EV0482
ePoster Viewing
Diagnostic bacteriology – non-culture based, including molecular and MALDI-TOF

Comparison of Illumigene Mycoplasma DNA amplification assay and real-time in-house PCR for detection of M. pneumoniae

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Background: The proportion of lower respiratory tract infections in children and adults, including community-acquired pneumonia, associated with *M. pneumoniae* infection during the past 10 years has ranged from 0% to more than 50%, varying with age, the geographic location of the population examined and the diagnostic methods used. Serological methods, in particular such as the complement fixation test (CFT) and EIAs, are most widely used to diagnose a *M. pneumoniae* infection. The application of PCR is more and more accepted as a rapid diagnostic test since culture is too slow and too insensitive to be therapeutically relevant..The aim of this study was to evaluate the performance of a new molecular assay based on the Loop Mediated Isothermal amplification (LAMP) technology, the Illumigene Mycoplasma DNA amplification assay on dilution series from titrated reference strains, on the 2014 *M. pneumoniae* Quality Control for Molecular Diagnostics (QCMD) panel and on 12 archived *M. pneumoniae* positive specimens.

Material/methods: Dilution series of 5 titrated reference strains (PI1428, JAP377, 3996PL, 4972BRA, 6303DES) were made. The stock concentration of the strains varied between $1,1.10^7$ and $6,5.10^7$ colour changing unit per ml (CCU/ml). In addition, the 2014 QCMD *M. pneumoniae* panel for External Quality assessment (EQA) was tested. Finally, twelve archived (-70°C) respiratory specimens, previously found to be *M. pneumoniae* positive by in-house real-time PCR were included in this study. Nucleic acids were extracted by using the NucliSens EasyMag (BioMérieux). Eluates were tested immediately using the Illumigene Mycoplasma DNA amplification assay. The same extract was amplified the day after by the in-house real-time PCR targeting the P1-gene.

Results: When analysing the dilution series of the *M. pneumoniae* reference strains, 1 discordant result between the in-house real-time PCR and the Illumigene Mycoplasma DNA assay was obtained with the lowest dilution of the reference strain with the lowest stock concentration ($1,1.10^7$CCU/ml). This concentration was at the limit of detection for both assays. No discordant results were obtained with the samples of the QCMD2014 *M. pneumoniae* panel. All 12 clinical samples were *M. pneumoniae* positive by the Illumigene Mycoplasma DNA amplification assay as well.

Conclusions: The Illumigene Mycoplasma DNA amplification assay is comparable in sensitivity and specificity to the in-house real-time PCR, with 1 discordant result, probably at the limit of detection. The assay is rapid and easy to use. Further testing on a larger number of positive and negative specimens is recommended.