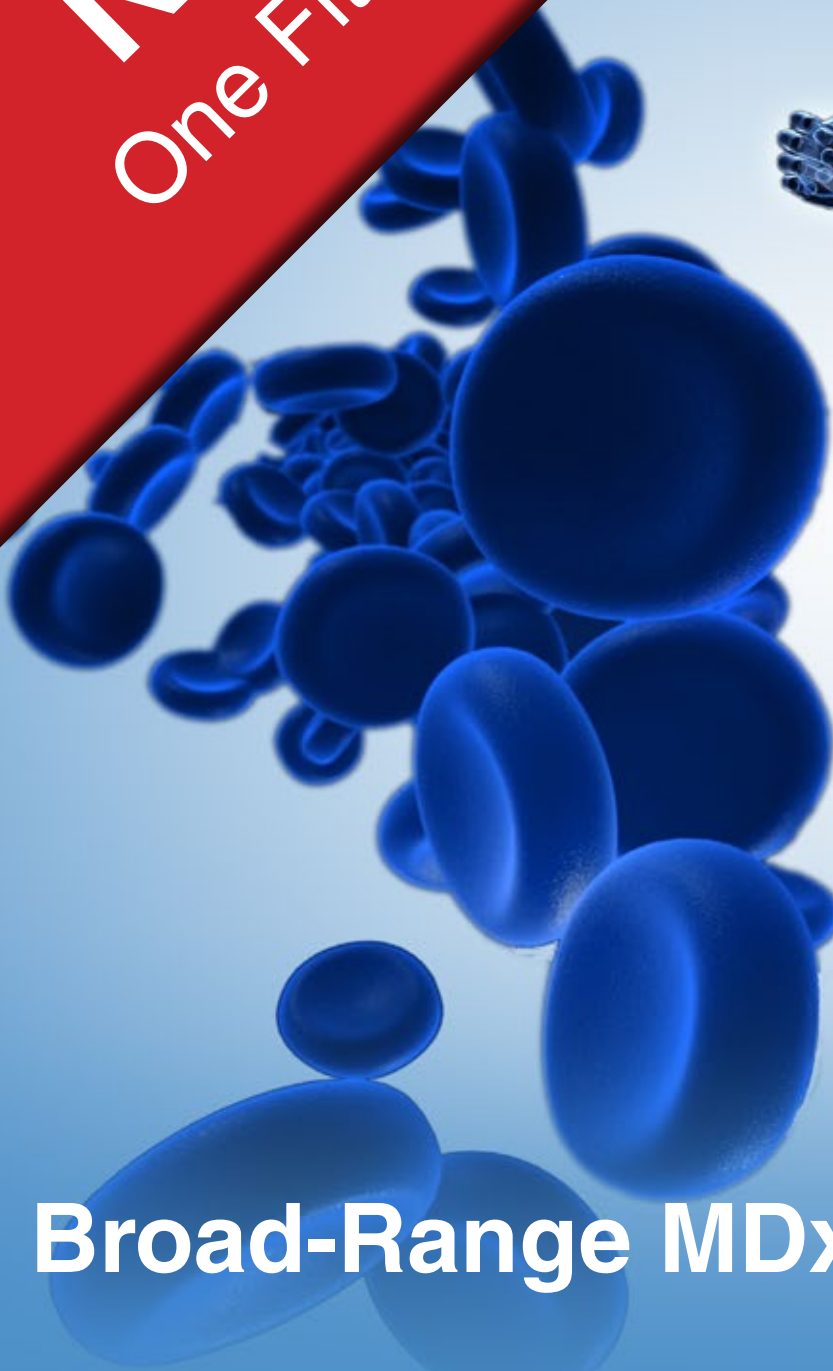


Now
One Fits All



Broad-Range MDx

CE IVD

SepsiTest™-UMD

**Identify >345 Bacteria and Fungi
in Tissues, Body Fluids, Swabs**



Universal Pathogen Identification

SepsiTest™-UMD is a precise culture-independent routine diagnosis to address:

- Non-growing pathogens under antibiotic treatment
- Rare pathogens, including anaerobic and fastidious organisms.

SepsiTest™-UMD allows the identification of more than 345 bacteria and fungi in relation to:

- Endocarditis
- Orthopedic infections
- Tuberculosis
- Wound infections
- Sepsis
- Meningitis
- Pneumonia and more...

