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

Powerful multiplex PCR technology combined with the broadened 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 over 100 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
- Implant & Tissue Infection – ITI
- Intra-Abdominal Infection – IAI
- Urinary Tract Infection – UTI

Leading the way to improve patient outcomes.
Implant and tissue infections can be complex and time-consuming to diagnose.

- Treatment of patients with implant and tissue infection can only be optimized after the causative microorganism and its associated resistance are known.
- Each sample collected is analyzed through conventional microbiology. Some of them are cultured for more than 14 days.

In the UK, average cost of a knee revision for infection is estimated to be around £30,000.2

- Empiric broad spectrum antibiotics may not provide optimal coverage and can exacerbate resistance.3
- Biofilm formation can often develop on orthopedic implants and is difficult to diagnose with culture methods.4

Faster detection enables earlier optimization of therapy

The Unyvero ITI Application includes a broad spectrum of microorganisms and resistance genes.

Unyvero ITI can be used for the diagnosis of:
- Burn wound infections
- Cardiomyopathy-associated infections
- Deep skin and tissue infections
- Diabetic foot infections
- Orthopedic implant infections
- Surgical site infections

Clinical evidence demonstrates the benefits provided by the Unyvero solution

Study 1
Comparison between Unyvero ITI and conventional methods focusing on cost analysis. Hospital Clínic de Barcelona.

- Eligibility: Patients who underwent implant removal due to suspicion of infection.
- Study design: Comparison of removed implants (hip 46%, knee 42%, shoulder 12%).
- Cost analysis model based on antibiotic treatment (empiric and specific), hospital stay and Unyvero costs.

Conclusion: Unyvero ITI supports a rapid diagnosis of PJI when an infection is suspected. Its use is associated with a shorter hospital length of stay compared to standard culture methods allowing cost savings at hospital level.

**Clinical performance**
- Aseptic loosening (n=33): Concordance = 100%, Sensitivity = 100%, Specificity = 100%.
- Chronic PJI (n=4): Concordance = 100%, Sensitivity = 68.7%, Specificity = 100%.
- Acute PJI (n=4): Concordance = 100%, Sensitivity = 87.5%, Specificity = 100%.

Mean time for conventional culture results was 6.4 days (range 48-552 hours) whereas Unyvero results were available in 3 hours.

Unyvero Implant & Tissue Infection (ITI) Cartridge

<table>
<thead>
<tr>
<th>Gram-positive</th>
<th>Enterococci/ streptococci</th>
<th>Coagulase negative</th>
<th>Staphylococci</th>
<th>Corynebacterium</th>
<th>Anaerobic bacteria</th>
<th>Deep skin and tissue infections</th>
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<td>Non-fermenting</td>
<td>Enterobacteriaceae</td>
<td>Citrobacter</td>
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<td>Resistance Gene</td>
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**Gr Herbs, Anti-Microbial Resistance, and Gene**

- **Tetracycline**
  - Resistance against tetracycline.
  - Tetracycline resistance.

**Accuracy**
88.3%

**Specificity**
100%

**Number of samples**
60 intra-operative joint aspirates.

**Study 2** Clinical evaluation of the ITI Application in patients suspected of prosthetic joint infection. Helios Endo Klinik Hamburg

- **Eligibility**: Patients > 18 years old undergoing hip or knee revision arthroplasty.
- **Study design**: Comparison of unrevised implants (n=10) vs Unyvero (n=14).
- **Cost analysis model based on antibiotic treatment (empiric and specific), hospital stay and Unyvero costs.

**Clinical performance**
- Aseptic loosening (n=33): Concordance = 100%, Sensitivity = 100%, Specificity = 100%.
- Chronic PJI (n=4): Concordance = 100%, Sensitivity = 68.7%, Specificity = 100%.
- Acute PJI (n=4): Concordance = 100%, Sensitivity = 87.5%, Specificity = 100%.

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