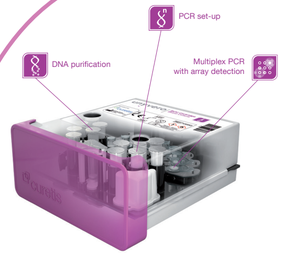
unyvero

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

Unyvero A50 Analyzer

Unyvero is designed to expand with your growing needs

Applications for severe infections:

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

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

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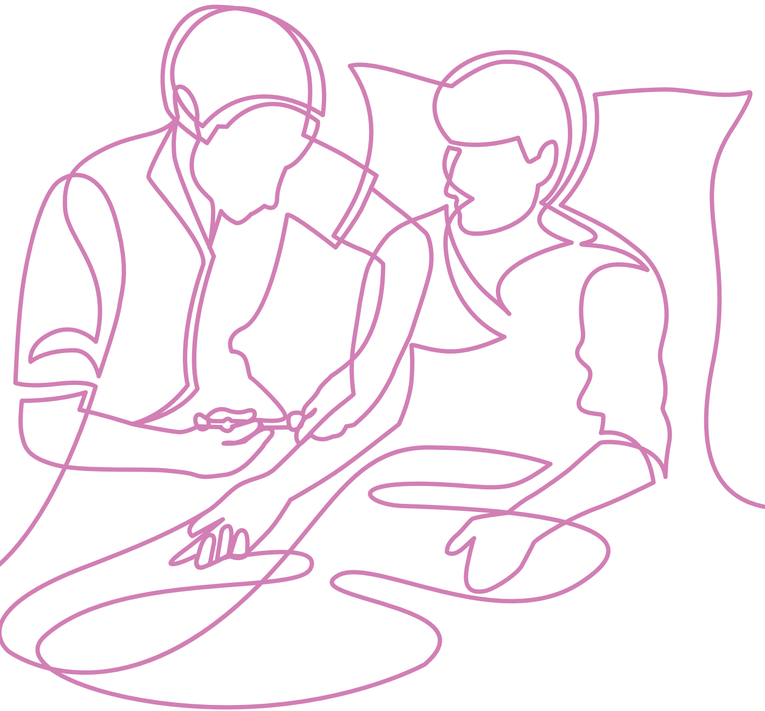


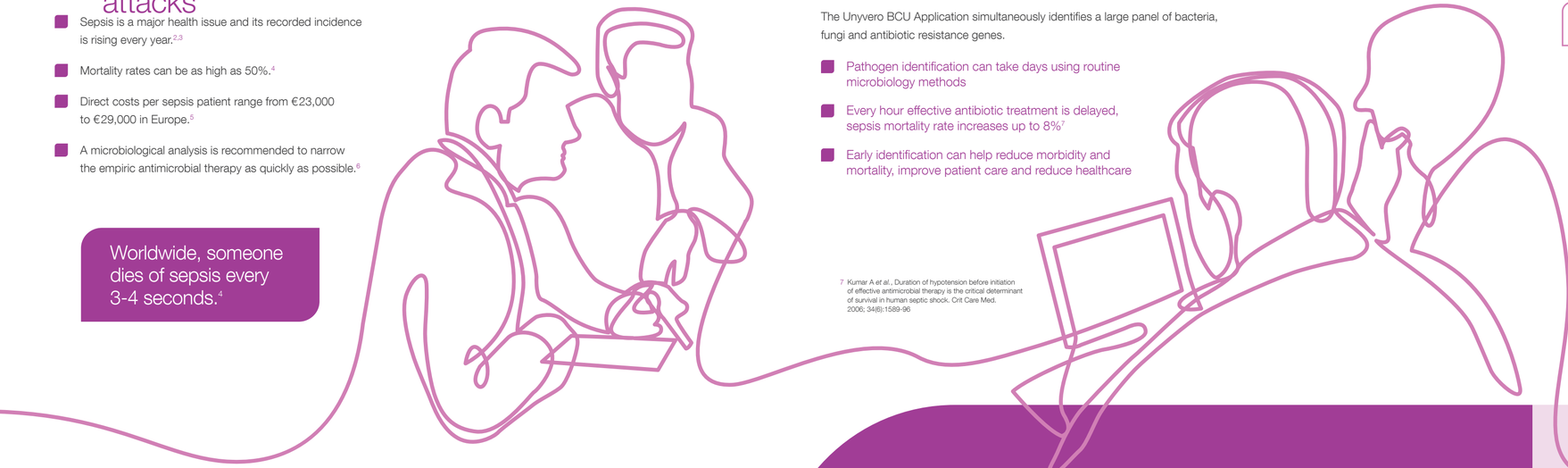
Blood Culture

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

In industrialized countries, sepsis is responsible for as many deaths as heart attacks[1]

- Sepsis is a major health issue and its recorded incidence is rising every year.[2,3]
- Mortality rates can be as high as 50%.[4]
- Direct costs per sepsis patient range from €23,000 to €29,000 in Europe.[5]
- A microbiological analysis is recommended to narrow the empiric antimicrobial therapy as quickly as possible.[6]

