

# BactoReal® Kit vanA & *Enterococcus* spp.



## BactoReal® Kit vanA & *Enterococcus*

Order no.	Reactions	Pathogen	Internal positive control
DHUS00453	50	FAM + VIC channel	Cy5 channel

### Kit contents:

- Detection assay (multiplex) for vanA, *Enterococcus* 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 vanA and *Enterococcus*



**Background:** Enterococci are Gram-positive, catalase-negative and anaerobic bacteria that play an important role in the digestive system. In immunocompromised individuals, enterococci can lead to urinary tract infections, wound infections and even sepsis. Enterococci are often resistant to vancomycin.

*Enterococcus faecalis* and *Enterococcus faecium* are the best-known representatives of the *Enterococcus* species. They are used to promote the intestinal flora in probiotic food. However, in people with a weakened immune system, these bacteria can lead to severe infections, including catheter-associated urinary tract infections and sepsis.

*Enterococcus casseliflavus*, *Enterococcus durans* and *Enterococcus hirae* can rarely lead to infections in humans. *Enterococcus avium* is often found in birds but can lead to infections in humans and may be resistant to vancomycin. *Enterococcus gallinarum* has a low resistance to vancomycin and in rare cases it can lead to infections in humans ranging from meningitis to sepsis.

**Intended use:** BactoReal® Kit vanA & *Enterococcus* spp. is a non-automatic *in-vitro* diagnostic real-time PCR test for the qualitative detection and identification of extracted DNA of *Enterococcus* spp. (23S rRNA gene) as well as of the vanA resistance gene of *Enterococcus* 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 vanA & *Enterococcus* spp..

The vanA gene is detected in FAM channel and *Enterococcus* 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).

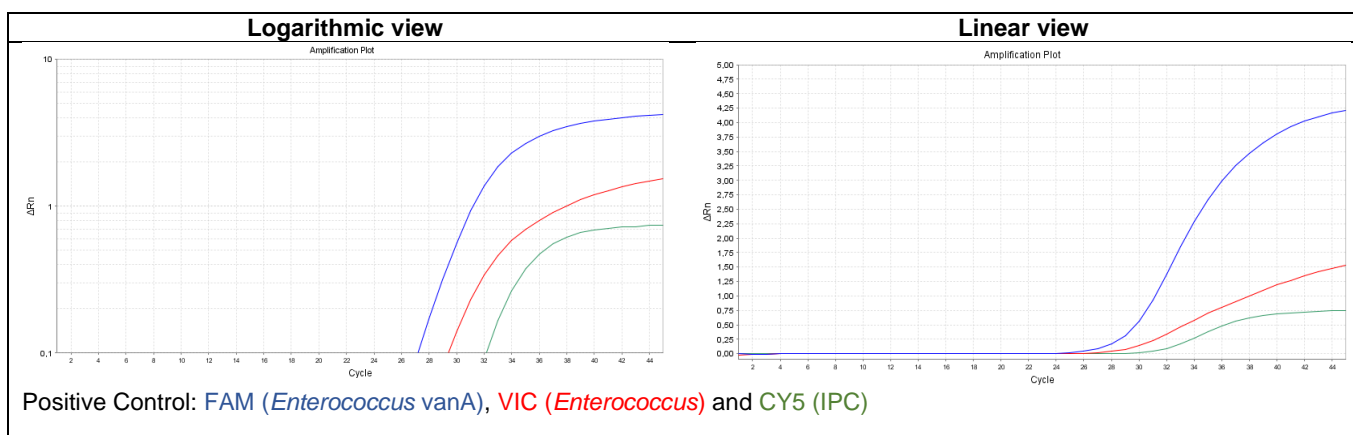
**Specificity and sensitivity:** The limit of detection (LoD95 = smallest number of target DNA copies which can be detected in 95% of cases) is 8 copies/reaction for the vanA gene and 100 copies/reaction for *Enterococcus* (corresponds to approx. 17 CFU). A cut-off with Cq=35 must be defined for *Enterococcus*.

This kit detects *E. avium*, *E. casseliflavus* (= *E. flavescens*), *E. dispar*, *E. durans*, *E. faecalis*, *E. faecium*, *E. flavescens*, *E. gallinarum*, *E. hirae*, *E. malodoratus*, *E. mundtii*, *E. pseudoavium*, *E. raffinosus* and *E. saccharolyticus*. Furthermore, it detects the vanA gene of *E. faecium* (the most common carrier of the vanA gene), of *E. durans*, *E. faecalis*, *E. gallinarum*, *E. saigonensis*, *E. casseliflavus*, *E. cecorum*, less commonly of *Clostridioides difficile*, *Staphylococcus aureus* and *Staphylococcus haemolyticus*.

**Diagnostic evaluation:** 20 blood samples and 12 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
<b>Enterococcus</b>	57.1%	100.0%	100.0%	100.0%	50.0%	100.0%	100.0%	100.0%	70.0%	25.0%	70.0%	100.0%



**Figure 1** Performance of BactoReal® Kit vanA & *Enterococcus* spp.

Further tests for diagnosis of sepsis, which can be combined with BactoReal® Kit vanA & *Enterococcus* spp.:

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

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

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

For further information on our products please visit our homepage ([www.ingenetix.com](http://www.ingenetix.com))