



Comparison of the Curetis Unyvero® Lower Respiratory Panel and Conventional Cultures in the Identification of Pneumonia Pathogens

Ji H. Shin¹ and David T. Pride^{1,2}

¹Department of Pathology, ²Department of Medicine, University of California, San Diego, La Jolla, CA, USA.

BACKGROUND

We compared the performance of the Curetis Unyvero Lower Respiratory Tract (LRT) Panel nucleic acid detection test with standard of care respiratory cultures on 200 total specimens in patients with suspected pneumonia. These specimens included sputum aspirates (induced or expectorated), tracheal aspirates (TA), and bronchoalveolar lavages (BAL) in patients from intensive care units, and various other hospital inpatient locations.

METHODS

Lower respiratory specimens (n=200; 47% sputum, 28% tracheal aspirates, and 25% BAL) were collected from hospitalized patients and tested by standard of care cultivation methods and the Curetis Lower Respiratory panel nucleic acid detection test. The majority of the specimens tested were from individuals ages 61 to 70 years old. Specimens were first inoculated aerobically at 35-37 °C for up to 48 hours on blood, chocolate, MacConkey, and CNA agar plates. Colonies representing pathogens were then identified using Maldi-tof. Remnant specimens were aliquoted for testing on the Curetis LRT panel. A sample was categorized as true positive (TP) if positive by culture methods for the same pathogen(s).

TURNAROUND TIMES

Assay	Sample Capacity	Mean Turnaround
Curetis Unyvero LRT	4	5.2 hours
Respiratory Culture	N/A	2.8 days



The Curetis Unyvero System used in this study has a sample loading capacity of up to 4 specimens per run.

The Unyvero LRT Panel reduced turnaround times from 2.8 days to 5.2 hours for results.

Equipment and reagents were supported by Curetis USA, Inc.

RESULTS

Figure 1. Specimens by location.

Most of the specimens were from standard inpatient floors, with substantial numbers from the intensive care units (ICUs).

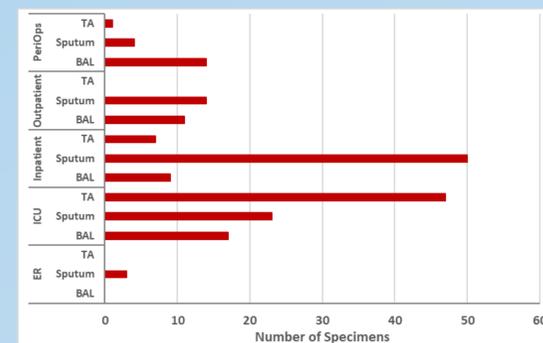


Figure 2. Unyvero LRT sensitivity and specificity compared to conventional culture.

Overall sensitivity and specificity compared to culture were 92% and 98%, respectively; however, many LRT positives not detected by culture could represent true positives.

All (n=200)	TP	FP	TN	FN	Sensitivity	Specificity
<i>Acinetobacter</i> spp.	2	3	195	0	100%	98%
<i>Chlamydia pneumoniae</i>	0	0	200	0	NA	100%
<i>Citrobacter freundii</i>	0	0	200	0	NA	100%
<i>Enterobacter cloacae</i> complex	7	3	190	0	100%	98%
<i>Escherichia coli</i>	24	6	169	1	96%	97%
<i>Haemophilus influenzae</i>	15	8	176	1	94%	96%
<i>Klebsiella oxytoca</i>	2	3	195	0	100%	98%
<i>Klebsiella pneumoniae</i>	11	6	182	1	92%	97%
<i>Klebsiella variscala</i>	0	0	200	0	NA	100%
<i>Legionella pneumophila</i>	0	1	199	0	NA	100%
<i>Moraxella catarrhalis</i>	3	6	191	0	100%	97%
<i>Morganella morganii</i>	2	0	198	0	100%	100%
<i>Mycoplasma pneumoniae</i>	0	0	200	0	NA	100%
<i>Proteus</i> spp.	7	3	190	0	100%	98%
<i>Pseudomonas aeruginosa</i>	32	3	162	3	91%	98%
<i>Serratia marcescens</i>	11	4	183	2	85%	98%
<i>Staphylococcus aureus</i>	40	6	148	6	87%	96%
<i>Stenotrophomonas maltophilia</i>	15	15	170	0	100%	92%
<i>Streptococcus pneumoniae</i>	3	2	194	1	75%	99%
Overall	174	69	3542	15	92%	98%

Figure 3. Number of pathogens positive by Unyvero LRT Panel compared to culture in the different sample types.

Substantial numbers of pathogens were identified using each test, with overall similar numbers of pathogens identified by each assay.

