Analytical and Clinical Evaluation of the Curetis Unyvero Lower Respiratory Panel at a Tertiary Care Cancer Center

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Abstract

Background: Diagnosis and management of pneumonia still relies on bacterial culture followed by antimicrobial susceptibility testing (AST), with an overall turn-around time (TAT) to results of 24-72 hours. The Curetis Unyvero LRT (CU LRT) panel is an FDA-approved multiplex nucleic acid-based method that detects 19 common bacterial pathogens and 10 resistance markers with a TAT of approximately 5 h. In this study, we evaluated the analytical performance of the CU LRT panel on bronchoalveolar lavage (BAL) fluids and bronchial washings (BW). Additionally, we retrospectively determined the potential impact of the CU LRT test on antibiotic management in an oncology patient population.

Methods: All BALs and BWs received for bacterial culture (February-August 2019) were included if sufficient volume was available following standard of care testing. All samples were saved within 24 h of collection and stored at -20°C prior to testing by the CU LRT. The overall and specimen/target specific sensitivity and specificity of the CU LRT were calculated when appropriate. The impact of the CU LRT panel on antibiotic management was evaluated by retrospective chart review.

Results: 236 respiratory samples (193 unique patients) were tested including 112 BALs and 124 BWs. Overall, 47/236 (20%) samples were positive by the CU LRT compared to 34/236 (14.4%) by culture. Positivity rate for BALS was 10/112 (8.9%) and 37/124 (29.8%) for BWs. When compared to bacterial culture, the overall sensitivity of the CU LRT panel was 88.3% (95% CI [72.55-96.7%]) with an overall specificity of 91.6% (95% CI [86.9-95.0%]). The top three organisms detected were *Staphylococcus aureus* (44.7%), *Pseudomonas aeruginosa* (19.1%) and *Haemophilus influenzae* with (14.9%). The sensitivity and specificity were respectively 82.4% (95%CI [56.6% to 96.2%]) and 98.2% (95%CI [95.4% to 99.5%]) for *S. aureus*, 100% (95%CI [54.1% to 100%]) and 98.7% (95%CI [96.2% to 99.7%]) for *P. aeruginosa* and 100% (95%CI [15.81% to 100%]) and 97.9% (95%CI [95.06% to 99.3%]) for *H. influenzae*. 21/43 patients had concordant results with culture, 22 were positive by the CU LRT only. 18/43 patients never received appropriate treatment. Of interest, there were no apparent harm to patients.

Conclusion: The Curetis Unyvero system is a simple to use platform that allows rapid and reliable detection of common LRTI pathogens in respiratory specimens. More studies are necessary to better understand the clinical impact of this assay for the diagnosis of LTRI.