Overview

Useful For
Diagnosis of infections due to *Mycoplasma 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 PCR requires the specimen to be processed in an environment in which contamination of the specimen by *Mycoplasma pneumoniae* DNA is unlikely.

Specimen source is required.

Submit only 1 of the following specimens:

**Supplies:** M4-RT (T605)

**Specimen Type:** Respiratory

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

**Container/Tube:**
Preferred: Sterile container
Acceptable: Specimen in M4, M4-RT (T605), M5, M6, or UTM

**Specimen Volume:** 1 mL

**Supplies:** M4-RT (T605), Culturette (BBL Culture Swab) (T092)

**Specimen Type:** Swab

**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: T092)

Acceptable: Culture transport swab (Stuart's media) or place swab in M4, M4-RT (T605), M5, M6, UTM, 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.

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

Reject Due To
| Swab/Other                  | Cotton or calcium alginate-tipped swab, wooden shaft swab, transport swab containing gel or charcoal, Port-a-Cul tube, anaerobic fluid vials, or dry swab (no pledget or sponge) |

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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</thead>
<tbody>
<tr>
<td>Varies</td>
<td>Refrigerated (preferred)</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>7 days</td>
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Clinical and Interpretive

Clinical Information
*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.\(^2\)\(^3\)\(^4\) 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 PCR 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 *Mycoplasma 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/pleural 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* PCR (Mayo) 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 *Mycoplasma*.

**Clinical Reference**


Test Definition: MPRP
Mycoplasma pneumoniae PCR

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 PCR 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

Day(s) and Time(s) Test Performed

Monday through Sunday

Analytic Time

3 days

Maximum Laboratory Time

4 days

Specimen Retention Time

7 days

Performing Laboratory Location

Rochester

Fees and 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 Regional Manager. For assistance, contact Customer Service.

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 U.S. Food and Drug Administration.

CPT Code Information

87581

LOINC® Information
### Test Definition: MPRP

**Mycoplasma pneumoniae PCR**

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<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<td>Mycoplasma pneumoniae PCR</td>
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<td>Mycoplasma pneumoniae PCR</td>
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