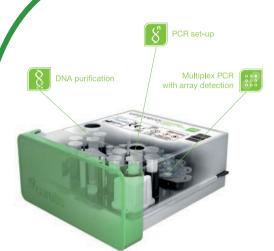
unyvero

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 L4 Lysator



Unyvero C8 Cockpit



Hovvero A50 Analyz



Applications for severe infections:

Blood Culture – BCU

unyvero

, [©]curetis

- Hospitalized Pneumonia HPN
- Intra-Abdominal Infection IAI
- Implant & Tissue Infection ITI
- Urinary Tract Infection UTI

The Unyvero System is distribuited on an exclusive basis by A.Menarini Diagnostics in the following countries: Benelux, France, Germany, Greece, Italy, Portugal, Spain, United Kingdom.

Distribuited by: A.Menarini Diagnostics S.r.I.
Legal Site: Via Sette Santi, 3 - 50131 Florence, Italy - Operative Site: Via Lungo L'Ema, 7 - 50012
Bagno a Ripoli (FI), Italy - Website: www.menarini.com

BENELUX - MENARINI BENELUX N.V./S.A: Division Diagnostics De Kleetlaan 3/1831 Machelen/Belgium Tel. 0032-2-721 49 30 - Fax 0032-2-721 50 49

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







Fast & Simple Syndromic Testing for Severe Infections - Improving 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.
- Biofilm formation can often develop on orthopedic implants and is difficult to diagnose with culture methods.
 - Bossard DA et al., Optimal Length of Cultivation Time for Isolation of Propionibacterium acnes in Suspected Bone and Joint Infections Is More than 7 Days. J Clin Microbiol. 2016;54(12):3043-3049.
- 2 Kallala RF et al., Financial analysis of revision knee surgery based on NHS tariffs and hospital costs: does it pay to provide a revision service? Bone Joint J.
- 3 WHO Antimicrobial Resistance. Global Report on Surveillance. 2014.
- 4 Torres C et al., ECCMID 2017.



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



Unyvero Implant & Tissue Infection (ITI) Cartridge

Gram-positive bacteria Staphylococcus aureus Coagulase negative staphylococci Streptococcus spp. Streptococcus agalactiae Streptococcus Streptococcus pyogenes dysgalactiae

Abiotrophia defectiva

Enterococcus spp.

Enterobacter cloacae complex Klebsiella aerogenes Klebsiella pneumoniae Klebsiella oxytoca Klebsiella variicola Proteus spp. Granulicatella adiacens Universal bacteria Detection of prokaryotic Enterococcus faecalis

genetic sequence

Enterobacteriaceae

Citrobacter freundii/koseri

Escherichia coli

Non-fermenting Corvnebacteriaceae bacteria Acinetobacter baumannii Corynebacterium spp. Pseudomonas aeruginosa

Anaerobic bacteria Cutibacterium acnes

P. acnes)

Finegoldia magna

Candida spp. Candida albicans Candida glabrata *Bacteroides fragilis* group . orientalis (C. krusei) Candida tropicalis

Fungi

Macrolide/ Lincosamide ermA ermC aac(6) Aminoglycoside *aph*(2´ aacA4 mecA Oxacillin mecC Vancomycin 3rd generation ctx-M Cephalosporins oxa-23 oxa-24/40 Carbapenem

oxa-48 oxa-58

Resistance Gene

Clinical evidence demonstrates the benefits provided by the Unyvero solution

Study ¹

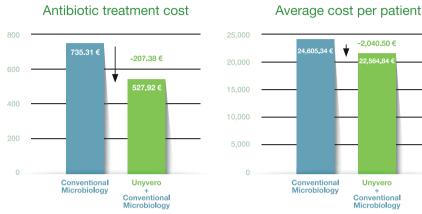
Comparison between Unyvero ITI and conventional methods focusing on cost-analysis. Hospital Clínic de Barcelona.

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 antibiotic treatment (empiric and specific), hospital stay and Unyvero costs.

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



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.

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.

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

88.3% Accuracy

100% Specificity

Lausmann et al., 2017 J Bone Jt Infect 2(4): 175-183.

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.

Systemic Inflammatory

2 patients with SIRS.

Response Syndrome

Joint aspirate culture negative vs positive with Unyvero ITI (1 CoNS, 1 E, cloacae),

ITI results later confirmed with tissue culture.





Sample Types

Sonication fluids, swabs, tissue, pus, aspirate/exudate, bone fragments, etc.

Multiple Sample Types



Results