Lab Dept: Microbiology

Test Name: RESPIRATORY PANEL PCR, VARIES

General Information

Lab Order Codes:	RPB
Synonyms:	N/A
CPT Codes:	0202U – Infectious disease, pathogen-specific nucleic acid, 22 targets including severe acute respiratory syndrome coronavirus 2, qualitative RT-PCR
Test Includes:	Rapid detection of respiratory infections caused by the following: Adenovirus, Coronavirus (serotypes HKU1, NL63, 229E, OC43), Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), Human Metapneumovirus, Human rhinovirus/enterovirus, Influenza A (H1, H1-2009, H3), Influenza B, Parainfluenza virus (serotypes 1-4), Respiratory syncytial virus (RSV), Bordetella pertussis, Bordetella parapertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae Reflex testing: Specimens positive for *Mycoplasma pneumoniae* will have *Mycoplasma pneumoniae* macrolide resistance performed at an additional charge. Test code: RPMPM M. pneumoniae Macrolide Resist PCR

Logistics

Test indications:	This test is a multiplex polymerase chain reaction test capable of qualitatively detecting DNA or RNA of 22 pathogens (bacteria and viruses) in approximately 1 hour using bronchoalveolar lavage and bronchial washing specimens.
Lab Testing Sections:	Microbiology - Sendout
Referred to:	Mayo Clinic Laboratories (Mayo Test: RPB)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	1 – 2 days
Special Instructions:	Coronavirus Disease 2019 (COVID-19), Influenza, and Respiratory Syncytial Virus Testing Algorithm

Specimen

Specimen Type:	Bronchoalveolar lavage (BAL) or bronchial washing
Container:	Sterile container
Draw Volume:	1 mL (Minimum: 0.5 mL) fluid
Processed Volume:	Same as Draw Volume
Collection:	Routine BAL or bronch washing collection
Special Processing:	Lab Staff: Aliquot 1 mL (Minimum: 0.5 mL) fluid to sterile container. Store and ship refrigerated. Specimens that cannot be shipped refrigerated to Mayo Clinic Laboratories within 3 days (72 hours) should be frozen prior to shipment.
Patient Preparation:	None
Sample Rejection:	Mislabeled or unlabeled specimens; Specimens received older than 72 hours (refrigerated) or older than 30 days (frozen)

Interpretive

Reference Range:	Undetected (for all targets) INTERPRETATION: Results are intended to aid in the diagnosis of illness and are meant to be used in conjunction with other clinical and epidemiological findings. A negative result should not rule out infection in patients with a high pretest probability for a respiratory infection. The assay does not test for all potential infectious agents of respiratory disease. Specimens collected too early or too late in the clinical course may not yield the organism causing disease. Negative results should be considered in the context of a patient's clinical course and treatment history, if applicable. Positive results do not distinguish between a viable or replicating organism and the presence of a nonviable organism or nucleic acid, nor do they exclude the potential for coinfection by organisms not included in the panel. Nucleic acid may persist in some patients for days to weeks, even following appropriate therapy. Detection of 1 or more organisms included in this test suggests that the virus or bacteria is present in the clinical sample; however, the test does not distinguish between organisms that are causing disease and those that are present but not associated with a clinical illness. Coinfections (eg, detection of multiple viruses or bacteria or viruses and bacteria) may be observed with this test. In these situations, the clinical history and presentation should be reviewed thoroughly to determine the clinical significance of multiple pathogens in the same specimen.

Critical Values: N/A

Limitations:

Test results should be used as an aid in diagnosis. The single assay should not be used as the only criteria to form a clinical conclusion, but results should be correlated with patient symptoms and clinical presentation. A negative result does not negate the presence of the organism or active disease.
The detection of microbial DNA or RNA is dependent upon proper sample collection, handling, transportation, storage, and preparation. There is a risk of false-negative results due to the presence of strains with sequence variability or genetic rearrangements in the target regions of the assays or levels of organism at or below the limit of detection of the test.

Positive results do not rule out coinfection with other pathogens.

Negative results combined with respiratory illness may be due to pathogens not detected by this panel.

Repeat testing should not be performed on samples collected less than 7 days apart.

For severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) results from this assay, if repeat testing is considered within a 7-day period after an initial negative SARS-CoV-2 result, consider ordering a targeted SARS-CoV-2 assay. If initial SARS-CoV-2 results from this assay were positive, it is recommended to wait 14 days until a subsequent test is performed, if desired.

Adenovirus

Assay may show variable detection with non-respiratory serotypes within species A, D, F, and G.

Influenza A

Performance characteristics were established when influenza A H1-2009, A H1, and A H3 were the predominant influenza A viruses in circulation. Performance of detecting influenza A may vary if other influenza A strains are circulating or a novel influenza A virus emerges. The performance of the FilmArray respiratory panel has not been established in individuals who received influenza vaccine. Recent administration of a nasal influenza vaccine may cause false-positive results for influenza A or influenza B. Some strains of human, swine, or avian origin are predicted to react with influenza A assays leading to an Influenza A (no subtype detected) result.

Assay detects and differentiates commonly occurring influenza A hemagglutinin subtypes based on only the hemagglutinin gene, through the use of 2 influenza A assays and 3 subtyping assays for the hemagglutinin gene.

Results are reported as "detected" when at least one of the influenza A assays and one of the subtyping assays are both positive. If both influenza A assays are positive without a hemagglutinin subtype, results are reported as influenza A (no subtype detected).

Equivocal results are reported following repeat testing in 2 scenarios:

-Neither of the influenza A assays are positive, but a hemagglutinin gene is positive

-One of the influenza A assays is positive, and hemagglutinin genes are negative.

The assay does not detect or differentiate the influenza A neuraminidase gene.

Rhinovirus/Enterovirus Group

Due to the genetic similarity of these viruses, the assay is unable to reliably differentiate them.

Bordetella pertussis/Bordetella parapertussis

Some acellular vaccines contain polymerase chain reaction (PCR)-detectable DNA. Contamination of specimens with vaccine can cause false-positive Bordetella pertussis PCR results. Specimens should not be collected or processed in areas that are exposed to B pertussis vaccine material. Assay targets the single-copy promoter region of the pertussis toxin gene. Results of this assay may not be concordant with commonly used Bordetella PCR assays, which target the multicopy insertions sequences (IS481). Cross reactivity could occur with high levels or rare sequence variants of other species such as Bordetella bronchiseptica and Bordetella parapertussis.

Coronavirus

Coronavirus OC43 assay may cross-react with coronavirus HKU1. As a result, when both HKU1 and OC43 are detected in the same patient specimen, the result may be due to assay cross-reactivity. A coinfection with these 2 viruses is also possible.

SARS-CoV-2

The following animal coronavirus strains, unlikely to be found in humans, may cross react with the SARS-CoV-2 target: Bat coronavirus RaTG13 (accession: MN996532), Pangolin coronavirus (accession: MT084071), and bat SARS-like coronavirus sequences (accession MG772933 and MG772934).

Methodology: Multiplex Polymerase Chain Reaction (PCR)

References: Mayo Clinic Laboratories (August 2022)