BactoReal® Kit *A. baumannii & P. mirabilis*

Kit version 1.1

For *in vitro* diagnostic use only

BactoReal® Kit *A. baumannii & P. mirabilis*			
Order no.	**Reactions**	**Pathogen**	**Internal positive control**
DHUS00653	50	FAM + VIC channel	Cy5 channel

Kit contents:

- Assay for detection of *A. baumannii, P. mirabilis* and of internal DNA positive control (IPC)
- IPC-Target DNA (control of DNA extraction and of PCR amplification)
- DNA reaction mix (contains a highly purified Taq Polymerase for rapid hot-start PCR, dNTPs with dUTP and Uracil-N glycosylase (UNG) to eliminate amplicon carryover, ROX™ dye (passive reference) and buffer components – additives optimized to handle PCR inhibitors)
- DNA positive control for *A. baumannii, P. mirabilis*
- Nuclease-free water

Pathogen information: *Acinetobacter baumannii* is a gram-negative, aerobic bacterium which is responsible for nosocomial infections. It occurs mainly in intensive care units. This bacterium is often resistant to antibiotics and thus difficult to treat. It can lead to pneumonia, catheter-associated infections and can also cause sepsis.
Proteus mirabilis is a gram-negative, facultatively anaerobic rod-shaped bacterium which frequently occurs in the large intestine and is generally non-pathogenic. However, in people with a weakened immune system, it can lead to urinary tract infections, wound infections, pneumonia, and sepsis.

Intended purpose: BactoReal® Kit *A. baumannii & P. mirabilis* is a non-automated CE-certified IVD real-time PCR test for the qualitative detection and identification of DNA of *Acinetobacter baumannii* (rpoB gene) and *Proteus mirabilis* (ureC gene).
Proper specimens are DNA extracts of samples purified from human EDTA blood, aspirates, and CSF.
In combination with other diagnostic tests such as culture this test supports a rapid and specific diagnosis for patients suspected of having a bacterial infection. Results must be interpreted in context of the overall picture and other clinical parameters. The diagnosis of sepsis must not be based solely on BactoReal® Kit *A. baumannii & P. mirabilis.*
The test is intended for professional use and is limited to qualified personnel instructed in the procedures of real-time PCR and *in vitro* diagnostic procedures.
A. baumannii DNA is detected in FAM channel and *P. mirabilis* 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 (artificial DNA) is extracted with the sample.

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PCR-platforms: This test has been validated with the ABI® 7500 Fast Real-time PCR System (fast cycle parameters are not supported, Thermo Fisher Scientific) and with the cobas z 480 Analyzer (Roche). However, it is also suitable for other real-time PCR instruments that can measure and differentiate fluorescence in the FAM, VIC and Cy5 channel (e.g., QuantStudio™ 5, QuantStudio™ 7 real-time PCR system (Thermo Fisher Scientific), qTOWER^{3}G (Analytik Jena), Mic instrument (bio molecular systems), LightCycler® 480 II (Roche)).

Performance data: The LoD95% (smallest number of target DNA copies which can be detected in 95% of cases) is 7 copies/reaction for both pathogens. This kit is specific for *A. baumannii* and *P. mirabilis*.
For diagnostic evaluation, 7 blood samples and 5 other specimens such as CSF and aspirates from 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
A. baumannii	100.0%	100.0%	100.0%	-	100.0%	100.0%	100.0%	-	14.3%	0.00%	100.0%	-
P. mirabilis	100.0%	100.0%	100.0%	-	100.0%	100.0%	100.0%	-	14.3%	0.00%	100.0%	-

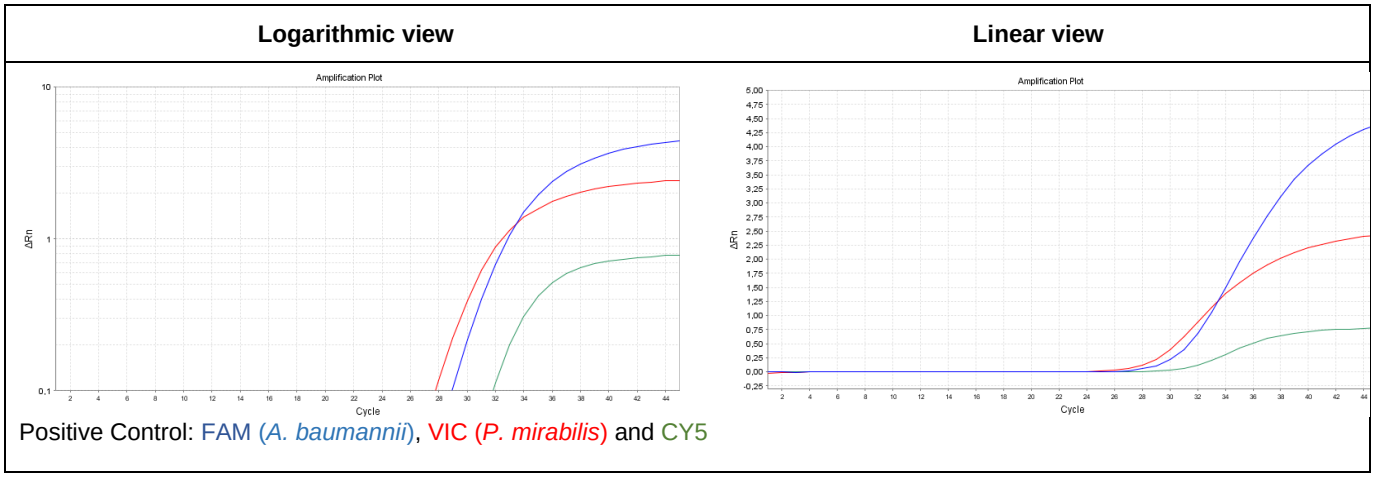

Figure 1 Performance of BactoReal® Kit *A. baumannii & P. mirabilis*

Further tests for diagnosis of sepsis, which can be combined with BactoReal® Kit *A. baumannii & P. mirabilis*:
BactoReal® Kit *E. coli* & *Klebsiella*, order no.: DHUS00153
BactoReal® Kit *Staphylococcus* spp. & *S. aureus*, order no.: DHUS00253
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
MycoReal® Kit *Candida* & *A. fumigatus*, order no.: DHUF00153

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