 and influenza during the early stages of illness, concurrent testing for these 3 respiratory tract viral pathogens may be warranted.

For the most up-to-date testing recommendations, visit:
www.cdc.gov/coronavirus/2019-ncov/index.html
www.cdc.gov/flu/symptoms/testing.htm

Shipping Instructions

Ship specimens refrigerated (if less than 72 hours from collection to arrive at Mayo Clinic Laboratories (MCL]) or frozen (if greater or equal to 72 hours from collection to arrive at MCL).

Specimen Required

Specimen Type: Nasopharyngeal (NP), 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 mucosa surface to maximize recovery of cells.
2. 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.
3**. Do not send** in glass tubes, vacutainer tubes, or tubes with push caps.
4. **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	Reject

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

Influenza, also known as the "flu," is an acute, contagious respiratory illness caused by influenza A, B, and C viruses. Of these, only influenza A and B are thought to cause significant disease, with infections due to influenza B usually being milder than infections with influenza A. Influenza A viruses are further categorized into subtypes based on the 2 major surface protein antigens: hemagglutinin (H) and neuraminidase (N).

Common symptoms of influenza infection include fever, chills, sore throat, muscle pains, severe headache, weakness,

fatigue, and a nonproductive cough. Certain patients, including infants, the elderly, the immunocompromised, and those with impaired lung function, are at risk for serious complications.

In the northern hemisphere, annual epidemics of influenza typically occur during the fall or winter months. However, the peak of influenza activity can occur as late as April or May, and the timing and duration of flu seasons vary.

Influenza infection may be treated with supportive therapy, as well as antiviral drugs such as the neuraminidase inhibitors, oseltamivir (Tamiflu) and zanamivir (Relenza). These drugs are most effective when given within the first 48 hours of infection, so prompt diagnosis and treatment are essential for proper management.

Reference Values

Undetected

Interpretation

A "Detected" result indicates that the specific virus is present and suggests infection with the virus. Test results 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 the specific virus 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. A negative result for the influenza A viral RNA polymerase chain reaction (PCR) assay does not rule out the presence of this viral infection, as mutations in the PCR target region of this virus can cause false-negative test results.

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 is recommended on a newly collection specimen 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 the specific virus in the specimen could not be determined with certainty after repeat testing in the laboratory, possibly due to reverse transcription-polymerase chain reaction inhibition. Submission of a new specimen for testing is recommended.

Cautions

The US Food and Drug Administration has provided emergency use authorization of this test for testing upper respiratory tract specimens only. The assay is not authorized currently to test lower respiratory tract specimens, such as sputum, bronchial washing, or bronchoalveolar lavage fluid.

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. This test should not be performed unless the patient meets clinical and epidemiologic criteria for testing.

The test is specific for detection of SARS-CoV-2, influenza A and B viruses, and positive test results do not exclude the

possibility of concurrent infection with other respiratory viruses. This assay does not distinguish among the different subtypes of influenza A virus.

Undetected (ie, negative) results do not rule out SARS-CoV-2, influenza A, or influenza B infection in patients and should not be used as the sole basis for treatment or other patient management decisions. A negative result for the influenza A viral RNA polymerase chain reaction (PCR) assay does not rule out the presence of this viral infection, as mutations in the PCR target region of this virus can cause false-negative test results. Results should be correlated with patient's history and clinical presentation. This assay detects both viable and nonviable virus.

Clinical Reference

1. 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
2. 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
3. Centers for Disease Control and Prevention. Overview of testing for SARS-CoV-2, the virus that causes COVID-19. CDC; Updated September 28, 2022. Accessed December 30, 2022. Available at www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html
4. Centers for Disease Control and Prevention. Information for clinicians on influenza virus testing. CDC; Updated August 29. 2022. Accessed December 30, 2022. Available at www.cdc.gov/flu/professionals/diagnosis/index.htm
5. US Food and Drug Administration. FAQs on diagnostic testing for SARS-CoV-2. FDA; Updated September 27, 2022. Accessed December 30, 2022. Available at www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-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, influenza A RNA, and influenza B RNA from human upper respiratory tract specimens. Viral target-specific primers and probes are used to amplify and detect the *ORF1ab* (nonstructural protein) sequence of SARS-CoV-2, *E* gene (structural envelope protein) sequence of *Sarbecovirus* group, encoding gene sequence for the matrix proteins 1 and 2 (M1/M2) of influenza A virus, and encoding sequence of the nuclear export protein (*NEP*)/nonstructural protein 1(*NS1*) genes of influenza B virus. Clinical samples undergo automated sample preparation (nucleic acid extraction and purification), during which viral nucleic acid in patient samples and added internal control RNA 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 and Influenza A/B: Qualitative assay for use on the cobas 6800/8800 Systems. Roche Molecular Systems, Inc; Doc Rev. 4.0, 06/2021)

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PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
1 to 3 days

Specimen Retention Time
5 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
87636

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
COFLU	SARS-CoV-2 and Influenza A+B PCR, V	95380-2

Result ID	Test Result Name	Result LOINC® Value
610295	Influenza A RNA PCR	In Process
610296	Influenza B RNA PCR	In Process
610294	SARS CoV-2 RNA PCR	94500-6
CFLUS	SARS-CoV-2 & Flu A/B Specimen	31208-2

	Source	
CFRAC	Patient Race	72826-1
CFETH	Patient Ethnicity	69490-1