BioAgilytix Diagnostics

Mycoplasma pneumoniae IgA Antibodies in Serum

Specimen Type	Serum
Specimen Volume	1.0 mL
Collection	Red top tube with no additives or serum gel tube. Allow sample to clot for 30 minutes. Centrifuge at 3000 rpm for 10 minutes and pour serum into a transfer tube.
Minimum Volume	0.6 mL
Handling	Ship frozen on dry ice.
Rejection Criteria	• Specimens outside of listed stability.
Stability	Refrigerated for 14 days. Frozen for 30 days.
Methodology	ELISA
Reference Range	Ratio <0.8 Negative Ratio ≥0.8 to <1.1 Borderline Ratio ≥1.1 Positive
Turnaround Time	Up to 7 business days.
CPT Code	86738
Clinical Significance	Mycoplasma pneumoniae is a is widely distributed bacterium and causes primary atypical pneumonia, often called 'walking pneumonia.' M. pneumonia can be cultured on artificial media but may take 21-30 days for growth to appear. Alternatively, M. pneumoniae IgA antibodies may be used for rapid and specific identification of this disease. A negative serological result does not exclude infection, as in early phase of infection, antibodies may not be present, or may be too low to be detectable. A borderline result indicates a solid (negative or positive) result was not obtained. A positive result indicates contact with the bacterium, Mycoplasma pneumoniae.
Principle	Procedure uses an ELISA method: M. pneumoniae (*M.pn*) antigens are used to coat a microplate. An *M.pn* IgA calibrator, *M.pn* IgA (positive & negative) controls, and patient sera are applied to the plate. Anti *M.pn* antibodies from samples bind to immobilized antigen. A peroxidase-labeled anti-human IgA secondary antibody is added. The amount of labeled secondary antibody that is bound to the plate is quantified by addition of peroxidase substrate, TMB (3,3',5,5'-tetramethylbenzidine). TMB is oxidized by peroxidase with color change from clear to blue, and an acidic solution is added to stop the reaction. Resulting yellow color read on an ELISA reader, and a ratio: OD of patient / OD of calibrator calculated to generate semi-quantitative patient results.