



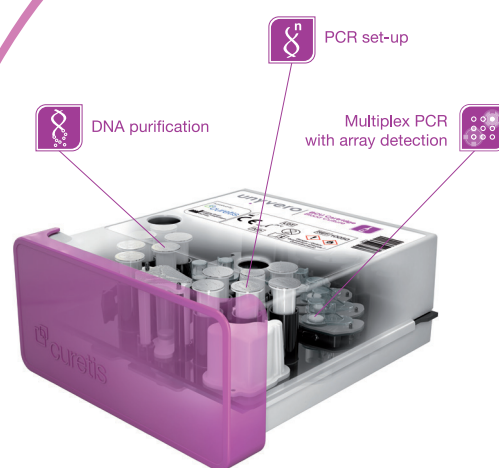
unyvero

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

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a product by curetis

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



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

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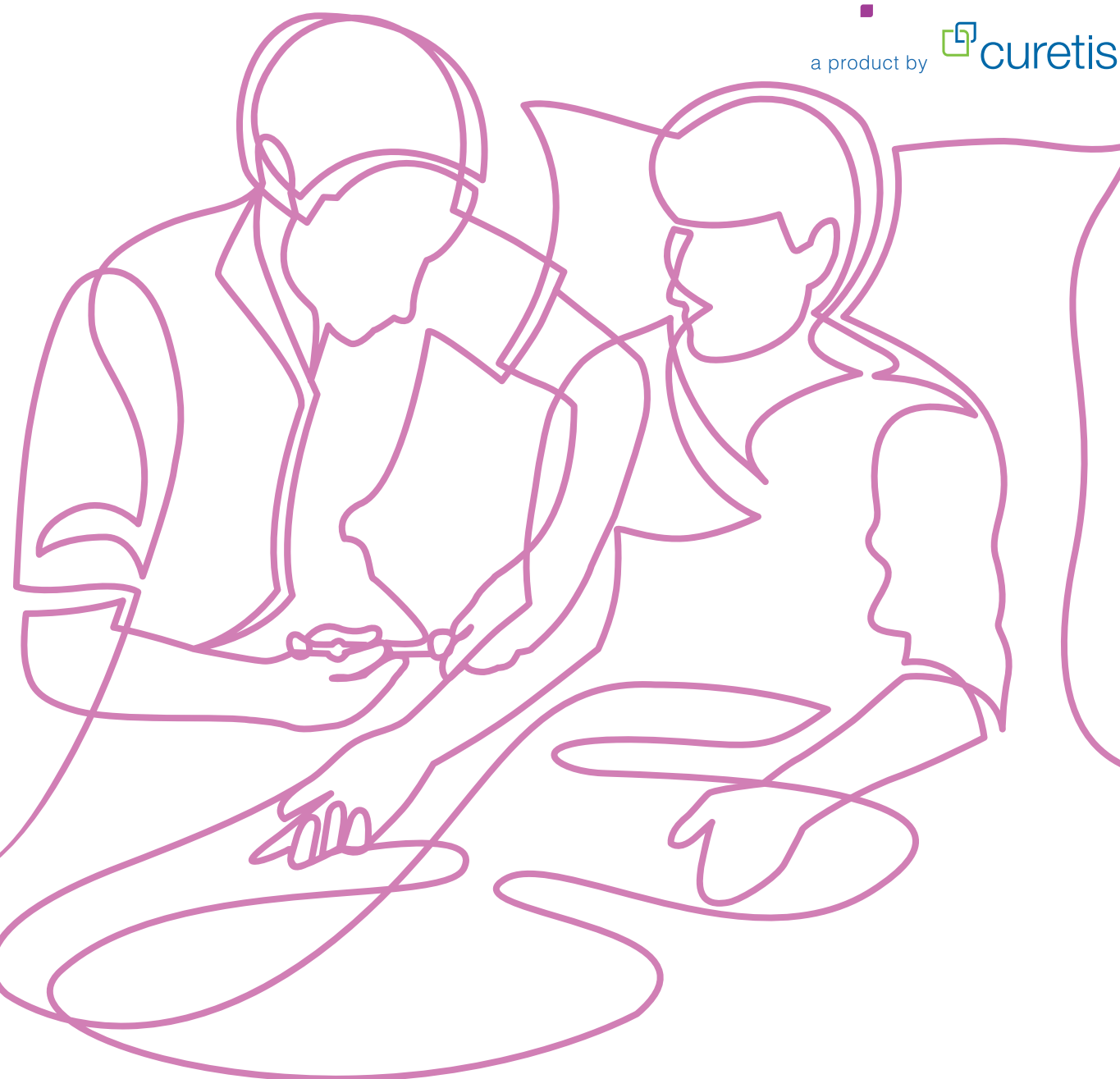
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Blood Culture

