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# A Clinical Evaluation of the Curetis Unyvero P50 Pneumonia Application for Diagnosis of Hospital-acquired and Ventilator-associated Pneumonia

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## Introduction & Aim

Lower respiratory tract infections (LRTIs) are a major global cause of morbidity and mortality. These infections can be caused by a range of aetiological agents, including bacteria, fungi and viruses. Traditional microbiological diagnosis of such infections can be slow and insensitive. In the meantime patients are normally treated with empirical antibiotics, which are increasingly compromised by antimicrobial resistance. Improvements to diagnosis of such infections are urgently needed.

The Curetis AG Unyvero P50 pneumonia application is a 'sample-in, answer-out' test designed for the microbiological diagnosis of lower respiratory tract infections. The PCR based test identifies 17 pathogens and 22 antimicrobial resistance markers in approximately 5h, with minimal operator time needed. The aim of this study was to evaluate the performance of the test using prospective samples from patients with suspected hospital acquired pneumonia (HAP) or ventilator-associated pneumonia (VAP).

## Results

65 specimens were collected, comprising of 36 sputa, 27 endotracheal aspirates and 2 bronchoalveolar lavages. Routine microbiology identified ≥1 significant pathogen in 30 samples. 31 were deemed to contain normal respiratory flora only and 4 produced no growth. The P50 test identified the same pathogen as routine microbiology in 27/30 of these specimens. The missed organisms were 2 *H. influenzae* isolates *and 1 E. faecalis*. The latter is not a target of the P50 test. In 11 specimens, additional species were also identified by the P50 pneumonia test. In the 21/35 specimens where standard culture identified normal flora or no growth, the P50 test found at least one pathogenic organism. (Figure 1 and Table 1).

In specimens where significant pathogens were cultured, results for detection of ESBLs, AmpCs, carbapenemases and *mecA* were concordant in 22/30 samples (Table 2). The P50 test was unable to detect 5 AmpC-producing Enterobacteriaceae, and 3 OXA-23 carbapenemase producing *A. baumannii,*. The test did however detect one additional MRSA which had been missed by routine methods. OXA-23 is not a target of the P50 test. Among the AmpC producers, 4/5 were negative with the Check-Points CT103XL test, suggesting they had overexpressed chromosomal AmpC enzymes, which would be difficult to detect with molecular methods.

## Methods

Anonymised surplus respiratory samples were collected from adult in-patients with suspected HAP or VAP at two large hospitals in London (Royal Free Hospital and University College London Hospital) between December 2014 and March 2015. Duplicate samples were excluded.

Fresh samples (< 48h old) were processed with the P50 test as per manufacturer's instructions. Results were compared to those obtained by routine methods comprising culture, MALDI-TOF identification and antimicrobial susceptibility testing with the BD Phoenix system. Where appropriate, standard tests were supplemented by the Check-Points CT103XL assay for detection of ESBL, AmpC and carbapenemase genes.

| Target Organism | No. of Positives by Routine Culture | No. of Positives by Curetis AG Unyvero P50 test |
|---|---|---|
| *A. baumannii* | 3 | 8 |
| *Enterobacter spp.* | 2 | 5 |
| *E. coli* | 1 | 3 |
| *H. influenzae* | 5 | 6 |
| *K. pneumoniae* | 0 | 6 |
| *M. catarrhalis* | 1 | 5 |
| *M. morganii* | 0 | 1 |
| *Proteus spp.* | 1 | 4 |
| *P. aeruginosa* | 10 | 13 |
| *S. marcescens* | 3 | 5 |
| *S. aureus* | 2 | 5 |
| *S. maltophilia* | 7 | 25 |
| *E. faecalis* | 1 | Not a target |

**Table 1.** Frequency of organisms detected by routine microbiology and the Curetis AG Unyvero P50 test

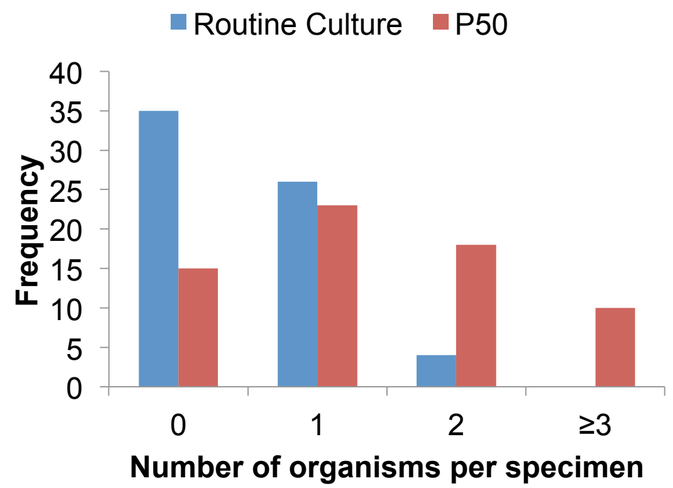


**Figure 1.** Number of organisms detected per specimen by routine microbiology and the Curetis AG Unyvero P50 test

| Category | Routine Micro (confirmed by Checkpoints) | Unyvero P50 |
|---|---|---|
| Fully Susceptible (or no relevant resistance) | 21 | 28 |
| ESBL/AmpC producer | 5 | 1 |
| Carbapenemase producer | 3 | 0 |
| MRSA | 1 | 3 |

**Table 2.** Number of resistance mechanisms detected by routine microbiology versus Curetis AG Unyvero P50 test

## Conclusions

The Curetis P50 pneumonia test displayed very good sensitivity (90% overall sensitivity) and is a useful tool in the microbiological diagnosis of HAP and VAP. As can be expected from a diagnostic test based on molecular methods from non-sterile samples, the P50 pneumonia test had the tendency to identify a greater number of potential pathogens than routine microbiology.