



Diagnosics

SeptiFast *the Impact of Rapid Results*

Innovation in the Laboratory



Innovating Microbiology with the LightCycler® SeptiFast Test – For *in-vitro* diagnostic use –

The LightCycler® SeptiFast Test will allow the laboratory to detect and identify 25 of the most common nosocomial bacterial and fungal species, directly from the blood sample, without prior incubation or culture steps. Combining the rapid amplification on the LightCycler® 2.0 Instrument with the highly specific melting point analysis enables the laboratory to provide a species result in less than 6 hours, from start of sample preparation to the final report.

SeptiFast provides rapid results with an unmatched sensitivity.

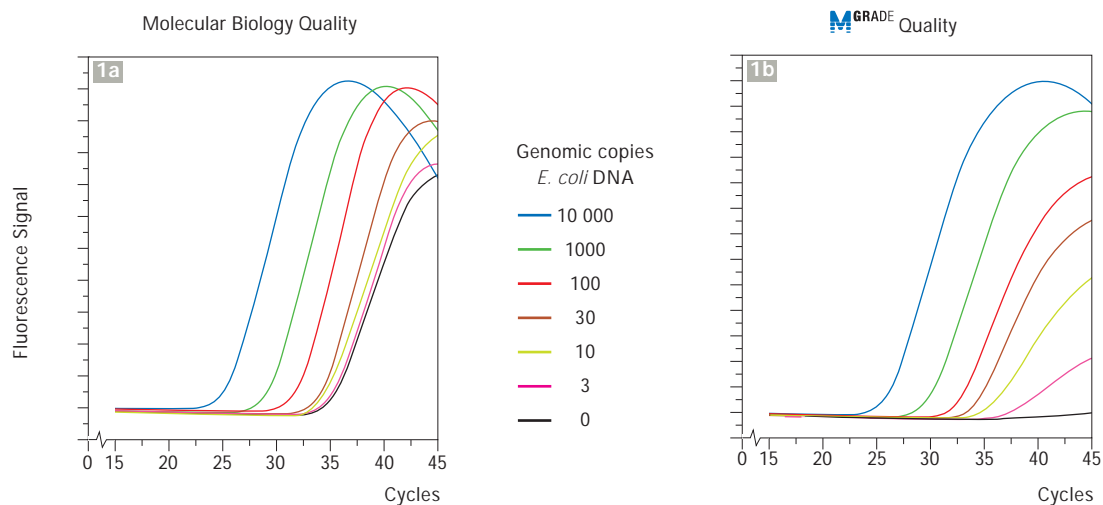
The ITS (Internal transcribed spacer) region of the bacterial and fungal genome was selected as an optimal target region to allow highly sensitive detection, as well as species differentiation in one step. The target DNA from the sample is amplified by PCR, and the species* identified by melting point analysis. An additional software tool will consolidate all data points into one patient report.

* Twenty-five of the most common nosocomial bacterial and fungal species are selected, and are reported in 20 groups relevant for decision making. (see table 1)

MGRADE® Reagents make a Reliable Result

In the past, minute amounts of bacterial and fungal DNA in standard quality reagents did not allow detection of low levels of organisms directly from patient samples. Therefore, Roche Diagnostics created a new quality standard for a new dimension

of sensitivity: MGRADE quality. Using MGRADE quality reagents and plasticware from Roche Diagnostics, or from one of our recommended suppliers, is the key to reliable results in your lab.



Standard quality reagents very often contain traces of bacterial and fungal DNA, which give unspecific background signals in highly sensitive PCR reactions for detection of bacteria or fungi. In the experiment above, a dilution series of *E. coli* DNA was analysed in

parallel with Molecular Biology Quality reagents (1a), and with MGRADE quality reagents (1b), respectively. Only with MGRADE reagents the negative control gave a negative result. **MGRADE reagents make the result reliable.**

Gram (-)	Gram (+)	Fungi
<ul style="list-style-type: none"> • <i>Escherichia coli</i> • <i>Klebsiella (pneumoniae / oxytoca)</i> • <i>Serratia marcescens</i> • <i>Enterobacter (cloacae / aerogenes)</i> • <i>Proteus mirabilis</i> • <i>Pseudomonas aeruginosa</i> • <i>Acinetobacter baumannii</i> • <i>Stenotrophomonas maltophilia</i> 	<ul style="list-style-type: none"> • <i>Staphylococcus aureus</i> • CoNS (Coagulase negative <i>Staphylococci</i>)* • <i>Streptococcus pneumoniae</i> • <i>Streptococcus spp.**</i> • <i>Enterococcus faecium</i> • <i>Enterococcus faecalis</i> 	<ul style="list-style-type: none"> • <i>Candida albicans</i> • <i>Candida tropicalis</i> • <i>Candida parapsilosis</i> • <i>Candida krusei</i> • <i>Candida glabrata</i> • <i>Aspergillus fumigatus</i>

