

Sepsis PCR Diagnostics

SepsiTest™ CE IVD

Detection of >345 bacteria and yeasts



Molzzy



SepsiTest™ Specifications

- ✓ > 345 Microbes Detectable
- ✓ High Clinical Utility
- ✓ Bacteria and Yeasts PCRs
- ✓ Rapid Results (4h)
- ✓ 2x 1 ml EDTA/Citrate Blood
- ✓ No Extra Instrumentation
- ✓ Open System
- ✓ CE IVD Marked (98/79 EC)

Molecular Sepsis Diagnostics

Sepsis is an inflammatory response to infection by bacteria or fungi, the estimated incidence of sepsis reaching approx. 0.3% [1]. The mortality of sepsis or, even more, septic shock is still very high (40% [1]). This places sepsis/septic shock to a major cause of death in the ICU worldwide. Accordingly, there is an urgent need to reduce the uncertainty and time of today's blood culture diagnosis for pathogens to reduce morbidity and mortality of patients. Generally, the positivity rate of blood culturing is only 15 to 25% and its time-to-first-results 8 to 48 hours [2], for slow growing bacteria and fungi even longer.

Molecular biological methods, particularly polymerase chain reaction (PCR), are generally accepted as a promising means of culture-flanking methods for early sepsis diagnosis, mostly because of its rapidity of time-to-result and independence of the growth of strains. **SepsiTest™** is a direct blood PCR test, designed for the needs of fast routine sepsis diagnosis.

Broad-Spectrum Diagnostics

SepsiTest™ is a broad-spectrum test detecting more than 345 species, among them mostly pathogenic bacteria and yeasts (see last page). In contrast to other PCR systems, covering only a limited number of strains, **SepsiTest™** is the first kit worldwide enabling the detection and identification of essentially any bacterial or yeast pathogen in whole blood. The high specificity and sensitivity of pathogen detection is obtained by Molzym's technology of human DNA removal. Because of its broad-spectrum detection capability, the test is particularly useful also for less frequently occurring but problematic infectious agents, including *Neisseria*, *Haemophilus*, *Gemella*, *Proteus vulgaris*, and others.

Therapy Monitoring

SepsiTest™ detects pathogens irrespective of the administration of antibiotics and the culturability of strains. While excluding free bacterial DNA and human DNA, **SepsiTest™** specifically detects pathogen DNA from intact live or dead cells. This makes **SepsiTest™** a very powerful test for pathogen detection and therapy monitoring, including hematological patients.

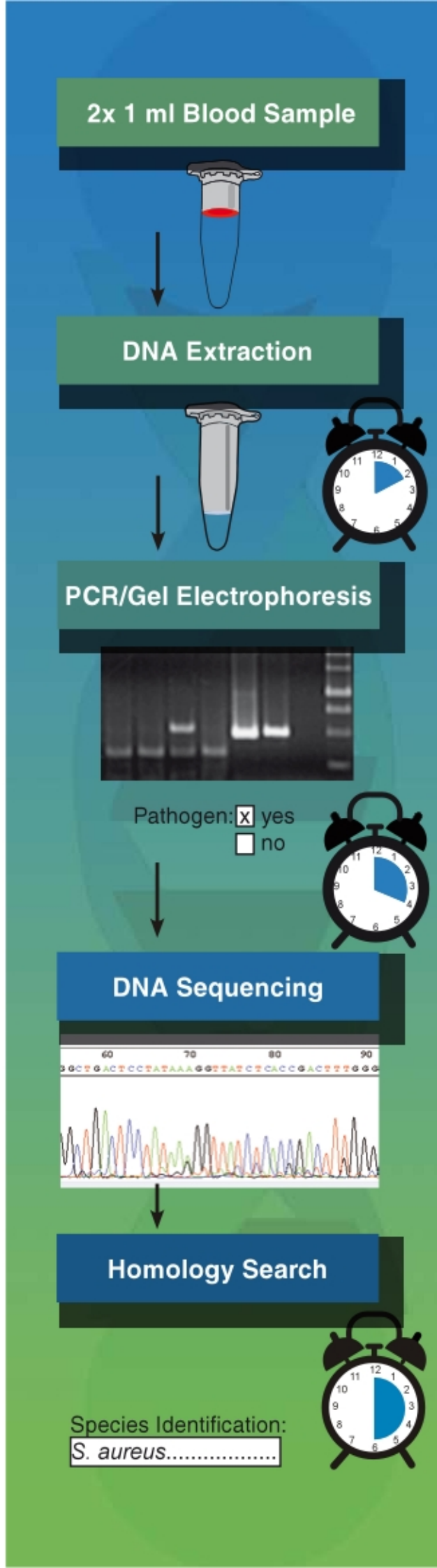
Clinical Utility

SepsiTest™ is for whole blood analysis with a time to positive-negative results within only 4 hours. Identification of pathogens is performed by sequencing analysis of amplicons obtained from positive PCR tests. Due to Molzym's proprietary technology of reagent DNA decontamination, **SepsiTest™** prevents false positive results.

