Mycoplasma pneumoniae (IgG) 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 pneumonia. *M. pneumoniae* accounts for 15 to 20% of total pneumonia. 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 reactions. *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 children.

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 management. 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 immunosorbant assays (EIA). The CF test frequently produces inconclusive results due to moderate titers of antibody derived from previous infections. Alternatively, increased titers of specific IgM antibody are indicative of a recent or current infection.

The ImmunoWELL Mycoplasma Pneumoniae Antibody (IgG) Test is an EIA which measures *M. pneumoniae* specific IgG in human serum and is designed to be used in conjunction with the *ImmunoWELL* Mycoplasma Pneumoniae Antibody (IgM) Test. Hence, the *ImmunoWELL* tests provide highly sensitive and reproducible results in detecting M. *pneumoniae* - specific antibodies.

Expected Results

Clear differences have been shown between IgG and IgM results, depending on the age of the group tested. It is reported that the percentage of pneumonias caused by *M. pneumoniae* is 10 - 33% in the general population, 35 - 74% in children (5 - 19 years old), 27 - 52% in college students, 8 - 54% in military recruits and 7 - 17% in civilian adults. An increase of IgG relative to IgM antibodies occurs with time after onset of illness. Also, adults respond with higher IgG antibody ratios than do children. IgM titers are significant in a high percentage of patients at admission.

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 (IgG) Antibody Test	1 kit / 96 wells	3120
Also available from GenBio		
ImmunoWELL Mycoplasma (IgM) Antibody Test	1 kit/96 wells	3130

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Principle

The *ImmunoWELL* Mycoplasma Pneumoniae (IgG) Antibody Test utilizes an EIA microtiter plate technique for the detection of antibodies. 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^R), 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. Predilute each patient specimen and control 1:100 in Specimen Diluent
- 3. Add 100 μ L of Specimen Diluent into the first well as a substrate blank.
- 4. Pipet 100 μ L of the Calibrator, diluted 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 100µL 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 100µL Color Developer to wells and incubate 30 minutes at room temperature
- 10. Add 100µL Stop Solution to wells and read results at 405nm

References

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