Test Definition: SCOF3

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

Overview

Useful For
Simultaneous detection and differentiation of SARS-CoV-2 (cause of COVID-19), influenza A virus, and influenza B virus in upper or lower respiratory tract specimens from individuals with flu-like illnesses

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

Highlights
This assay simultaneously detects SARS CoV-2 and influenza viruses type A and type B in upper and lower human respiratory tract specimens in individual with signs or symptoms of upper or lower respiratory tract infection.

Method Name
Multiplex Reverse Transcriptase, Real-Time Polymerase Chain Reaction (RT-qPCR)

NY State Available
Yes

Specimen

Specimen Type
Varies

Specimen Required
Preferred:
Specimen Type: Nasopharyngeal swab
Container/Tube: Sterile container with viral transport media
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 mucosa surface to maximize recovery of cells.
2. Swab must be placed into viral transport media (eg, M4-RT, M4 or M5), saline, or phosphate buffered saline (PBS).
Media should not contain guanidine thiocyanate (GTC).

Specimen Type: Bronchoalveolar lavage fluid
Container/Tube: Sterile container
Specimen Volume: 0.6 mL
Additional Information: Do not aliquot into viral transport media.

Acceptable:
Specimen Types: Oropharyngeal (throat) swab, nasal mid-turbinate, or nares/nasal swab
Supplies:
-Culturette (BBL Culture Swab) (T092)
-Mid Turbinate (MT) Swab (FLOQSwab/COPAN) (T864)
-Swab, Sterile Polyester (T507)
Container/Tube: Sterile container with transport media
Specimen Volume: Entire specimen with a minimum of 1.5 mL (maximum 3 mL) of transport media.
Preferred: BBL Culture Swab, COPAN Mid-turbinate Swab
Acceptable: Dacron-tipped swab with plastic handle
Collection Instructions: Swab must be placed into viral transport media (eg, M4-RT, M4, or M5), saline, or PBS. **Media should not contain guanidine thiocyanate (GTC).**

Specimen Types: Bronchial washings, endotracheal aspirate, sputum
Container/Tube: Sterile container
Specimen Volume: 0.6 mL
Additional Information: Do not aliquot into viral transport media.

Specimen Minimum Volume

Upper respiratory tract swab: See Specimen Required; lower respiratory specimens: 0.3 mL

Reject Due To

Bloody specimens Calcium alginate-tipped swab Wooden swab Dry swab Glass transport tubes Transport swab containing gel or charcoal additive Transport media tubes containing the entire swab	Reject

Sample tubes containing guanidine isothiocyanate, guanidine thiocyanate, or guanidine hydrochloride	

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 illness. 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 disease, the symptoms maybe nonspecific and resemble other common respiratory infections, such as influenza. If testing for other respiratory infections is negative, specific testing for SARS-CoV-2 (COVID-19) may be warranted.

Severe acute respiratory syndrome coronavirus 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) may be more likely to have detectable SARS-CoV-2.

Influenza, otherwise 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, older individuals, patients who are immunocompromised, and those with impaired lung function, are at risk for serious complications. In the United States, influenza results in 10,000 to 30,000 deaths and more than 200,000 hospitalizations each year.

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.

Influenza viruses can be detected in respiratory secretions, including upper and lower respiratory tract specimens, by molecular test methods. Nasopharyngeal swabs or aspirates are the preferred specimen types for detection of SARS-CoV-2, influenza A virus, and influenza B virus. Nasal swabs have also been shown to provide comparable yield to nasopharyngeal specimens for molecular detection of SARS-CoV-2 RNA and influenza A and B viral RNA.

Reference Values

Undetected

Interpretation

A "Detected" (positive) test result indicates that the patient is presumptively infected with the indicated virus. The test does not indicate the stage of infection. Rarely, more than one virus may be detected from the same patient specimen. Laboratory test results should always be considered in the context of clinical observations and epidemiologic data in making a final diagnosis.

An “Undetected" (negative) test result suggests that the patient is not infected with SARS-CoV-2, influenza A virus, and influenza B virus.