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



Unyvero L4 Lysator



Unyvero C8 Cockpit



Unyvero A50 Analyzer

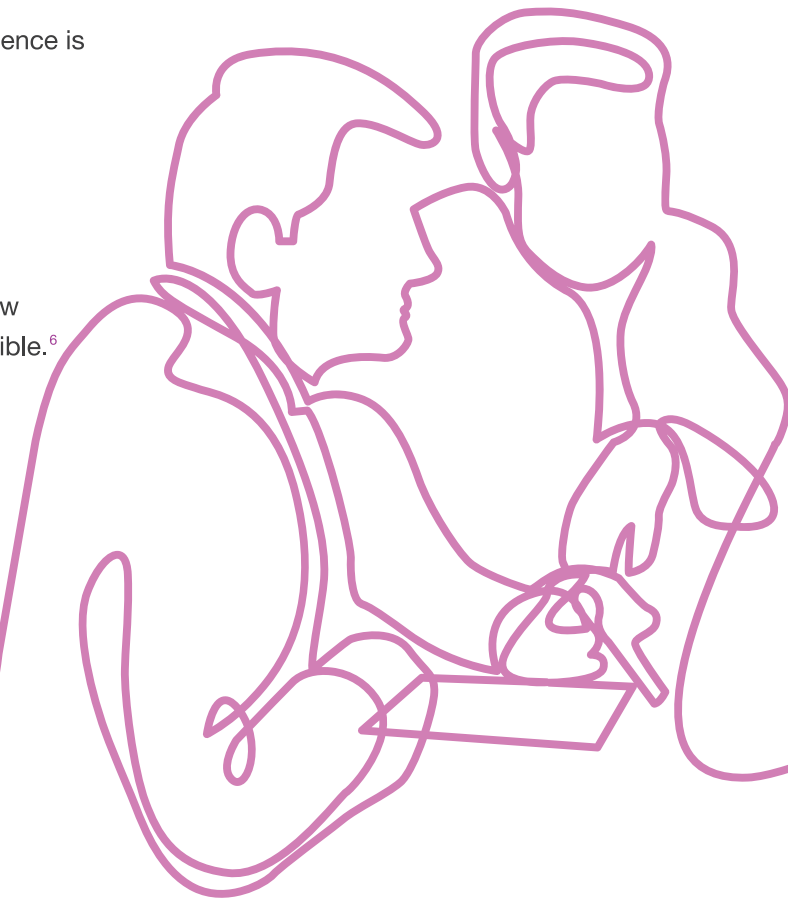
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## In industrialized countries, sepsis is responsible for as many deaths as heart attacks<sup>1</sup>

