Curetis Unyvero™ - a new solution for the rapid detection of bacteria and antibiotic resistances

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Introduction
Pneumonia is a severe, life-threatening, predominantly bacterial infection of the lower respiratory tract. It is a fast progressing disease with high mortality rates and treatment costs. Here we describe a new solution for the rapid detection of pathogens causing pneumonia in hospitalized patients.

Materials and Methods
The Curetis Unyvero™ instrument platform in combination with the pneumonia cartridge detects 16 bacteria, 22 antibiotic resistance markers and one fungus which are responsible for approximately 80% of severe non-viral pneumonia. Included pathogens are either common, need a complicated treatment or are not addressed by current guidelines. The resistance markers cover frequent resistance genes highly relevant for antibiotic therapy decision. The Unyvero™ solution is fully automated: the whole process is software controlled and includes sample preparation of native patient samples, DNA isolation and purification, end-point multiplex PCR, detection of amplified DNA fragments by hybridization and result interpretation and presentation. The sample preparation, used to liquefy patient samples to enable DNA isolation, can handle diverse, clinically relevant respiratory sample types like broncho alveolar lavage (BAL), tracheal aspirate, protected brush and even mucous sample types like sputum. The direct use of native patient samples together with the simultaneous detection of pathogens and resistance markers offers significant time savings, resulting in 4 hours for the Unyvero™ results compared to 2-3 days for classical clinical microbiology.

Results
A sample set consisting of 48 fresh or frozen native patient samples of different sample types was tested with the Unyvero™ solution compared against standard clinical microbiology, showing an excellent concordance with positive microbiology results. Microbiology positive pathogen findings can be reproduced by the Unyvero™ solution and phenotypic resistance can be predicted by the system's genotypic markers. In addition to these correlating results, some species like *Streptococcus pneumoniae* or *Stenotrophomonas maltophilia* showed non-correlating results, characterized by a significantly lower than average signal intensity. These species are suspected to be part of the respiratory flora. This aside, strains like *Pseudomonas aeruginosa*, which are not part of a normal respiratory flora and important for therapy decision were also additionally detected in some cases. All bacteria lacking a positive microbiology were independently confirmed by bidirectional sequencing.

Conclusion
The Unyvero™ system is able to detect pathogens and resistance markers in respiratory samples concordant with standard clinical microbiology. Additionally detected pathogens are either part of the sample specific flora or were confirmed to be present and have been missed by traditional microbiology.