EVALUATION OF THE DIESSE CHORUS MYCOPLASMA PNEUMONIAE Igm ASSAYS FOR THE DIAGNOSIS OF ACUTE MYCOPLASMA PNEUMONIAE INFECTION

<u>Mai Khuu</u>, Tony Panayotou, John Hamblin, Tony Korman Department of Microbiology, Monash Medical Centre Southern Cross Pathology Australia

Introduction: Mycoplasma pneumoniae is a common cause of community acquired pneumonia. The infection is diagnosed mostly in the 5 to 40 year age group. Onset of the disease is gradual with an incubation period between 10 to 14 days, affecting the upper and lower respiratory tracts. Mycoplasma pneumoniae is a pleomorphic bacteria with specialized filamentous tips that enables it to burrow itself into the respiratory epithelium thereby causing inflammation and ultimately "pneumonia-like" illness. Rapid early differential diagnosis between Mycoplasma pneumoniae and other pneumonia-like agents is important for treatment and patient management.

The Diesse Chorus (distributed by Laboratory Diagnostics) Mycoplasma Pneumoniae IgM and the Immuno Card Mycoplasma IgM (distributed by Meridian Bioscience, Inc.) both provide qualitative assays for the detection of IgM antibodies to Mycoplasma pneumoniae in serum. Testing samples by both the Chorus and the Immuno Card can be performed easily on a daily basis. Total time required for test preparation and assay duration is significantly less than that of an enzyme immunoassay (EIA) or particle agglutination, with minimal calibration and controls required due to the use of separate, self-contained disposable testing strips.

Methods: 30 samples from patients with varying age group between 1 to 50 years with symptoms characteristic of pneumonia or respiratory illness have been tested so far with the Diesse Chorus and the Immuno *Card* Mycoplasma IgM assays according to manufacturers' guidelines. An overall consensus result was determined for each of the specimens, allowing the sensitivity and specificity to be compared for each of the two assays. A specimen was categorised as being either detected or not detected if the same result was achieved from both assays. Any specimen results that did not correspond were repeated and sent to a reference laboratory for total antibody particle agglutination and IgM ELISA testing. Precision testing was performed on both the Diesse Chorus Mycoplasma IgM and the Immuno *Card* Mycoplasma IgM by repeat testing of a patient serum with known low reactivity. A commercially available quality control sample was also tested in a number of runs for both methods to ensure validity of results.

Results: Of 30 samples tested 9 were positive and 13 were negative by both assays. 6 samples that were positive by the Immuno *Card* Mycoplasma IgM were negative by the Diesse Chorus Mycoplasma IgM. These were retested with the Immuno *Card* Mycoplasma IgM and 4 became negative and 2 remained positive. 2 samples that were tested negative by the Immuno *Card* Mycoplasma IgM, 1 was equivocal and 1 was positive on the Diesse Chorus Mycoplasma IgM. On repeat with the Immuno *Card*, the former result remained negative and the latter became a weak positive. These discrepant samples were sent to a reference laboratory for further testing and results are pending, 1 sample was insufficient for confirmation.

Discussion: The results of the study so far show that both the DIESSE *Chorus* and the Immuno*Card* Mycoplasma IgM have good correlation and either assay is acceptable for routine screening. The DIESSE *Chorus* offers the advantages of automation, minimal sample volume, a self contained disposable strip and improved turn around times but at a higher cost per test. The Immuno*Card* Mycoplasma IgM also offers a quick, cost effective and minimal volume result. The Immuno*Card* Mycoplasma IgM is a visual colour based interpretation. This can be problematic as the result can be subjective to the individual visualising the test. A limitation of the the Immuno*Card* Mycoplasma IgM is that the result is given as either detected or not detected without an equivocal interpretation.

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