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 microorganisms 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

Unyvero L4 Lysator
Unyvero C8 Cockpit
Unyvero A50 Analyzer

Hospitalized Pneumonia

Fast & Simple Syndromic Testing for Severe Infections - Improving Patient Outcomes
Antibiotic resistance threatens the effective treatment of pneumonia1

- Nosocomial pneumonia is among the most difficult complications to diagnose2
- Traditional test results may take too long, delaying effective treatment
- Antimicrobial resistance makes the choice of initial antibiotics a major challenge3
- Broad-spectrum antibiotics may not provide optimal coverage and exacerbate resistance2

Traditional test results take too long, delaying effective treatment.

Nosocomial pneumonia is among the most difficult complications to diagnose.

Faster detection enables earlier optimization of therapy

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

1 WHO Antimicrobial Resistance Fact Sheet 2018
4 O’Neill J.

Clinical evidence demonstrates the potential benefits provided by the Unyvero solution

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. Eibetella pneumoniae and Acinetobacter baumannii complex
- Infections with multidrug-resistant bacteria, which may not be targeted by empirical treatment

Unyvero expands the diagnostic capability of pneumonia through rapid detection of potential pathogens per specimen, thus shortening turnaround time and reducing costs.

WHO report confirms the serious situation of antibiotic resistance worldwide.

Mortality and costs are expected to rise with increasing antibiotic resistance.

Mortality and costs are expected to rise with increasing antibiotic resistance.

Lower respiratory infections have a mortality rate of over 30% and cost billions.

WHO report confirms the serious situation of antibiotic resistance worldwide.

Mortality and costs are expected to rise with increasing antibiotic resistance.

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

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

Study 1
University College London, Royal Free Campus, London, UK.
Comparing Unyvero HPN to traditional culture.

Study 2
Multicenter US clinical trial at nine major hospitals.

Study 1

| Number of samples | 65 respiratory samples | Routine microbiology | Unyvero | Unyvero results are not affected by prior antibiotic treatment.
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive cultures</td>
<td>19% (13/65)</td>
<td>15% (10/65)</td>
<td>24% (16/65)</td>
</tr>
<tr>
<td>Overall PPA</td>
<td>89.9%</td>
<td>91.4%</td>
<td>94.9%</td>
</tr>
<tr>
<td>Overall specificity</td>
<td>94.9%</td>
<td>88.8%</td>
<td>99.9%</td>
</tr>
<tr>
<td>Number of samples</td>
<td>1343 (HPN)</td>
<td>125 (routine)</td>
<td>125 (HPN)</td>
</tr>
<tr>
<td>Positive cultures</td>
<td>48% (647)</td>
<td>9% (11)</td>
<td>9% (11)</td>
</tr>
<tr>
<td>Overall PPA</td>
<td>90.3%</td>
<td>94.5%</td>
<td>95.2%</td>
</tr>
<tr>
<td>Overall specificity</td>
<td>94.9%</td>
<td>96.7%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Study 2

| Number of samples | >2000 tracheal aspirate and lavage (BAL/miniBAL) specimens | Routine microbiology | Unyvero | Transferable Resistance markers
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive cultures</td>
<td>16% (338)</td>
<td>10% (23)</td>
<td>30% (67)</td>
<td>Overall NPA: 99.3%</td>
</tr>
<tr>
<td>Overall PPA</td>
<td>90.5%</td>
<td>94.9%</td>
<td>99.5%</td>
<td></td>
</tr>
<tr>
<td>Overall specificity</td>
<td>92.5%</td>
<td>96.8%</td>
<td>99.5%</td>
<td></td>
</tr>
</tbody>
</table>

Results

- Overall PPA: positive percent agreement; NPA: negative percent agreement
- Overall specificity: positive percent agreement

Conclusion

Unyvero significantly improves the diagnostic capability of pneumonia diagnosis, providing instant results and sufficient antibiotic resistance information.

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

Unyvero Hospitalized Pneumonia (HPN) Cartridge

- Easy Workflow
- Multiple Sample Types
- 24/7 Results

Easy Workflow

Multiple Sample Types

24/7 Results

Gram-positive bacteria
- Staphylococcus aureus
- Streptococcus pneumoniae

Gram-negative bacteria
- Enterobacteriaceae
- Acinetobacter baumannii complex
- Pseudomonas aeruginosa
- Klebsiella pneumoniae
- Enterobacter spp.
- Eibetella pneumoniae
- Klebsiella oxytoca
- Morganella morganii
- Enterococcus spp.
- Citrobacter freundii
- Serratia marcescens
- Haemophilus influenzae
- Legionella pneumophila
- Pneumocystis jirovecii
- Mycoplasma pneumoniae
- Chlamydophila pneumoniae

Others / Fungi
- Candida spp.
- Aspergillus spp.

Transferable Resistance markers
- Oxacillin resistance
- Oxazolidinone resistance
- Fluoroquinolone resistance
- Sulfonamide resistance
- Carbapenem resistance
- Ceftazidime resistance
- Piperacillin resistance
- Gentamicin resistance
- Vancomycin resistance
- Tobramycin resistance
- Teicoplanin resistance
- Linezolid resistance

Agarwal et al., ASM Microbe 2017.