

Mycoplasma pneumoniae (IgM) Enzyme Immunoassay

Mycoplasma pneumoniae is the only known Mycoplasma species that is a primary pathogen in man. Clinical manifestations can range from asymptomatic respiratory infections to severe pneumonia¹. *M. pneumoniae* accounts for 15 to 20% of total pneumonia^{2,3}. Other symptoms associated with *M. pneumoniae* infection include abnormalities of the central nervous system (meningitis, encephalitis), cardiac involvement (myocarditis, pericarditis), hemolytic anemia, arthritis, G.I. inflammations, and mucocutaneous reactions⁴. Mycoplasma pneumoniae is identified as a common infectious cause of Stevens-Johnson Syndrome, a well defined systemic disease that can develop into a life-threatening illness in children⁵.

The *Mycoplasma pneumoniae* organism is sensitive to erythromycin and tetracyclines however, it is resistant to drugs more routinely given in the treatment of acute pneumonia. Thus, a rapid and reliable diagnosis of *M. pneumoniae* infection is essential to proper patient management⁶. Culturing of *M. pneumoniae* is too difficult and slow for clinical diagnostic utility. Serology provides the primary diagnostic tool with current methods including complement fixation (CF), indirect immunofluorescence assays (IFA) and enzyme immunosorbent assays (EIA). The CF test frequently produces inconclusive results due to moderate titers of antibody derived from previous infections^{1,7}. Alternatively, increased titers of specific IgM antibody are indicative of a recent or current infection⁸.

The **ImmunoWELL** Mycoplasma Pneumoniae Antibody (IgM) Test is an EIA which measures *M. pneumoniae* specific IgM in human serum. The **ImmunoWELL** Test utilizes an IgG absorbent to eliminate interference by IgG in the serum sample (*M.pneumoniae*-specific IgG and rheumatoid factor). Hence, the **ImmunoWELL** test provides highly sensitive and reproducible results in detecting *M. pneumoniae* -specific IgM.

Expected Results

Clear differences have been shown between IgG and IgM results, depending on the age of the group tested. An IgM test better detects Mycoplasma infection in the younger group, while rises in IgG titer were more useful in the older group, presumably indicating recurrent infections. The glycolipid antigen used in complement fixation assays may be cross-reactive with organ-specific antigens from brain, pancreas, and antigens from various organisms of group A *Neisseria meningitidis*. It is unknown whether such interactions occur with the purified form of glycolipid used in this assay. The Mycoplasma IgM response has been reported to persist for several months following infection.

Performance Characteristics

Overall relative performance following both **ImmunoWELL** IgM and IgG is detailed in the package inserts. The sensitivity is 96% (87-100%) and specificity is 89% (52-100%).

Ordering Information

Product Description	Quantity	GenBio Product No.
ImmunoWELL Mycoplasma (IgM) Antibody Test	1 kit / 96 wells	3130
<i>Also available from GenBio</i>		
ImmunoWELL Mycoplasma (IgG) Antibody Test	1 kit/96 wells	3120

Principle

The **ImmunoWELL** Mycoplasma Pneumoniae (IgM) Antibody Test utilizes an EIA microtiter plate technique for the detection of antibodies. Antihuman IgG treated serum is added to antigen coated microtiter wells and allowed to react. After removal of unbound antibodies, horseradish peroxidase-conjugated antihuman IgM antibodies are allowed to react with bound antibodies. The bound peroxidase reacts with 2,2'-azino-di-[3-ethylbenzthiazoline sulfonate] (ABTS), the chromogenic substrate, developing a color. Finally, the substrate reaction is stopped and the optical density is read with a spectrophotometric microwell reader.

Procedural Summary

1. Prepare Wash Buffer from Wash Buffer Concentrate
2. Add 100 μ L of each diluted specimen or prediluted control to 20 μ L of Absorbent. Mix and incubate 30 min at room temperature.
3. Add 100 μ L of Specimen Diluent into the first well as a substrate blank.
4. Pipet 100 μ L of the treated calibrator, controls and specimens to coated microwells and incubate 60 min at room temperature
5. Aspirate wells and wash microwells three times with Wash Buffer
6. Add 100 μ L of Conjugate to wells and incubate 30 minutes at room temperature
7. Aspirate microwells and wash wells three times with Wash Buffer
8. Prepare fresh Color Developer
9. Add 100 μ L Color Developer to wells and incubate 30 minutes at room temperature
10. Add 100 μ L Stop Solution to wells and read results at 405nm

References

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