Laboratory evaluation of the Biofire® FilmArray® Pneumonia Panel *plus* compared to Standard-of-care testing at a private laboratory in Cape Town, South Africa

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Background: Pneumonia causes significant mortality and morbidity worldwide. The standard method for the laboratory diagnosis of lower respiratory tract infections is culture, which has a long turnaround time (TAT), poor sensitivity and does not test for atypical bacteria and viruses. The Biofire® FilmArray® Pneumonia Panel *plus* (FA-PP) is a comprehensive syndromic testing molecular panel that provides rapid results for 34 targets. Our aim was to compare the FA-PP to standard-of-care testing.

Materials/methods: This was a prospective evaluation conducted in a private laboratory in Cape Town, South Africa. Residual sputum, tracheal aspirate and broncho-alveolar lavage specimens were tested in parallel with conventional culture and the FA-PP. Standard-of-care (SOC) testing includes culture as well as other tests that were performed on clinician order only (Biofire® FilmArray® RP2*plus*, *Legionella* urine antigen and blood cultures). Detection rates and TAT of the FA-PP were compared to culture. Percentage agreement between the FA-PP and SOC was assessed.

Results: Thirty* samples from unique patients were tested from August-November 2019. The FA-PP was positive in 80% (24/30) of samples (14 with bacteria only, 7 viruses only, 3 co-detections of bacteria and viruses). Co-detections for ≥2 bacteria occurred in 6 samples. The FA-PP detected 2 *Mycoplasma pneumoniae* and 1 *Legionella pneumophila*.

Culture was only positive in 53% (16/30) of samples. Detection of additional organisms on culture (n=9) were only those not included in the FA-PP (*Candida* species, *Haemophilus* species other than *H. influenzae*, *Raoultella ornithinolytica*). Bacterial detection of ≥10^7 on the FA-PP correlated best with culture-based reporting, especially in bacterial co-detections. Resistance mechanisms were detected in two samples.

The mean TAT for negative and positive cultures were 42 and 62 hours respectively, versus 2-hours for FA-PP. Overall agreement between FA-PP and SOC for at least one significant pathogen was 73% (22/30). Non-concordance was due to RP2*plus* not requested or the cultured organism was not included in FA-PP.

Conclusions: The FA-PP offers a rapid TAT and high yield of bacteria, atypical bacteria and viruses. The potential impact of this panel on antimicrobial stewardship, infection control and clinical factors needs to be evaluated in further studies.
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