In clinical studies, **SepsiTest™** has proven clinical relevance by its high diagnostic sensitivity compared to blood culture (e.g. 87%, 187 patients [3,4]) and high analytical sensitivity (e.g. 20 to 40 cfu/ml, *S. aureus* [5]). Sample analysis by **SepsiTest™** is performed in duplicate for reasons of increasing the sensitivity and reliability of pathogen detection. **SepsiTest™** reagents are assembled in portions, thereby minimising the risk of contamination of buffers and reagents. **SepsiTest™** is an open system and can be run on standard lab equipment (any PCR cycler) and does not require investments in costly platform systems.

References

- [1] <http://www.sepsis-gesellschaft.de/>
- [2] Hunfeld et al. (2008) Molekularbiologischer Erregernachweis bei Patienten mit Sepsis. *Der Anaesthesist* 4: 326-337
- [3] Disqué et al. (2008) PCR detection of sepsis-inducing pathogens in blood using SepsiTest™ Blood. *Int. J. Med. Microbiol.* 298: DVP06
- [4] C. Disqué, personal communication
- [5] Mühl et al. (2008) Activity and DNA contamination of commercial polymerase chain reaction reagents for the universal 16S rDNA real-time polymerase chain reaction detection of bacterial pathogens in blood. *Diag. Microbiol. Infect. Dis.* (in press): doi:10.1016/j.diagmicrobio.2008.07.011



Sepsis-causing strains among the >345 microorganisms detectable by Sepsitest™ *

Bacteria				Yeasts		
Gram-negative	Species	Gram-negative	Species	Gram-positive	Species	
<i>Achromobacter</i>	1	<i>Methylobacterium</i>	1	<i>Actinomyces</i>	1	<i>Candida albicans</i>
<i>Acinetobacter</i>	5	<i>Moraxella</i>	2	<i>Aerococcus</i>	1	<i>Candida glabrata</i>
<i>Actinobacillus</i>	2	<i>Morganella</i>	1	<i>Arthrobacter</i>	1	<i>Candida krusei</i>
<i>Aeromonas</i>	7	<i>Neisseria</i>	2	<i>Bacillus</i>	20	<i>Candida parapsilosis</i>
<i>Aggregatibacter</i>	3	<i>Ochrobactrum</i>	2	<i>Clostridium</i>	2	<i>Candida tropicalis</i>
<i>Alcaligenes</i>	2	<i>Pantoea</i>	2	<i>Corynebacterium</i>	2	<i>Cryptococcus neoformans</i>
<i>Alteromonas</i>	1	<i>Pasteurella</i>	1	<i>Enterococcus</i>	7	
<i>Anaplasma</i>	1	<i>Photobacterium</i>	1	<i>Erysipelothrix</i>	1	
<i>Bacteroides</i>	2	<i>Plesiomonas</i>	1	<i>Exiguobacterium</i>	1	
<i>Bifidobacterium</i>	9	<i>Proteus</i>	2	<i>Geobacillus</i>	2	
<i>Brevibacterium</i>	1	<i>Pseudomonas</i>	18	<i>Frankia</i>	1	
<i>Brevundimonas</i>	2	<i>Rahnella</i>	1	<i>Kocuria</i>	1	
<i>Burkholderia</i>	6	<i>Ralstonia</i>	3	<i>Lactobacillus</i>	28	
<i>Butyrivibrio</i>	1	<i>Riemerella</i>	1	<i>Lactococcus</i>	3	
<i>Campylobacter</i>	2	<i>Salmonella</i>	2	<i>Leifsonia</i>	1	
<i>Chlamydophila</i>	2	<i>Serratia</i>	4	<i>Leuconostoc</i>	2	
<i>Citrobacter</i>	1	<i>Shewanella</i>	3	<i>Microbacterium</i>	2	
<i>Comamonas</i>	1	<i>Sphingomonas</i>	1	<i>Micrococcus</i>	1	
<i>Delftia</i>	1	<i>Stenotrophomonas</i>	1	<i>Mycobacterium</i>	10	
<i>Ehrlichia</i>	2	<i>Vibrio</i>	7	<i>Nocardia</i>	3	
<i>Enterobacter</i>	6	<i>Xanthomonas</i>	1	<i>Paenibacillus</i>	3	
<i>Escherichia</i>	1	<i>Yersinia</i>	2	<i>Pediococcus</i>	2	
<i>Flavobacterium</i>	3			<i>Propionibacterium</i>	1	
<i>Haemophilus</i>	4			<i>Rhodococcus</i>	3	
<i>Hafnia</i>	1			<i>Staphylococcus</i>	19	
<i>Helicobacter</i>	1			<i>Streptococcus</i>	6	
<i>Klebsiella</i>	2			<i>Streptomyces</i>	2	
<i>Leptospira</i>	5			<i>Weissella</i>	2	
<i>Megasphaera</i>	1	Sum:	114	Sum:	128	

* the complete list of species is available on request

Order information:

Product	Content	Order No.
Sepsitest™ CEIVDP athogen Detection	24/12 BloodSample Tests*	A-020-024
	48/24 BloodSample Tests*	A-020-048

* in duplicate



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