

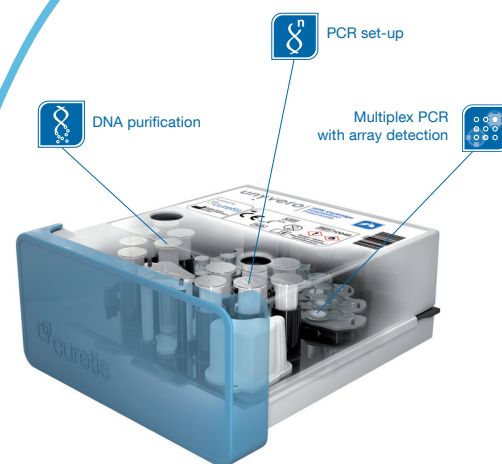
unyvero

Unyvero's sample-to-answer platform provides rapid results for severe infectious diseases in hospitalized patients

Powerful multiplex PCR technology combined with the broadest range of microorganism and resistance targets sets the Unyvero system apart.

The Unyvero system consists of:

- **Lysator** to lyse and process a variety of native samples
- **Cockpit** to manage testing process, display, store, and transmit results
- **Analyzer** to perform DNA testing with random-access, multiplex PCR



A single test handles one patient sample, analyzes 40 DNA analytes and delivers reliable results within just 4-5 hours



Unyvero is designed to expand with your growing needs

Applications for severe infections:

- Blood Culture – BCU
- Hospitalized Pneumonia – HPN
- Intra-Abdominal Infection – IAI
- Implant and Tissue Infection – ITI
- Urinary Tract Infection – UTI



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Caution – Investigational Device. Limited by Federal US Law to investigational Use. Not available for Sale in the United States.



Unyvero L4 Lysator



Unyvero C8 Cockpit



Unyvero A50 Analyzer

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# Hospitalized Pneumonia

Fast & Simple Syndromic Testing for Severe Infections - Improving Patient Outcomes

Antibiotic resistance threatens the effective treatment of pneumonia<sup>1</sup>

- Nosocomial pneumonia is among the most difficult complications to diagnose.<sup>2</sup>
- Traditional test results take too long, delaying effective treatment.
- Antimicrobial resistance makes the choice of initial antibiotics a major challenge.<sup>3</sup>
- Empiric broad spectrum antibiotics may not provide optimal coverage and exacerbate resistance.<sup>3</sup>

Lower respiratory infections have a mortality rate of over 30% and cost billions.<sup>4</sup>

- WHO report confirms the serious situation of antibiotic resistance worldwide.<sup>5</sup>
- Mortality and costs are expected to rise with increasing antibiotic resistance.

<sup>1</sup> WHO Antimicrobial Resistance Fact Sheet 2018. <sup>2</sup> Magill SS et al. Multistate Point-Prevalence Survey of Health Care-Associated Infections. N Engl J Med. 2014;370(13):1198-208. <sup>3</sup> Kali AC et al. Management of Adults With Hospital-acquired and Ventilator-associated Pneumonia: 2016 Clinical Practice Guidelines by the Infectious Diseases Society of America and the American Thoracic Society. Clin Infect Dis. 2016;63(5):e61-e111. <sup>4</sup> O'Neill J. Review on Antimicrobial resistance: tackling a crisis for the health and wealth of nations. Rev Antimicrob Resist. 2014. <sup>5</sup> Global antimicrobial resistance surveillance system (GLASS) report: early implementation 2016-2017. Geneva: World Health Organization; 2017.

Faster detection enables earlier optimization of therapy

The Unyvero HPN Application simultaneously identifies a large panel of bacteria, fungi and antibiotic resistance genes.

Unyvero HPN detects the most dangerous and highly resistant microorganisms defined by WHO:

- Pathogens causing severe forms of pneumonia, e.g. *Pseudomonas aeruginosa*
- Pathogens carrying antibiotic resistance e.g. *Klebsiella pneumoniae* and *Acinetobacter baumannii* complex
- Infections with multidrug-resistant bacteria, which may not be targeted by empirical treatment

Clinical evidence demonstrates the potential benefits provided by the Unyvero solution

Study 1

University College London, Royal Free Campus, London, UK. Comparing Unyvero HPN to traditional culture.

Number of samples

85 respiratory samples (sputum, tracheal aspirate, bronchoalveolar lavage).