Clinical Benefit

SepsiTest™-UMD increases the rate of diagnosis of true infections (40% to 67%, Fig. 1) by the identification of pathogens in culture-negative patients.

SepsiTest™-UMD identifies pathogens in 35% [2] to 45% [5] of patients 12 h to 3 days earlier than blood culture. In infective endocarditis, **SepsiTest™-UMD** provides pathogen identity even up to 8 days earlier [6].

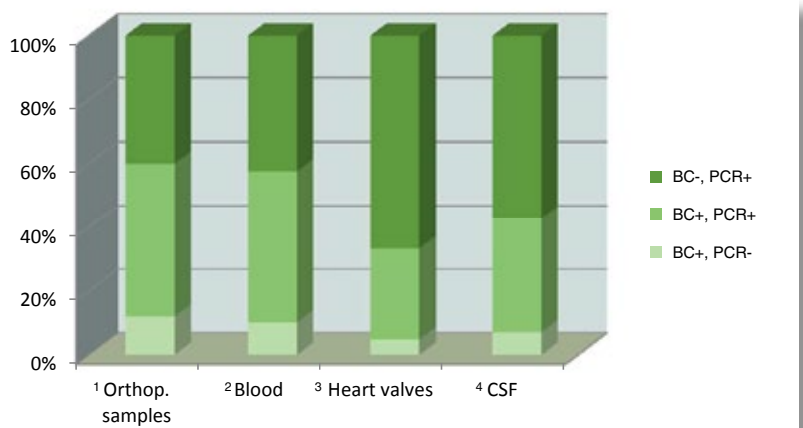
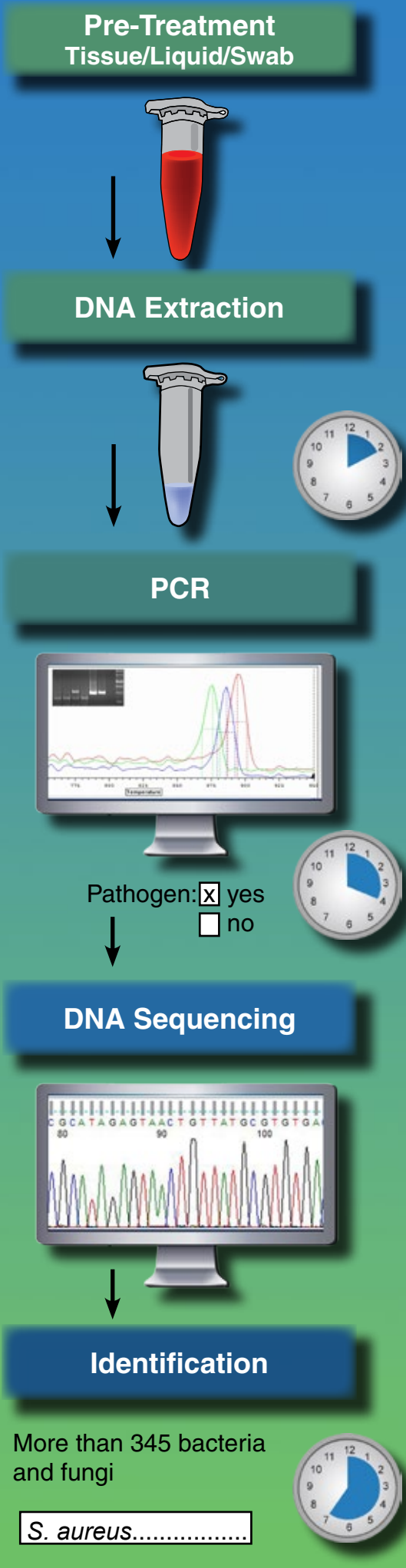


Fig. 1: Ratio of positive results by culture (BC), SepsiTest™-UMD (PCR) or both methods obtains with orthopaedic (combined BC and PCR positivity: 25/84 patients [30%; ¹]), blood (59/187 [32%; ²]), heart valves (21/30 [70%; ³]) and CSF (14/20 [70%; ⁴]). Note the considerable ratio of culture-negative patients with clinically relevant PCR positive results (BC-/PCR+).

