

BactoReal® Kit

Staphylococcus spp. & S. aureus



BactoReal® Kit Staphylococcus spp. & S. aureus

Order no.	Reactions	Pathogen	Internal positive control
DHUS00253	50	FAM + VIC channel	Cy5 channel

Kit contents:

- Detection assay (multiplex) for *Staphylococcus*, *S. aureus* and for internal DNA positive control (control of PCR amplification and DNA extraction)
- Target for internal DNA positive control
- DNA reaction mix
- Nuclease-free water
- Positive control for *Staphylococcus* and *S. aureus*



Background: *Staphylococcus aureus* is a Gram-positive bacterium, which can be found on skin and in mucous membranes. This bacterium can cause pneumonia, meningitis and sepsis. *S. aureus* is a microorganism responsible for nosocomial infections. Some strains are resistant to antibiotics like methicillin and vancomycin and therefore more difficult to treat.

Staphylococcus epidermidis is a Gram-positive bacterium colonizing skin and mucous membranes of humans. It can lead to infections through various implanted medical devices such as joint prostheses, cardiovascular devices or heart valves. *Staphylococcus saprophyticus* can lead to urinary tract infections, with young women being more severely affected. Other species of staphylococci such as *S. lugdunensis*, *S. haemolyticus*, *S. warneri*, *S. schleiferi*, *S. intermedius* are generally non-pathogenic but can lead to infections in rare cases.

Intended use: BactoReal® Kit *Staphylococcus* & *S. aureus* is a non-automatic *in-vitro* diagnostic real-time PCR test for the qualitative detection and identification of extracted DNA of *Staphylococcus aureus* (nuc gene) and *Staphylococcus* spp. (23S rRNA gene) from samples purified from human EDTA blood, aspirates, CSF and biopsies. In combination with other diagnostic tests such as culture it supports a rapid and specific diagnosis for patients suspected of having a bacterial infection. Results have to be interpreted in context of the overall picture and other clinical parameters. Sepsis diagnosis must not be based solely on BactoReal® Kit *Staphylococcus* & *S. aureus*.

Staphylococcus DNA is detected in FAM channel and *S. aureus* in VIC channel. The internal DNA positive control (DNA IPC) is detected in Cy5 channel and is used as DNA extraction as well as PCR inhibition control. The DNA IPC target is extracted with the sample.

PCR-platforms: This test has been validated with the Applied Biosystems® 7500 Real-time PCR System (Thermo Fisher Scientific) and with the cobas z 480 Analyzer (Roche). However, it is also compatible with other real-time PCR instruments that can measure and differentiate fluorescence in the FAM, VIC and Cy5 channel (e.g. LightCycler® 480 II).

Specificity and sensitivity: The limit of detection (LoD95 = smallest number of target DNA copies which can be detected in 95% of cases) is 500 copies/reaction for *Staphylococcus* (corresponds to approx. 83 CFU) and 2 copies/reaction for *S. aureus*. A cut-off with Cq=35 must be defined for *Staphylococcus*. This kit detects *S. agnetis*, *S. argenteus*, *S. arlettae*, *S. aureus*, *S. capitis*, *S. caprae*, *S. cohnii*, *S. delphini*, *S. epidermidis*, *S. equorum*, *S. felis*, *S. haemolyticus*, *S. hominis*, *S. hyicus*, *S. kloosii*, *S. lugdunensis*, *S. lutrae*, *S. muscae*, *S. nepalensis*, *S. pasteurii*, *S. pettenkoferi*, *S. piscifermentans*, *S. pseudintermedius*, *S. saprophyticus*, *S. schleiferi*, *S. sciuri*, *S. simulans*, *S. stepanovicii*, *S. succinus*, *S. warneri*, *S. xylosus* and *Macrocooccus* spp. *S. carnosus*, *S. condimentii*, *S. chromogenes*, *S. lutrae*, *S. muscae* will not be detected or only weakly detected.

Diagnostic evaluation: 27 blood samples and 17 other specimens such as CSF, aspirates and biopsies of patients with suspected bacterial infection were analyzed (see Table 1).

Table 1 Statistical clinical evaluation for blood samples and other specimens

	Sensitivity		Specificity		NPV		PPV		Prevalence		Accuracy	
	Blood	Other	Blood	Other	Blood	Other	Blood	Other	Blood	Other	Blood	Other
Staphylococcus	36.4%	100.0%	100.0%	100.0%	26.3%	100.0%	100.0%	100.0%	81.5%	52.9%	48.1%	100.0%
S. aureus	42.9%	100.0%	100.0%	100.0%	33.3%	100.0%	100.0%	100.0%	77.8%	29.4%	55.6%	100.0%

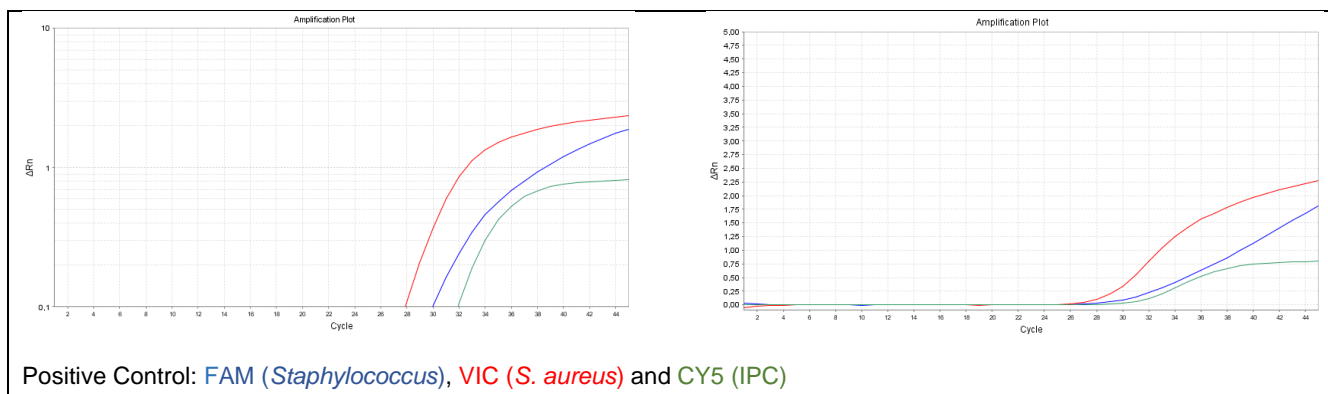


Figure 1 Performance of BactoReal® Kit *Staphylococcus* & *S. aureus*

Further tests for diagnosis of sepsis, which can be combined with *Staphylococcus* & *S. aureus*:

BactoReal® Kit *E. coli* & *Klebsiella*, order no.: DHUS00153

BactoReal® Kit *S. pneumoniae* & *Streptococcus* spp., order no.: DHUS00353

BactoReal® Kit vanA & *Enterococcus* spp., order no.: DHUS00453

BactoReal® Kit *P. aeruginosa* & *Enterobacter* spp., order no.: DHUS00553

BactoReal® Kit *A. baumannii* & *P. mirabilis*, order no.: DHUS00653

MycoReal Kit *Candida* & *A. fumigatus*, order no.: DHUF00153

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