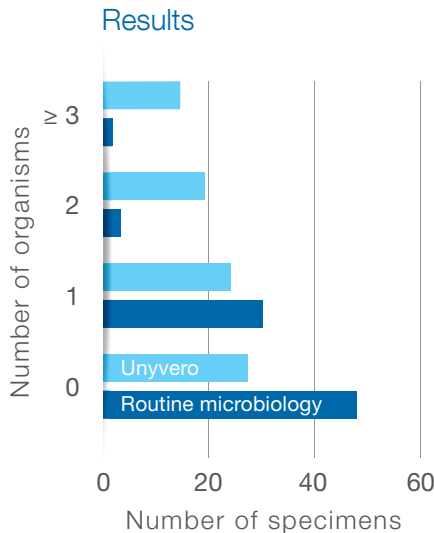
Eligibility

Hospitalized patients with pneumonia.



4-5 Turnaround time

Mean turnaround time from specimens received to results from the routine laboratory was 53 h (range 21 h-166 h).



94.9% Specificity

88.8% Sensitivity

Unyvero identified more potential pathogens per specimen than routine culture (1.34 vs. 0.47 per specimen)

Ozongwu et al., Biomed Detect Quantif. 2017;13:1-6. Investigational device. Not available in the US.

Unyvero Hospitalized Pneumonia (HPN) Cartridge

| Gram-positive bacteria                                          | Enterobacteriales                                                                                                                                                                                                                                                                                                          | Non-fermenting bacteria                                                                                                                                                         | Others / Fungi                                                                                                                                                | Resistance                                                                                                                        | Gene                                                                                                                                                                                                                                                                  |
|-----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Staphylococcus aureus</i><br><i>Streptococcus pneumoniae</i> | <i>Citrobacter freundii</i><br><i>Escherichia coli</i><br><i>Enterobacter cloacae</i> complex<br><i>Klebsiella aerogenes</i> (E. aerogenes)<br><i>Proteus</i> spp.<br><i>Klebsiella pneumoniae</i><br><i>Klebsiella oxytoca</i><br><i>Klebsiella variicola</i><br><i>Serratia marcescens</i><br><i>Morganella morganii</i> | <i>Moraxella catarrhalis</i><br><i>Pseudomonas aeruginosa</i><br><i>Acinetobacter baumannii</i> complex<br><i>Stenotrophomonas maltophilia</i><br><i>Legionella pneumophila</i> | <i>Pneumocystis jirovecii</i><br><i>Haemophilus influenzae</i><br><i>Mycoplasma pneumoniae</i><br><i>Chlamydia</i> ( <i>Chlamydomydia</i> ) <i>pneumoniae</i> | Macrolide/Lincosamide<br>Oxacillin<br>Penicillin<br>3rd generation Cephalosporins<br>Carbapenem<br>Sulfonamide<br>Fluoroquinolone | <i>ermB</i><br><i>mecA</i><br><i>mecC</i><br><i>tem</i><br><i>shv</i><br><i>ctx-M</i><br><i>kpc</i><br><i>imp</i><br><i>ndm</i><br><i>oxa-23</i><br><i>oxa-24/40</i><br><i>oxa-48</i><br><i>oxa-58</i><br><i>vim</i><br><i>sul1</i><br><i>gyrA83</i><br><i>gyrA87</i> |

Study 2

Multicenter US clinical trial at nine major hospitals.

Number of samples

>2000 tracheal aspirate and lavage (BAL/miniBAL) specimens.

Eligibility

Hospitalized adults with suspicion of lower respiratory tract infection.

Atypical pathogens: High clinical significance, difficult to culture

- Not routinely ordered or tested.
- Not covered by empiric therapy for hospitalized pneumonia.
- Unsuspected cases were detected using Unyvero including 5 confirmed cases of *Mycoplasma pneumoniae*.

Negative cultures

- Unyvero results are not affected by prior antibiotic treatment.

Conclusion

Unyvero expands the diagnostic capability of pneumonia through rapid microorganism identification and simultaneous detection of associated resistance markers.

Agarwal et al., ASM Microbe 2017. US clinical trial. Investigational device. Not available in EMEA. PPA: positive percent agreement; NPA: negative percent agreement



Easy Workflow



Multiple Sample Types



24/7 Results