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Title: Rapid detection of *Mycoplasma pneumoniae* IgM antibodies using ImmunoCard Mycoplasma kit compared with complement fixation (CF) tests and clinical application

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Body: [Purpose]*Mycoplasma pneumoniae* is a leading cause of community-acquired pneumonia. For a rapid diagnosis of *M. pneumoniae* infection, we often use ImmunoCard Mycoplasma kit (IC), a 10-min-card-based enzyme-linked immunosorbent assay (ELISA) of IgM antibodies to *M. pneumoniae*. However, widespread clinical application of this test is hampered by an inability to identify pathogen directly with adequate sensitivity and specificity. Therefore, we examined the clinical usefulness of IC test retrospectively. [Method]We evaluated 316 samples which are measured by IC from October,2008 to March,2009. We also compared IC with the complement fixation (CF) test, and estimated false positive and negative rate based on the clinical course and other laboratory findings. [Results]Among 316 samples, 69 (21.8%) were positive of IC and 247 (78.2%) negative. Sixteen cases were also measured by CF test with the paired serum, and in 5 (31.3%) cases of these, there was a discrepancy between the result of IC and that of CF test. On the basis of a clinical diagnosis, IC gave the false positive rate of 80.0%, false negative rate of 31.3%. [Conclusion]IC has so far been attributed to the rapid diagnosis of *M. pneumoniae* infection because it is unnecessary to use paired serum and possible to judge the infection rapidly. But a positive result of IC does not always indicate acute infection because the result of IC were not always concordant with that of CF test. According to our results, it seems that the interpretation of the result of IC is very difficult in order to use it clinically.