References:

- ¹ Grif et al., J. Clin. Microbiol. 2012, 50: 2250
- ² Wellinghausen et al. 2009, J. Clin. Microbiol 47: 2759
- ³ Kühn et al., J. Clin. Microbiol. 2011, 49: 2919
- ⁴ Meyer et al., J. Clin. Microbiol. 2014, 52: 1751
- ⁵ Orszag et al., J. Clin. Microbiol. 2013, 52: 307
- ⁶ Marsch et al., Interact. Cardia Vas. Thorac Surg. 2015, doi: 10.1093/icvts/ivv006



Unique DNA Extraction

High sensitivity and specificity gained by the DNA extraction protocol of **SepsiTest™-UMD**:

- > 99% removal of human and free floating microbial DNA
- Broad-range lysis of bacteria and fungi
- DNA enrichment and isolation of live bacteria and fungi.

Highly Sensitive PCR Performance

SepsiTest™-UMD includes DNA-free PCR reagents for the detection of bacterial and fungal DNA:

- Assays: 16S / 18S rRNA gene PCR
- Amplification: 40 cycles routinely
- Controls: PCR-positive & negative, extraction control
- Identification: Sanger sequencing analysis.

Microbe Differentiation

SepsiTest™-BLAST is a free online BLAST tool for sequence analysis that relies on edited sequences from more than 7,000 cultivated reference strains of bacteria, yeasts and *Aspergillus* spp.

Analytical Sensitivity

Best performance with **SepsiTest™-UMD** for highly sensitive pathogen diagnostics:

Strain	cfu/ml blood
<i>Escherichia coli</i>	40
<i>Klebsiella pneumoniae</i>	50
<i>Staphylococcus aureus</i>	20
<i>Streptococcus pneumoniae</i>	50
<i>Enterococcus faecalis</i>	20
<i>Candida albicans</i>	10
<i>Candida glabrata</i>	10

Automation

SelectNA™ plus: Fully-Automated DNA Extraction:

- Hands on time: 10min*
- Total process time: 90min*
- 1 - 12 samples
- For fluid and tissue samples



SelectNA™: Semi-Automated DNA Extraction :

- Hands on time: 40min*
- Total process time: 160min*
- 1 - 12 samples
- For fluid and tissue samples



*Depending on specimens and number of samples

Specimens



Heart Valve



Ascites Fluid



BAL Fluid



Synovial Fluid



CSF



Swab

Current List of Identified Pathogens:

