



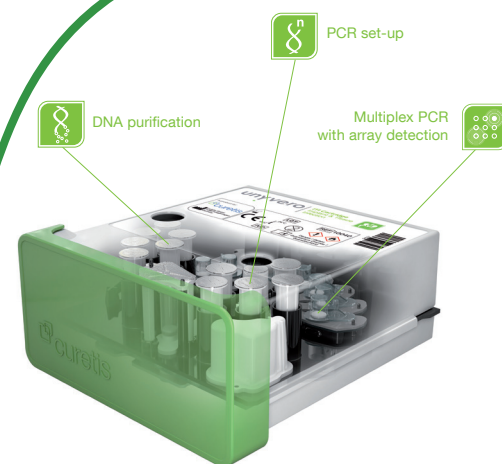
unyvero

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 over 100 DNA analytes and delivers reliable results within just 4-5 hours

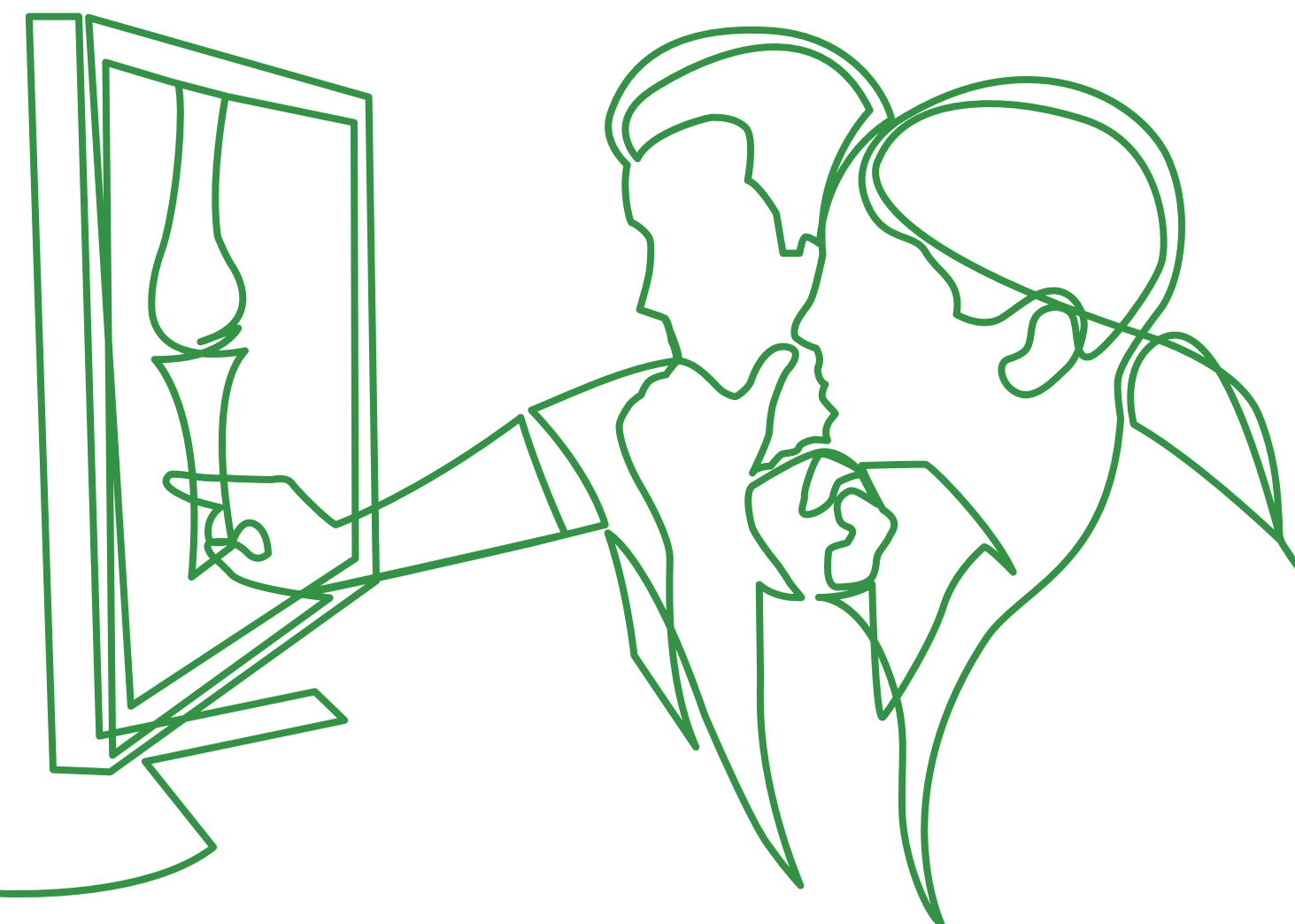
Unyvero is designed to expand with your growing needs

Applications for severe infections:

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

unyvero

curetis



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

Implant & Tissue Infection

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



Unyvero L4 Lysator

Unyvero C8 Cockpit

Unyvero A50 Analyzer

➤ 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 resistances are known.
- Each sample collected is analyzed through conventional microbiology. Some of them are cultured for more than 14 days.¹

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.