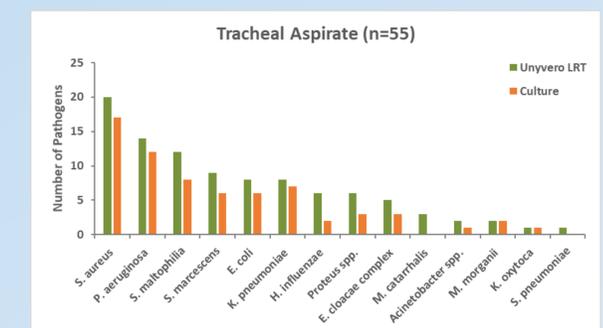


Figure 4. Concordance between Unyvero LRT pathogen detection and culture results.

Both culture and LRT identified 174 (67%) pathogens (complete concordance of panel organisms). LRT detected 69 (27%) additional positive pathogens that were missed by culture, and culture detected 15 (6%) additional positive pathogens that were undetected by LRT.

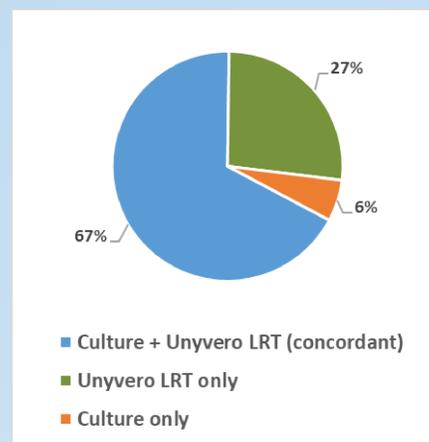
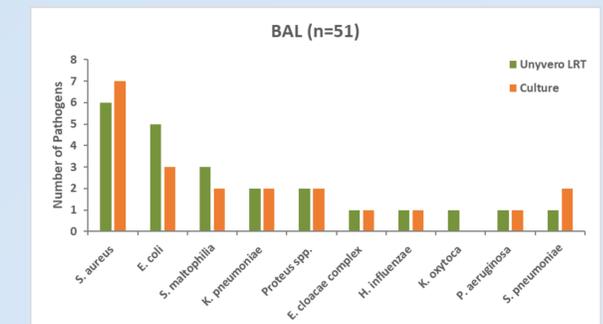
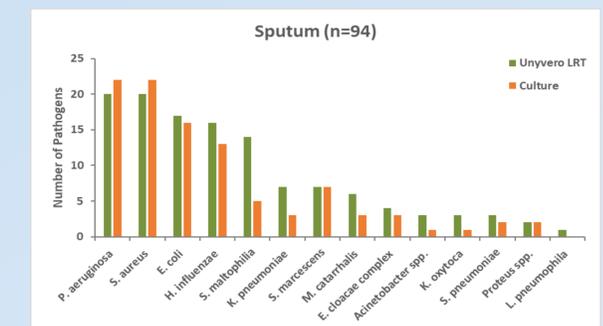
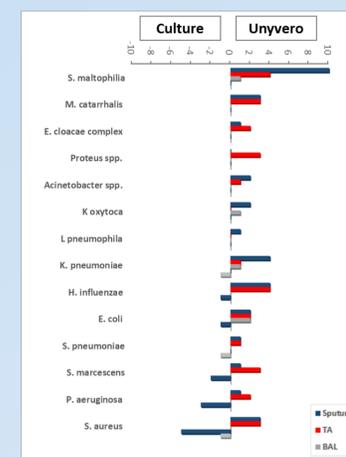


Figure 5. Discrepancies in the Unyvero LRT compared to culture.

Significantly more pathogens were identified by the LRT panel compared to culture, including *S. maltophilia*, *K. pneumoniae*, *H. influenzae*, *M. catarrhalis*, *Proteus* spp., *E. coli*, *E. cloacae*, and *Acinetobacter* spp. Importantly, LRT detected *Legionella*.



CONCLUSIONS

- The Curetis Unyvero LRT Panel demonstrated comparable clinical sensitivity and specificity when compared to conventional culture.
- We identified 69 additional pathogens using the LRT panel, including *Legionella* and fastidious organisms such as *H. influenzae* and *M. catarrhalis*.
- The additional pathogens identified by the LRT panel were detected in bronchoalveolar lavages, sputum aspirates and endotracheal aspirates, suggesting that they are present across various lower respiratory specimens obtained from patients suspected of lower respiratory infections with different levels of acuity.
- There were only a few specimens (6%) where additional pathogens were identified in culture that were not found using the LRT panel. Many of these pathogens were present in small quantities (e.g. one colony, scant, light) that fell below the defined cut-off of the LRT panel.
- Additional studies will aid in understanding the clinical impact of the additional pathogens identified by the LRT panel in patients with suspected lower respiratory infections.