Gram-negative bacteria	<i>Edwardsiella tarda</i>	<i>Providencia stuartii</i>	<i>Dolosigranulum pigrum</i>	<i>Propionibacterium</i> spp.
<i>Achromobacter xylosoxidans</i>	<i>Elizabethkingia meningoseptica</i>	<i>Pseudomonas</i> spp.	<i>Eggerthella lenta</i>	<i>Rhodococcus</i> spp.
<i>Acidovorax</i> spp.	<i>Enhydrobacter aerosaccus</i>	<i>Ralstonia</i> spp.	<i>Enterococcus</i> spp.	<i>Rothia</i> spp.
<i>Acinetobacter</i> spp.	<i>Enterobacter</i> spp.	<i>Raoultella planticola</i>	<i>Eremococcus coleocola</i>	<i>Staphylococcus</i> spp.
<i>Aeromonas veronii</i>	<i>Escherichia</i> spp.	<i>Rickettsia typhi</i>	<i>Eubacterium</i> spp.	<i>Streptococcus</i> spp.
<i>Afipia broomeae</i>	<i>Fusobacterium</i> spp.	<i>Serratia marcescens</i>	<i>Facklamia</i> spp.	<i>Tropheryma whipplei</i>
<i>Aggregatibacter aphrophilus</i>	<i>Haemophilus</i> spp.	<i>Shigella</i> spp.	<i>Finegoldia magna</i>	<i>Tsukamurella</i> spp.
<i>Anaerotruncus colihominis</i>	<i>Hafnia alvei</i>	<i>Stenotrophomonas maltophilia</i>	<i>Gardnerella vaginalis</i>	<i>Ureaplasma urealyticum</i>
<i>Bacteroides</i> spp.	<i>Helicobacter pylori</i>	<i>Veillonella</i> spp.	<i>Gemella</i> spp.	<i>Vagococcus</i> spp.
<i>Bartonella quintana</i>	<i>Kingella</i> spp.	<i>Weeksella</i> spp.	<i>Gordonia</i> spp.	<i>Wolbachia</i> sp.
<i>Bordetella</i> spp.	<i>Klebsiella</i> spp.	<i>Yersinia</i> spp.	<i>Granulicatella adiacens</i>	Fungi
<i>Borrelia garinii</i>	<i>Kerstersia</i> spp.	Gram-positive bacteria	<i>Janibacter</i> spp.	<i>Aspergillus</i> spp.
<i>Bosea</i> spp.	<i>Kluyvera cryocrescens</i>	<i>Abiotrophia</i> spp.	<i>Kocuria</i> spp.	<i>Candida</i> spp.
<i>Brucella</i> spp.	<i>Lautropia mirabilis</i>	<i>Actinomyces</i> spp.	<i>Lactobacillus</i> spp.	<i>Cladosporium cladosporioides</i>
<i>Burkholderia</i> spp.	<i>Legionella pneumophila</i>	<i>Aerococcus</i> spp.	<i>Lactococcus</i> spp.	<i>Cryptococcus</i> spp.
<i>Campylobacter</i> spp.	<i>Leptotrichia</i> spp.	<i>Alloiococcus otitis</i>	<i>Leifsonia</i> spp.	<i>Didymella exitialis</i>
<i>Cand. Neoehrlichia mikurensis</i>	<i>Massilia</i> spp.	<i>Anaerococcus</i> spp.	<i>Listeria monocytogenes</i>	<i>Davidiella tassiana</i>
<i>Capnocytophaga</i> spp.	<i>Methylobacterium</i> spp.	<i>Atopobium</i> spp.	<i>Microbacterium</i> spp.	<i>Fusarium</i> spp.
<i>Chryseobacterium indologenes</i>	<i>Moraxella</i> spp.	<i>Bacillus</i> spp.	<i>Micrococcus</i> spp.	<i>Malassezia</i> spp.
<i>Citrobacter freundii</i>	<i>Morganella morganii</i>	<i>Bifidobacterium</i> spp.	<i>Mogibacterium timidum</i>	<i>Pseudallescheria boydii</i>
<i>Cloacibacterium normanense</i>	<i>Neisseria</i> spp.	<i>Brevibacterium</i> spp.	<i>Mycobacterium</i> spp.	<i>Saccharomyces cerevisiae</i>
<i>Comamonas testosteroni</i>	<i>Pantoea agglomerans</i>	<i>Carnobacterium</i> spp.	<i>Mycoplasma</i> spp.	<i>Schizophyllum radiatum</i>
<i>Coxiella burnetii</i>	<i>Paracoccus</i> spp.	<i>Clostridium</i> spp.	<i>Nocardia</i> spp.	<i>Sporobolomyces</i> spp.
<i>Cronobacter sakazakii</i>	<i>Pasteurella</i> spp.	<i>Coprococcus catus</i>	<i>Paenibacillus</i> spp.	<i>Issatchenkia orientalis</i>
<i>Curvibacter</i> spp.	<i>Porphyromonas</i> spp.	<i>Corynebacterium</i> spp.	<i>Parvimonas micra</i>	
<i>Delftia</i> spp.	<i>Prevotella</i> spp.	<i>Dermabacter hominis</i>	<i>Peptoniphilus</i> spp.	Protist
<i>Dialister</i> spp.	<i>Proteus</i> spp.	<i>Dietzia</i> spp.	<i>Peptostreptococcus</i> spp.	<i>Plasmodium</i> spp.

Order Information:

Product*	Application	Content	Order No.
SepsiTest™-UMD	Broad-range applications (fluids, tissues, swabs), manual DNA extraction protocol	24 reactions	U-010-024
		48 reactions	U-010-048
UMD-SelectNA™	Broad-range applications (fluids, tissues, swabs), semi-automated DNA extraction protocol	24 reactions	U-050-024
		48 reactions	U-050-048
Add-On 10	Add on kit for the extraction of pathogen DNA for volumes up to 10ml	24 reactions	U-120-024
		48 reactions	U-120-048
Micro-Dx™	Broad-range applications (fluids, tissues, swabs), fully-automated DNA extraction protocol	24 reactions	U-200-024
		48 reactions	U-200-048

* Not available in the U.S.

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