MAYO CLINIC LABORATORIES

Test Definition: RSVQL

RSV RNA PCR Detect, V

Overview

Useful For

Detection of respiratory syncytial virus (RSV) in upper or lower respiratory tract specimens from individuals at risk for RSV infection with flu-like illness

See following website on indications and recommendations for testing:

www.cdc.gov/rsv/clinical/index.html#lab

Testing Algorithm

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

Highlights

This test provides qualitative detection of respiratory syncytial virus (RSV) RNA in upper and lower respiratory tract specimens from at-risk patients with flu-like illness caused by RSV. See Coronavirus Disease 2019 (COVID-19), Influenza, and Respiratory Syncytial Virus Testing Algorithm for the list of individuals at risk for RSV infection.

Method Name

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

NY State Available

No

Specimen

Specimen Type

Varies

Ordering Guidance

Due to the nonspecific clinical presentation of COVID-19, influenza A, influenza B, and respiratory syncytial virus infection during the early stages of flu-like illness, concurrent testing for these 4 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/professionals/diagnosis/index.htm

www.cdc.gov/rsv/clinical/index.html#lab

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), oropharyngeal (OP; ie, throat), nasal mid-turbinate, or nares/nasal swab

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)

Note: 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. For more information on OP swab specimen collection, see COVID-19 Oropharyngeal Collection Instructions.

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.

Reject Due To

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

Respiratory syncytial virus (RSV) is an infectious pathogen that infects the human respiratory tract causing an

influenza-like illness. Most healthy people spontaneously recover from RSV infection in 1 to 2 weeks, but infection can be severe in infants, young children, and older adults. The virus is the most common cause of bronchiolitis (inflammation of the small airways in the lung) and pneumonia in children under 1 year of age in the United States, and it is recognized increasingly as a frequent cause of respiratory illnesses in older adults.

RSV can be detected by polymerase chain reaction in upper and lower respiratory tract specimens. Nasopharyngeal swabs or aspirates are the preferred specimen types for detection of RSV RNA. Nasal swabs may not yield as high detection rate as those of nasopharyngeal specimens for molecular detection of RSV RNA. Bronchoalveolar lavage fluid, bronchial washings, endotracheal aspirate, and sputum are suitable specimens for detection of RSV infection of the lower respiratory tract.

Reference Values

Undetected

Interpretation

"Detected" result indicates that respiratory syncytial virus (RSV) RNA is present and suggests the presence of RSV infection in the symptomatic patient.

"Undetected" result indicates that RSV RNA is absent in the patient’s specimen.

An "Inconclusive" result indicates that the presence or absence of RSV RNA in the specimen could not be determined with certainty after repeat testing in the laboratory, possibly due to inhibition of polymerase chain reaction from interfering substances present in the respiratory tract specimen. Submission of a new specimen for testing is recommended when clinically indicated.

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 respiratory syncytial virus (RSV), and positive test results do not exclude the possibility of concurrent infection with other respiratory viruses, such as SARS-CoV-2, influenza A and B viruses.

Undetected (ie, negative) results do not rule out RSV infection in patients and should not be used as the sole basis for treatment or other patient management decisions. Results should be correlated with patient's history and clinical

presentation. This assay detects both viable (ie, replicating) and nonviable virus.

Clinical Reference

1. Mammas IN, Drysdale SB, Rath B, et al: Update on current views and advances on RSV infection. Int J Mol Med. 2020; Aug;46(2):509-520

2. Griffiths C, Drews SJ, Marchant DJ: Respiratory syncytial virus: infection, detection, and new options for prevention and treatment. Clin Microbiol Rev. 2017; Jan;30(1):277-319

3. Hall CB, Simoes EAF, Anderson LJ: Clinical and epidemiologic features of respiratory syncytial virus. Curr Top Microbiol Immunol. 2013;372:39-57

4. National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases, Centers for Disease Control and Prevention (CDC). Respiratory syncytial virus infection (RSV). Updated December 2020. Accessed December 17, 2021. Available at www.cdc.gov/rsv/clinical/index.html

Performance

Method Description

This assay is a laboratory-developed, TaqMan probe-based, real-time reverse transcription polymerase chain reaction assay using a commercially available test designed for qualitative detection of respiratory syncytial virus (RSV) in human upper and lower respiratory tract specimens. Viral target-specific primers and probe are used to amplify and detect the matrix protein (M)-encoding sequence of RSV. 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. Known positive and negative controls are processed in the same way in each assay run.(Package insert: cobas Influenza A/B and RSV UC: Qualitative nucleic acid test for use on the cobas 6800/8800 Systems. Roche Molecular Systems, Inc; Doc Rev. 1.0, 09/2021)

PDF Report

No

Specimen Retention Time

Negative samples: 5 days; Positive samples: 30 days

Performing Laboratory Location

Rochester

Fees & Codes

Test Classification

This test was developed, and its performance characteristics 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

87634

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
RSVQL	RSV RNA PCR Detect, V	85479-4

Result ID	Reporting Name	LOINC®
616200	RSV RNA PCR	85479-4
RSVQS	RSV Specimen Source	31208-2