MAYO CLINIC LABORATORIES

Test Definition: MPRP

Mycoplasma pneumoniae PCR

Overview

Useful For

Diagnosis of infections due to *Mycoplasmoides pneumoniae*

Method Name

Rapid Polymerase Chain Reaction (PCR) using Light Cycler and Fluorescent Resonance Energy Transfer (FRET)

NY State Available

Yes

Specimen

Specimen Type

Varies

Necessary Information

Specimen source is required.

Specimen Required

The high sensitivity of amplification by polymerase chain reaction requires the specimen to be processed in an environment in which contamination of the specimen by *Mycoplasmoides pneumoniae* DNA is unlikely.

Submit only 1 of the following specimens:

Specimen Type: Respiratory

Supplies:

-Bartels FlexTrans VTM-3 mL (T892)

-Jiangsu VTM-3 mL (T891)

-M4-RT (T605)

Sources: Bronchial washing, bronchoalveolar lavage, tracheal secretions, sputum

Container/Tube:

Preferred: Sterile container

Acceptable: Specimen in M4, M4-RT, M5, M6, or universal transport medium

Specimen Volume: 1 mL

Specimen Type: Swab

Supplies:

-Culturette (BBL Culture Swab) (T092)

-BD Eswab (T853)

-Steriflock NP Swab (T861)

-Nasopharyngeal Swab (Rayon Mini-Tip Swab) (T515)

-Bartels FlexTrans VTM-3 mL (T892)

-Jiangsu VTM-3 mL (T891)

-M4-RT (T605)

Sources: Throat, nasal, or nasopharyngeal

Container/Tube:
Preferred: Culture swab transport system (Dacron or rayon swab with aluminum or plastic shaft with either Stuart or Amies liquid medium)
Acceptable: Culture transport swab (Stuart's media) or place swab in M4, M4-RT, M5, M6, universal transport media, or ESwab
Specimen Volume: Swab
Collection Instructions:
1. Collect specimen by swabbing back and forth over mucosa surface to maximize recovery of cells.
2. Place swab back into swab cylinder.
Specimen Type: Fluid
Sources: Pleural, pericardial, cerebrospinal
Container/Tube: Sterile vial
Specimen Volume: 0.5 mL

Forms
If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Reject Due To

Cotton or calcium alginate-tipped swab, wooden shaft swab, transport swab containing gel or charcoal	Reject
Port-a-Cul tube	
Anaerobic fluid vials	
Dry swab (no pledget or sponge)	

Specimen Minimum Volume
Respiratory, Fluid: 0.5 mL
Swab: 1 swab

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated (preferred)	7 days	
	Frozen	7 days	

Clinical & Interpretive

Clinical Information
Mycoplasmoides pneumoniae, previously *Mycoplasma pneumoniae,* is a small bacterium transmitted via organism-containing droplets. It is a cause of upper respiratory infection, pharyngitis, and tracheobronchitis, particularly in children, and has been associated with approximately 20% of cases of community acquired pneumonia.(1) Central nervous system and cardiac manifestations are probably the most frequent extrapulmonary complications of infections due to *M pneumoniae*. The disease is usually self-limited although severe disease has been reported in immunocompromised patients.(2)
Identification of *M pneumoniae* by culture-based methods is time consuming and insensitive. Serology based assays for *M pneumoniae* have several drawbacks. The development of IgM antibodies takes approximately 1 week and the IgM response in adults may be variable or it may be decreased in immunosuppressed individuals.(3,4) Confirmation of the

disease may be dependent on the observation of a 4-fold rise in IgG antibody titers between acute and convalescent specimens, several weeks following the initial onset of illness, providing clinical utility only for retrospective testing.(4) Real-time polymerase chain reaction testing offers a rapid and sensitive option for detection of *M pneumoniae* DNA from clinical specimens.

Reference Values

Not applicable

Interpretation

A positive result indicates the presence of *Mycoplasmoides pneumoniae*.

A negative result does not rule out the presence of *M pneumoniae* and may be due to the presence of inhibitors within the specimen matrix, or the presence of organisms at numbers below the limits of detection of the assay.

Cautions

This assay should only be used for testing of respiratory tract specimens (throat swabs, nasopharyngeal swabs, tracheal secretions, sputum, and bronchoalveolar lavage fluid) and pleural/chest fluid, pericardial fluid, and cerebrospinal fluid.

Supportive Data

Accuracy:

The assay was validated in a blinded manner using 30 *Mycoplasma pneumoniae*-positive specimens received from a reference lab and 6 negative specimens. The *M pneumoniae* polymerase chain reaction (PCR) test had 100% sensitivity and specificity when compared to the Focus Diagnostics *M pneumoniae* primer pair PCR assay. Whole organism spiking studies (near the limit of detection of the assay) were also performed using the following specimens: bronchoalveolar lavage/bronchial wash, nasopharyngeal and throat swabs, sputum, pericardial/pleural fluid, and cerebrospinal fluid. These specimens were confirmed as being negative for *M pneumoniae* prior to spiking. The sensitivity and specificity of the spiked specimens combined for all the matrices were 99% (154/155) and 100% (57/57), respectively.

Limit of detection:

The limit of detection of the assay is less than 5 target copies/mcL for all validated specimen types.

Analytical specificity:

The assay was tested against a panel of 45 organisms consisting of bacteria and viruses representing normal respiratory flora and/or respiratory pathogens. There was no cross reactivity among these organisms, which included 16 other species of *Mycoplasmoides*.

Clinical Reference

1. Waites KB, Taylor-Robinson D: *Mycoplasma* and *Ureaplasma*. In: Versalovic J, Carroll K, Funke G, et al, eds. Manual of Clinical Microbiology. ASM Press; 2011: 970-985

2. Jensen JS, Heilmann C, Valerius NH: *Mycoplasma pneumoniae* infection in a child with AIDS. Clin Infect Dis. 1994;19:207

3. Daxboeck F, Krause R, Wenisch C: Laboratory diagnosis of *Mycoplasma pneumoniae* infection. Clin Microbiol Infect. 2003;9:263-273

4. Waites KB, Talkington DF: *Mycoplasma pneumoniae* and its role as a human pathogen. Clin Microbiol Rev. 2004;17:697-728

Performance

Method Description

Throat swabs, nasopharyngeal swabs, sputum, bronchoalveolar lavage fluid, pericardial/pleural/chest fluid, and cerebrospinal fluid specimens are processed according to specimen type. Nucleic acid is extracted by the MagNA Pure automated instrument (Roche Applied Science). A specific target sequence from *Mycoplasma pneumoniae* is targeted by primers and fluorescence resonance energy transfer (FRET) hybridization probes. The LightCycler instrument (Roche Applied Science) amplifies and monitors the development of target nucleic acid sequences after the annealing step during polymerase chain reaction cycling. Detection of the *M pneumoniae* target is performed through melting curve analysis using the LightCycler software.(Schmitt BH, Sloan LM, Patel R: Real-time PCR detection of *Mycoplasma pneumoniae* in respiratory specimens. Diagn Microbiol Infect Dis. 2013 Nov;77[3]:202-205)

PDF Report

No

Specimen Retention Time

7 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

87581