

# LightCycler® SeptiFast Test MGRADE



Registration Status

CE-IVD

## *The Impact of Rapid Results*

### **Rapid detection and identification of bloodstream infections by real-time PCR – directly from blood**

Provides rapid species identification of pathogens causing blood stream infections.

SeptiFast is designed to detect and identify the most important bacteria and fungi causing nosocomial bloodstream infections – within just a few hours! SeptiFast detects the pathogenic bacteria and fungi directly from whole blood, no preculture is required.

Rapid pathogen detection by molecular diagnostic tools may facilitate the rapid diagnosis of bacteremia/fungemia and earlier administration of appropriate antibiotic therapy, while also reducing inappropriate overuse of broad-spectrum antibiotics.<sup>1,2</sup>

This test can be used with the LightCycler® SeptiFast Meca Test MGRADE.

### **Features and Benefits**

#### Features

- Designed for the LightCycler® 2.0 Instrument – Combines rapid amplification with highly specific melting point analysis for rapid species results
- SeptiFast Identification Software consolidates all data points into one patient report
- Optional mecA gene detection – when samples test positive for *Staphylococcus aureus*, test for the presence of the mecA gene in a subsequent run using the LightCycler® SeptiFast Meca Test MGRADE

#### Benefits

- Detects and identifies bacterial and fungal DNA directly from a 1.5 mL whole blood sample, without prior incubation or culture steps in less than 6 hours
- Detects and identifies the 25 most common pathogens known to cause to blood stream infections:

Gram (-)

- Escherichia coli
- Klebsiella (pneumoniae/oxytoca)
- Serratia marcescens/Enterobacter (cloacae/aerogenes)
- Proteus mirabilis
- Pseudomonas aeruginosa
- Acinetobacter baumannii/Stenotrophomonas maltophilia

#### Gram (+)

- Staphylococcus aureus
- CoNS (Coagulase negative Staphylococci)
- Streptococcus pneumoniae
- Streptococcus spp.
- Enterococcus faecium
- Enterococcus faecalis

#### Fungi

- Candida albicans
- Candida tropicalis
- Candida parapsilosis
- Candida krusei
- Candida glabrata
- Aspergillus fumigatus

- High analytical sensitivity due to amplification of a multicopy target region – Internal Transcribed Spacer. Detects 300 cfu/ml or less
- Reliable results without interference from background DNA – MGRADE quality reagents and disposables provide highly sensitive bacterial and fungal nucleic-acid detection

#### Intended Use

This test is an *in vitro* nucleic acid amplification test for the detection and identification of bacterial and fungal DNA from microorganisms specified in the SeptiFast Test Master List (SML) in human K-EDTA blood using the LightCycler® 2.0 Instrument. The test is used in conjunction with clinical presentation, established microbiological assays and/or other laboratory markers as an aid in the management of patients with suspected sepsis and other bacterial/fungal blood stream infections.

Not available in the United States

1. Suttrop N. "Changing populations and future trends in the management of serious infections" from the Academy for Infection Management Website (now closed).

2. Peterson LR, et al. Towards targeted prescribing: will the cure for antimicrobial resistance be specific, directed therapy through improved diagnostic testing?, J Antimicrob Chemother 2004, 53: 902-5.

#### More Information

For regulatory reasons we are not able to provide further details on our products on this website, but more information may be available from our regional sales representatives.

[Contact](#)

## Contact

Contact your local sales representative for **detailed information**, questions and ordering.

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[> LightCycler® SeptiFast MecA Test MGRADE](#)

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