Worldwide, someone dies of sepsis every 3-4 seconds.[4]



1 Institut Pasteur, Disease Sheet -Sepsis, 2014.
2 Hotchkiss RS *et al.*, Sepsis and septic shock. Nat Rev Dis Primers. 2016; 2:16045.
3 Fleischmann C *et al.*, Assessment of Global Incidence and Mortality of Hospital-treated Sepsis. Current Estimates and Limitations. Am J Respir Crit Care Med. 2016; 193(3):259-72.
4 WSD Fact Sheet 2018 (www.world-sepsis-day.org).
5 Burchardi H and Schneider H. Economic aspects of severe sepsis: a review of intensive care unit costs, cost of illness and cost effectiveness of therapy. Pharmacoeconomics. 2004; 22(12):793-813.
6 Rhodes A. *et al.*, Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016. Intensive Care Med. 2017; 43:304–377.

Faster detection enables earlier optimization of therapy

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

- Pathogen identification can take days using routine microbiology methods
- Every hour effective antibiotic treatment is delayed, sepsis mortality rate increases up to 8%[7]
- Early identification can help reduce morbidity and mortality, improve patient care and reduce healthcare

7 Kumar A *et al.*, Duration of hypotension before initiation of effective antimicrobial therapy is the critical determinant of survival in human septic shock. Crit Care Med. 2006; 34(6):1589-96

Unyvero Blood Culture (BCU) Cartridge

Gram-positive bacteria	Enterobacterales	Non-fermenting bacteria	Fungi
Staphylococcus aureus *Coagulase negative staphylococci* *Streptococcus spp.* *Streptococcus agalactiae* *Streptococcus pneumoniae* *Streptococcus pyogenes/ dysgalactiae* *Enterococcus spp.* *Enterococcus faecalis* *Listeria monocytogenes*	*Citrobacter freundii/koseri* *Escherichia coli* *Enterobacter cloacae complex* *Klebsiella aerogenes (E. aerogenes)* *Klebsiella oxytoca* *Klebsiella pneumoniae* *Klebsiella variicola* *Proteus* spp. *Serratia marcescens*	*Acinetobacter baumannii complex* *Pseudomonas aeruginosa* *Stenotrophomonas maltophilia*	*Aspergillus* spp. *Candida* spp. *Candida albicans* *Candida dubliniensis* *Candida glabrata* *I. orientalis (C. krusei)* *Candida parapsilosis* *Candida tropicalis*
Corynebacteriaceae		Anaerobic bacteria	
Corynebacterium spp.		*Cutibacterium acnes (P. acnes)*	
		Other Gram-negative bacteria	*Mycobacteriaceae*
		Haemophilus influenzae *Neisseria meningitidis*	*Mycobacterium* spp.

Resistance	Gene
Aminoglycoside	*aac(6')/aph(2'')* *aacA4*
Macrolide/ Lincosamide	*ermA*
Oxacillin	*mecA* *mecC*
Vancomycin	*vanA* *vanB*
3rd generation Cephalosporins	*ctx-M*
Carbapenem	*kpc* *imp* *ndm* *oxa-23* *oxa-24/40* *oxa-48* *oxa-58* *vim*

Easy Workflow

Multiple Sample Types

24/7 Results

Clinical evidence demonstrates the benefits provided by the Unyvero solution

Study 1

Multicenter performance evaluation.
Clinical laboratories from HDZ Bad Oeynhausen, UKE Hamburg and OWS Vienna.

Number of samples

178 positive blood cultures.

96.8% Sensitivity

99.8% Specificity

Value of resistance genes

- 119 resistance genes detected during study period.
- Important information for earlier targeted therapy and infection control.

Rapid identification is critical for survival

Using Unyvero, the average time to results was:

- Reduced by 11h compared to identification results.
- Reduced by 34h compared to full AST results.

Polymicrobial infections are severe

- 6/7 polymicrobial infections, with pathogens included in the panel, correctly identified.
- 5 samples with an additional micro-organism were detected using Unyvero.

11 hours saved (ID)

34 hours saved (AST)

Burrack-Lange *et al.*, Multicenter assessment of the rapid Unyvero Blood Culture molecular assay J. Med. Microbiology 2018; 67(9): 1294-1301
ID: Identification
AST: Antibiotic Susceptibility Testing

Study 2

Comparison with routine microbiology.
University Hospital Essen, Germany.

Number of samples

50 positive blood cultures.
7 spiked blood cultures.

Study population

- 46 patients.
- Age 1 month-45 years.

Unyvero turnaround time 4-5 hours

100% Agreement for resistance markers

95% Agreement with ID results

Spiked cultures

- 7/7 Spiked bacteria correctly identified.
- 3/3 Resistance markers correctly identified (*mec*C, *van*A and *van*B).

*mec*C ✓ *van*A ✓ *van*B ✓

Conclusion

The Unyvero BCU Application is a useful tool for the rapid detection of pathogens and resistance markers directly from positive blood cultures.

Schmidt *et al.*, (2018) poster presentation DGHM.