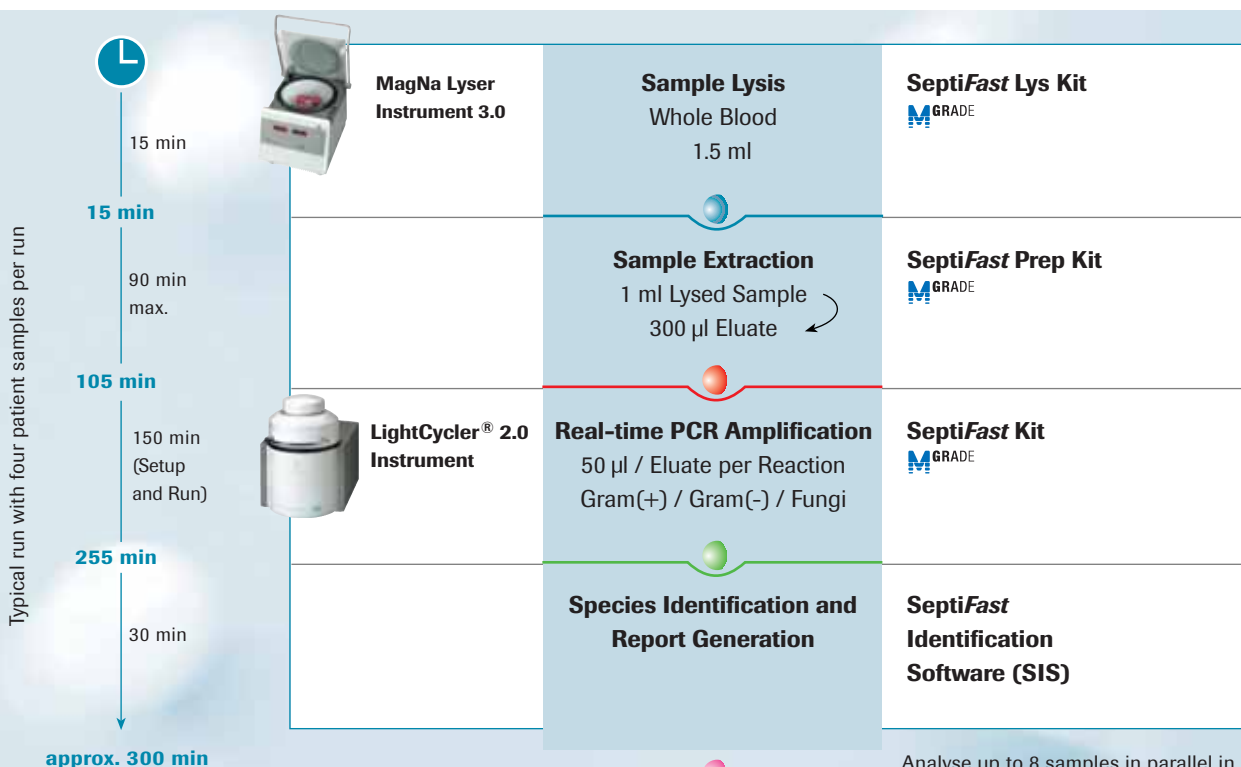
△ Table 1

S. epidermidis*, *S. haemolyticus* *S. pyogenes*, *S. agalactiae*, *S. mitis*

How to read the table: each bullet point in the table represents one of the possible results in the report. As an example, the table contains the bullet point “*Enterobacter (cloacae / aerogenes)*”. This means that both *E. cloacae* and *E. aerogenes* are detectable, and a positive result for either of them

will be reported as “*E. cloacae/aerogenes*” – thereby not differentiating between the two species in the report. In another example, the table lists two separate bullet points for *Enterococcus faecium* and *E. faecalis*, which means that the two results are given separately in the report.

Optimize your Laboratory Workflow with the LightCycler® SeptiFast Test.



Optionally followed by *mecA* Gene Detection

Analyse up to 8 samples in parallel in one run. In case of a positive result for *Staphylococcus aureus*, the presence of the *mecA* gene** can be tested in a subsequent run from the purified DNA generated in the workflow above.

** LightCycler® SeptiFast *mecA* Kit

Ordering Information



Instrumentation	Content	Article code
SeptiFast Cooling Block	1 piece	04 555 864 001♦
SeptiFast Software Set	1 set	04 705 220 001♦
MagNA Lyser Instrument 3.0	110V 220V	03 358 968 001♦ 03 358 976 001♦
LightCycler® Carousel Centrifuge 2.0	110V 220V	03 709 507 001♦ 03 709 582 001♦
LightCycler® 2.0 Instrument (Software 4.05. [415] or higher)	1 piece	03 531 414 201♦
Consumables	Content	Article code
LightCycler® Capillaries (100µl) M GRADE	8 x 96 capillaries	03 612 066 001♦
Kits	Content	Article code
SeptiFast Lys Kit M GRADE	100 vials	04 404 432 001♦
SeptiFast Prep Kit M GRADE	for 10 preparations	04 404 459 001♦
LightCycler® SeptiFast Kit M GRADE	for 54 reactions (14 samples tested)	04 469 046 001♦
LightCycler® SeptiFast <i>mecA</i> Kit M GRADE	for 30 reactions (10 samples tested)	04 488 814 001♦
LightCycler® Multicolor Compensation Set	5 tests	04 484 355 001♦



MGRADE

MGRADE products are designed for highly sensitive bacterial and fungal nucleic-acid detection. Proprietary manufacturing processes are developed in order to eliminate DNA contaminations that might interfere with such assays.



From partnering suppliers

greiner bio-one	Content	Article Code
5 ml Filter Tips M GRADE	378 pcs.	940 525 MG
1000 µl Filter Tips (E) M GRADE	600 pcs.	750 289 MG
100 µl Filter Tips M GRADE	1152 pcs.	772 289 MG
20 µl Filter Tips M GRADE	1152 pcs.	774 289 MG
Serum Pipettes 153 mm M GRADE	400 pcs.	612 302 MG
Reaction Tubes 1,5 ml M GRADE	400 pcs.	616 202 MG



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Fax: +43 7583 6318
Inquiries: office@at.gbo.com
List of distributors:
<http://www.gbo.com/en/contact>

BBI Diagnostics	Content	Article Code
Sepsis Positive Control	6 vials	ACCURUN 500 series 250



375 West Street
West Bridgewater MA USA
Inquiries: info@bbii.com
List of distributors:
<http://www.seracare.com/bbidx/distributors.htm>

For further information, visit
<http://molecular.roche.com>
or contact our local representative.



Diagnostics

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