Performance characteristics of the Unyvero™ system in the routine clinical microbiology lab

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Routine diagnostic microbiology
Molecular biology in routine diagnostic microbiology
community-, hospital-, and ventilator-acquired respiratory tract infections

Curetis - Unyvero

Universal Components
- 1- Unyvero A50 Analyzer
- 2- Unyvero C8 Cockpit
- 3- Unyvero L4 Lysator
- 4- Unyvero Cartridge
Materials and Methods

- Unyvero in parallel to culture
- Routine diagnostic setting
- No selection of clinical samples
  - 41 respiratory tract samples
    - Sputum (n=13)
    - Tracheal secretion (n=23)
    - Bronchic secretion (n=3)
    - Nasopharyngeal washes (n=2)
Pathogen detection in respiratory specimen

**Culture**
- 13 no pathogen
- 19 1 pathogen
- 9 >1 pathogen

**Unyvero**
- 27 no pathogen
- 11 1 pathogen
- 3 >1 pathogen
Comparison between culture and Unyvero

<table>
<thead>
<tr>
<th></th>
<th>number</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pathogens in both systems</td>
<td>3</td>
</tr>
<tr>
<td>Identical pathogens</td>
<td>6</td>
</tr>
<tr>
<td>Additional pathogens by Unyvero</td>
<td>23</td>
</tr>
<tr>
<td>Additional pathogens by culture</td>
<td>1</td>
</tr>
<tr>
<td>Identical pathogens + different pathogens</td>
<td>3</td>
</tr>
<tr>
<td>Total different pathogens</td>
<td>4</td>
</tr>
</tbody>
</table>

- **no pathogens**: 8%
- **identical pathogens**: 10%
- **additional pathogens by Unyvero**: 7%
- **additional pathogen by culture**: 3%
- **identical pathogens + different pathogens**: 15%
- **totally different pathogens**: 57%
### Pathogens additional detected

<table>
<thead>
<tr>
<th></th>
<th>culture</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No pathogen</td>
</tr>
<tr>
<td><strong>Unyvero</strong></td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>6</td>
</tr>
<tr>
<td><strong>total</strong></td>
<td>12</td>
</tr>
</tbody>
</table>

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### Relevance of additional detected pathogens

<table>
<thead>
<tr>
<th>culture</th>
<th>Unyvero</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pathogen</td>
<td><em>Streptococcus pneumoniae</em> (+)</td>
</tr>
<tr>
<td></td>
<td><em>Staphylococcus aureus</em> (+)</td>
</tr>
<tr>
<td></td>
<td><em>Streptococcus pneumoniae</em> (+++)</td>
</tr>
<tr>
<td></td>
<td><em>Haemophilus influenzae</em> (+), <em>Streptococcus pneumoniae</em> (+)</td>
</tr>
<tr>
<td></td>
<td><em>Haemophilus influenzae</em> (++)</td>
</tr>
<tr>
<td></td>
<td><em>Streptococcus pneumoniae</em> (++)</td>
</tr>
<tr>
<td></td>
<td><em>Escherichia coli</em> (+)</td>
</tr>
<tr>
<td>Gram-negativ</td>
<td><em>Staphylococcus aureus</em> (+)</td>
</tr>
<tr>
<td></td>
<td><em>Streptococcus pneumoniae</em> (+++)</td>
</tr>
<tr>
<td>Gram-negativ / Gram-positive</td>
<td><em>Stenotrophomonas maltophilia</em></td>
</tr>
<tr>
<td>Gram-negativ / Gram-positive</td>
<td><em>Pneumocystis jirovecii / Legionella pneumophila</em></td>
</tr>
</tbody>
</table>
Resistance marker

- Panel design
  - based on treatment guidelines*
  - 22 genetic markers encoding for
    - macrolide-resistance
    - ß-lactam-resistance, including ESBL
    - carbapeneme-resistance
    - multi-drug-resistance
    - quinolone-resistance

Impact of resistance marker – prediction of therapy

Exclusion of ESBL
- *Klebsiella oxytoca*
- *Klebsiela pneumoniae*
- *Escherichia coli*

Exclusion of cotrimoxazole resistance
- *Pseudomonas aeruginosa*

Exclusion of MRSA

Exclusion of Macrolide/lincosamide resistance
- *S. aureus*

Prediction of chinolone resistance
- *P. aeruginosa*
- *Escherichia coli*

Awareness of antibiotic degrading enzymes from „physiological flora“
Summary / Conclusions

The Unyvero™ system

- detects all relevant pathogens
- detects pathogens which might be overlooked easily
- identifies the relevant pathogens approximately 2-3 days earlier as compared to culture
- provides the clinicians with the most important resistance patterns of the respective pathogens (and physiological flora)
- Is easily done by staff without experience in molecular techniques
- Needs only a minimum “on-hands-time”
- Can be operated the whole day (and night)
Thank you very much for your attention