An "Inconclusive" result indicates that the presence or absence of SARS-CoV-2, influenza A virus, and influenza B virus in the specimen could not be determined with certainty after repeat testing in the laboratory, possibly due to real-time, reverse transcription polymerase chain reaction 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. 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 virus, and influenza B virus, and a positive result does not exclude the possibility of concurrent infection with other respiratory viruses. This assay detects influenza A viral RNA but does not distinguish among the different viral subtypes, such as H5N1, H7N9. Influenza C virus is not detected by this assay.

"Undetected' (negative) results do not preclude infection with influenza A virus, influenza B virus, or SARS-CoV-2 and should not be used as the sole basis for treatment or other patient management decisions.

This assay detects both replicating and nonreplicating virus (ie, remnant viral nucleic acid). Test performance depends on viral load in the specimen and may not correlate with cell culture performed on the same specimen.

Clinical Reference

1. 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
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;59:102903. doi:10.1016/j.ebiom.2020.102903
3. Centers for Disease Control and Prevention. Testing for COVID-19. CDC; Updated June 25, 2024. Accessed August 22, 2024. Available at www.cdc.gov/covid/testing/index.html
4. US Food and Drug Administration. FAQs on diagnostic testing for SARS-CoV-2. FDA; Updated November 8, 2023. Accessed August 22, 2024. Available at www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2
5. Centers for Disease Control and Prevention. Information for clinicians on influenza virus testing. CDC; Updated December 11, 2023. Accessed August 22, 2024. Available at www.cdc.gov/flu/professionals/diagnosis/index.htm

Performance

Method Description

The SARS-CoV-2/Flu A/B/RSV assay (Panther Fusion System, Hologic, Inc.) is a fully automated, multiplexed, real-time polymerase chain reaction (PCR) in vitro diagnostic assay cleared by the US Food and Drug Administration (FDA) for qualitative detection and differentiation of SARS-CoV-2, influenza A virus (Flu A), influenza B virus (Flu B), and respiratory syncytial virus (RSV) in nasopharyngeal specimens (ie, upper respiratory tract: URT) obtained from individuals exhibiting signs and symptoms of a respiratory tract infection. In addition to testing URT specimens, this assay is being used to test lower respiratory tract (LRT) specimens, which are not cleared by FDA for testing with this assay. In the testing laboratory, 0.5 mL of the viral transport medium with URT swab is transferred to the Hologic Specimen Lysis Tube (SLT) to be loaded onto the Panther Fusion system. For LRT specimens, 0.25 mL of the specimen from the transport container and 0.25 mL of sterile Gibco 1x PBS, pH 7.4 are transferred into the SLT for loading onto the instrument system.

This assay involves the following steps: sample lysis, nucleic acid capture and elution transfer, and multiplex RT-PCR in which analytes are simultaneously amplified, detected, and differentiated. Nucleic acid capture and elution takes place in a single tube on the Panther Fusion system. The Internal Control-S (IC-S) is added to each test specimen and positive and negative assay controls via the working Panther Fusion Capture Reagent-S. The IC-S reagent monitors specimen processing, amplification, and detection. The eluate is transferred to the Panther Fusion system reaction tube containing the assay reagents, and multiplex RT-PCR is then performed on the eluted nucleic acid.

Viral target-specific forward and reverse primers and probes simultaneously amplify, detect, and differentiate among the viral target sequences with various fluorescence channels. The assay software compares the fluorescence signals generate to predetermined cutoff values to produce a qualitative result for the presence or absence of each virus.(Instruction manual: SARS-CoV-2/Flu A/B/RSV assay [Panther Fusion System], AW-27555-001. Hologic, Inc.; Rev.

001, 05/2023)

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
Same day/1 to 2 days

Specimen Retention Time
4 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

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 modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
87636

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
SCOF3	SARS-CoV-2 and Influenza A/B PCR, V	95422-2

Result ID	Test Result Name	Result LOINC® Value
SCOS3	SARS-CoV-2 & Flu A/B, Source	31208-2
622028	Influenza A virus PCR	92142-9
622029	Influenza B virus PCR	92141-1

622030	SARS CoV-2 RNA, PCR	94500-6