➤ 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
- Cardiology-associated infections
- Catheter-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

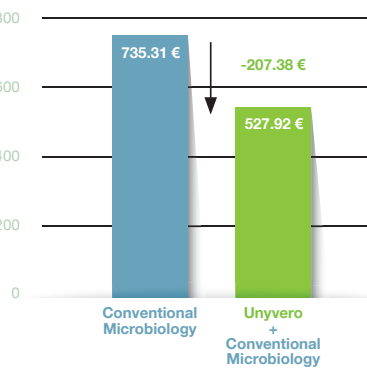
Patients who underwent implant removal due to suspicion of infection.

Study design:

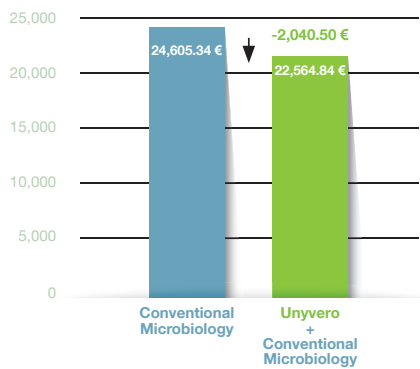
- Sonication of removed implants (hip 46%, knee 42%, shoulder 12%).
- Comparison of patient management cost between traditional microbiology (n=10) vs Unyvero (n=14).
- Cost analysis model based on anti-biotic treatment (empiric and specific), hospital stay and Unyvero costs.

Torres *et al.*, poster presented at European Congress of Clinical Microbiology (ECCMID) 2017.

Antibiotic treatment cost



Average cost per patient



Conclusion

Unyvero ITI supports a rapid diagnosis of PJI (prosthetic joint infection) 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.

Study 2

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

Number of samples

60 intra-operative joint aspirates.

Eligibility

Patients > 18 years old undergoing hip or knee revision arthroplasty.

Clinical performance

- Aseptic loosening (n=26): Concordance = 100%.
- Chronic PJI (n=26): Sensitivity = 76.9%, Specificity = 100%.
- Acute PJI (n=8): Sensitivity = 85.7%, Specificity = 100%.

Time to results

- Mean time for conventional culture results was 6.4 days (range 48-552 hours) whereas Unyvero results were available in 5 hours.



148 hours saved

Systemic Inflammatory Response Syndrome

- 2 patients with SIRS.
- Joint aspirate culture negative vs positive with Unyvero ITI (1 CoNS, 1 *E. cloacae*).
- ITI results later confirmed with tissue culture.

88.3% Accuracy

100% Specificity

Lausman *et al.*, 2017 J Bone Jt Infect 2(4): 175–183.

Unyvero Implant & Tissue Infection (ITI) Cartridge

Gram-positive bacteria	Enterobacterales	Non-fermenting bacteria	Corynebacteriaceae	Resistance	Gene
<i>Staphylococcus aureus</i> Coagulase negative staphylococci (CoNS) <i>Streptococcus</i> spp. <i>Streptococcus agalactiae</i> <i>Streptococcus pneumoniae</i> <i>Streptococcus pyogenes</i> / <i>dysgalactiae</i> <i>Granulicatella adiacens</i> <i>Abiotrophia defectiva</i> <i>Enterococcus</i> spp. <i>Enterococcus faecalis</i>	<i>Citrobacter freundii</i> / <i>koseri</i> <i>Escherichia coli</i> <i>Enterobacter cloacae</i> complex <i>Klebsiella aerogenes</i> (<i>E. aerogenes</i>) <i>Klebsiella pneumoniae</i> <i>Klebsiella oxytoca</i> <i>Klebsiella varicola</i> <i>Proteus</i> spp.	<i>Acinetobacter baumannii</i> complex <i>Pseudomonas aeruginosa</i>	<i>Corynebacterium</i> spp.	Macrolide/ Lincosamide Aminoglycoside Oxacillin Vancomycin 3rd generation Cephalosporins Carbapenem	<i>ermA</i> <i>ermC</i> <i>aac(6)/aph(2'')</i> <i>aacA4</i> <i>mecA</i> <i>mecC</i> <i>vanA</i> <i>vanB</i> <i>ctx-M</i> <i>kpc</i> <i>imp</i> <i>ndm</i> <i>oxa-23</i> <i>oxa-24/40</i> <i>oxa-48</i> <i>oxa-58</i> <i>vim</i>
		Anaerobic bacteria	Fungi		
		<i>Cutibacterium acnes</i> (<i>P. acnes</i>) <i>Finnegoldia magna</i> <i>Bacteroides fragilis</i> group	<i>Candida</i> spp. <i>Candida albicans</i> <i>Candida glabrata</i> <i>L.orientalis</i> (<i>C.krusei</i>) <i>Candida tropicalis</i>		



Easy Workflow



Multiple Sample Types



24/7 Results