

## Overview

### Useful For

Screening for IgM antibodies in the indication of recent or past exposure to *Mycoplasma pneumoniae*

### Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
MMYCO	M. pneumoniae Ab, IgM, S by IFA	No	No

### Method Name

Only orderable as part of a profile. For more information see MYCO / *Mycoplasma pneumoniae* Antibodies, IgG and IgM, Serum.

Enzyme Immunoassay (EIA)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Specimen Required

Only orderable as part of a profile. For more information see MYCO / *Mycoplasma pneumoniae* Antibodies, IgG and IgM, Serum.

**Supplies:** Sarstedt Aliquot Tube, 5 mL (T914)

**Collection Container/Tube:**

**Preferred:** Serum gel

**Acceptable:** Red top

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 1 mL

**Collection Instructions:** Centrifuge and aliquot serum into a plastic vial.

### Specimen Minimum Volume

0.5 mL

**Reject Due To**

Gross hemolysis	Reject
Gross lipemia	Rejected
Heat inactivated specimen	Reject

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Frozen	14 days	

**Clinical & 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. 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.

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 may be variable in adults or decreased in immunosuppressed individuals. Confirmation of the disease is 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. Real-time polymerase chain reaction offers a rapid and sensitive option for detection of *M pneumoniae* DNA from clinical specimens for diagnosis of acute or current infection.

**Reference Values**

Only orderable as part of a profile. For more information see MYCO / *Mycoplasma pneumoniae* Antibodies, IgG and IgM, Serum.

Negative

**Interpretation**

IgG ELISA Result	IgM ELISA Result	Interpretation
Positive	Negative	Results suggest past exposure.
Positive	Reactive	Prior exposure to <i>Mycoplasma pneumoniae</i> detected.

	Equivocal	Confirmatory testing for IgM to <i>M pneumoniae</i> will be performed by an immunofluorescence assay.
Negative	Negative	No antibodies to <i>M pneumoniae</i> detected. Acute infection cannot be ruled out as antibody levels may be below the limit of detection. If clinically indicated, a second serum should be submitted in 14 to 21 days.
Negative	Reactive	No prior exposure to <i>Mycoplasma pneumoniae</i> . Confirmatory testing for IgM to <i>M pneumoniae</i> will be performed by an immunofluorescence assay.
	Equivocal	
Equivocal	Negative	Recommend follow-up testing in 10 to 14 days if clinically indicated.
	Reactive	Confirmatory testing for IgM to <i>M pneumoniae</i> will be performed by an immunofluorescence assay.
	Equivocal	

ELISA = Enzyme-linked immunosorbent assay

## Cautions

A diagnosis of *Mycoplasma pneumoniae* infection should not be solely based on results of serologic testing for this agent. Test results should be interpreted in conjunction with clinical evaluation and the results of other diagnostic procedures (eg, molecular detection).

The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.

Testing should not be performed as a screening procedure for the general population. Testing should only be done when clinical evidence suggests the diagnosis of *M pneumoniae*-associated disease.

The performance of this test has not been established on neonates and immunocompromised patients.

Performance of the IgM assay has not been tested with specimens known to be positive for antibodies to organisms that are known to be associated with lower respiratory illness (ie, influenza A and B, cytomegalovirus, *Chlamydomphila pneumoniae*, parainfluenza), and closely related serovars known to cross-react with *M pneumoniae*, such as *Mycoplasma genitalium* and *Mycoplasma hominis*, as well as various *Ureaplasma* species. Cross-reactivity studies with such organisms have not been performed with this assay.

The IgG removal system included with the IgM test system has been shown to functionally remove the IgG from specimens containing total IgG levels ranging from 300 to 600 mg/mL. The effectiveness of this removal system at IgG levels exceeding 600 mg/mL has not been established.

## Clinical Reference

1. Smith T. *Mycoplasma pneumoniae* infections: diagnosis based on immunofluorescence titer of IgG and IgM antibodies. Mayo Clin Proc 1986;61(10):830-831
2. Holzman RS, Simberkoff MS, Leaf HL. *Mycoplasma pneumoniae* and atypical pneumonia. In: Bennett JE, Dolin R, Blaser MJ, eds. Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases. 9th ed. Elsevier; 2020:2332-2339

## Performance

### Method Description

IgM Enzyme Immunoassay:

Test sera are diluted with the sample diluent provided. The sample diluent contains antihuman IgG that precipitates and removes IgG and rheumatoid factor from the sample, leaving IgM free to react with immobilized antigen. Diluted sera are incubated in antigen-coated microwells. Any antigen-specific antibody in the samples will bind to the immobilized antigen. The plate is washed to remove unbound antibody and other serum components. Peroxidase-conjugated goat-antihuman IgM (chain specific) is added to the wells and incubated. The conjugate will react with the IgM antibody/antigen on the solid phase. The wells are washed to remove unbound conjugate. The microwells containing immobilized conjugate are incubated with peroxidase substrate solution. Hydrolysis of the substrate by peroxidase produces a color change. After a period of time the reaction is stopped by the addition of diluted acid, and the color changes are measured photometrically. The color intensity of the solution depends on the antibody concentration in the serum sample. (Package insert: *M pneumoniae* IgM Test System. Zeus Scientific, Inc; Revision Date 9/22/2016)

IgM Indirect Immunofluorescence Assay:

*Mycoplasma pneumoniae* antigenic substrate is fixed onto microscope slide wells. Serum that has been pretreated to remove IgG antibodies is incubated with the substrate. If IgM antibody to *M pneumoniae* is present, it will bind to the substrate. Fluorescein-labeled antihuman-IgM conjugate is added to the slide wells, and the slide is incubated. If antibody is present, it can be observed as a characteristic positive, bright, apple-green fluorescent reaction when the slide is read on a fluorescence microscope. (Package insert: *Mycoplasma pneumoniae* IgM IFA Antibody Test System. Zeus Scientific, Inc; 09/2019)

### PDF Report

No

### Day(s) Performed

Monday through Friday

### Report Available

Same day/1 to 3 days

### Specimen Retention Time

14 days

### Performing Laboratory Location

Rochester

## 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

86738

### LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
MYCOM	M. pneumoniae Ab, IgM, S	5257-1

Result ID	Test Result Name	Result LOINC® Value
MYCOM	M. pneumoniae Ab, IgM, S	5257-1