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

Worldwide, someone dies of sepsis every 3-4 seconds.<sup>4</sup>

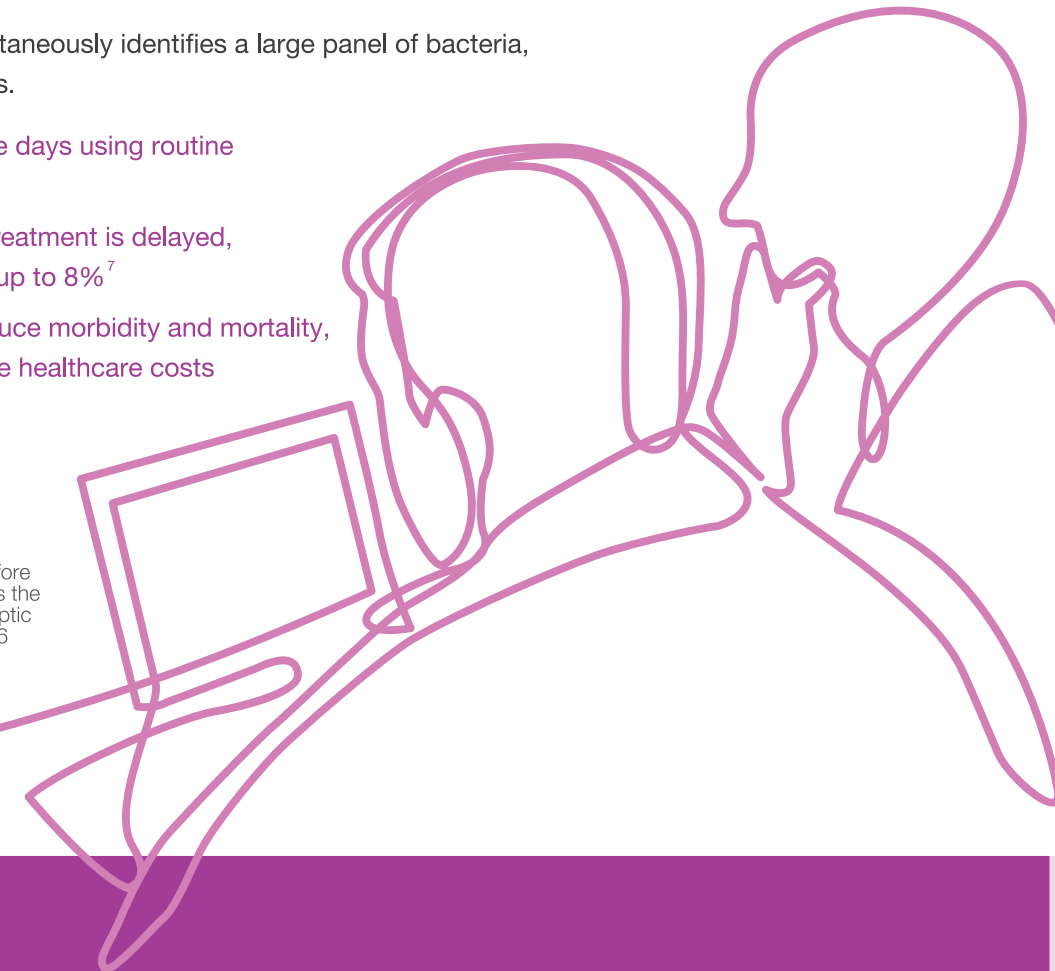


## Faster detection enables earlier optimization of therapy

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%<sup>7</sup>
- Early identification can help reduce morbidity and mortality, improve patient care and reduce healthcare costs

<sup>7</sup> 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	Enterobacteriaceae	Non-fermenting bacteria	Fungi	Resistance Gene
<i>Staphylococcus aureus</i> <i>Coagulase negative staphylococci</i> <i>Streptococcus</i> spp. <i>Streptococcus agalactiae</i> <i>Streptococcus pneumoniae</i> <i>Streptococcus pyogenes/dysgalactiae</i> <i>Enterococcus</i> spp. <i>Enterococcus faecalis</i> <i>Listeria monocytogenes</i>	<i>Citrobacter freundii/koseri</i> <i>Escherichia coli</i> <i>Enterobacter cloacae</i> complex <i>Klebsiella aerogenes</i> ( <i>E. aerogenes</i> ) <i>Klebsiella oxytoca</i> <i>Klebsiella pneumoniae</i> <i>Klebsiella variicola</i> <i>Proteus</i> spp. <i>Serratia marcescens</i>	<i>Acinetobacter baumannii</i> complex <i>Pseudomonas aeruginosa</i> <i>Stenotrophomonas maltophilia</i>  <b>Anaerobic bacteria</b>  <i>Cutibacterium acnes</i> ( <i>P. acnes</i> )	<i>Aspergillus</i> spp. <i>Candida</i> spp. <i>Candida albicans</i> <i>Candida dubliniensis</i> <i>Candida glabrata</i> <i>I. orientalis</i> ( <i>C. krusei</i> ) <i>Candida parapsilosis</i> <i>Candida tropicalis</i>	Aminoglycoside <i>aac(6)/aph(2')</i> <i>aacA4</i>  Macrolide/Lincosamide <i>ermA</i>  Oxacillin <i>mecA</i> <i>mecC</i>  Vancomycin <i>vanA</i> <i>vanB</i>  3rd generation Cephalosporins <i>ctx-M</i>    Carbapenem <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>
<i>Corynebacteriaceae</i>	Universal bacteria	Other Gram-negative bacteria	<i>Mycobacteriaceae</i>	
<i>Corynebacterium</i> spp.	Detection of prokaryotic genetic sequence	<i>Haemophilus influenzae</i> <i>Neisseria meningitidis</i>	<i>Mycobacterium</i> spp.	

## 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

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

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



34 hours saved



### 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

Spiked cultures

- 7/7 Spiked bacteria correctly identified.
- 3/3 Resistance markers correctly identified (*mecC*, *vanA* and *vanB*).



*mecC*



*vanA*



*vanB*

95% Agreement with ID results

### 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.

<sup>1</sup> Institut Pasteur, Disease Sheet -Sepsis, 2014.

<sup>2</sup> Hotchkiss RS et al., Sepsis and septic shock. Nat Rev Dis Primers. 2016; 2:16045.

<sup>3</sup> 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.

<sup>4</sup> WSD Fact Sheet 2018 (www.world-sepsis-day.org).

<sup>5</sup> 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.

<sup>6</sup> Rhodes A, et al., Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016. Intensive Care Med. 2017; 43:304-377.



Easy Workflow



Multiple Sample Types



24/7 Results