VIASURE

L.

"Ready & Easy-to-use" kits. Lyophilised product

> Transport and storage at room temperature. Shelf-life: 24 months

CE Validated according to ISO 13485 and CE marked

E. faecalis & E. faecium

• Enterococci are Gram-positive facultative anaerobic cocci of the family Enterococcaceae. They are widespread in nature and can be found in soil, plants, water, food and animals and can survive harsh conditions in nature.

In humans, they are predominantly inhabitants of the gastrointestinal tract and are less commonly found in other sites, such as in the genitourinary tract, the oral cavity, and skin.

Enterococcus transmission occurs endogenously (through translocation from the gut to the bloodstream) and exogenously (in the hospital environment, e.g., via inanimate objects and the hands of health care workers and visitors) or through the consumption of contaminated food and water, the latter being the most common route of transmission, especially in developing countries.

Enterococci have intrinsic resistance to some antibiotics and acquire and transfer resistance to other bacteria via mobile genetic elements. Their detection is aided by conventional Gram stain and cultures and newer techniques like MALDI-TOF, NAAT, and PCR. Antibiotic sensitivities should be obtained early on to help physicians formulate treatment plans. To avoid the high morbidity and mortality associated with this condition, it must be promptly diagnosed and treated.

VIASURE E. faecalis & E. faecium Real Time PCR Detection Kit is designed for the diagnosis of Enterococcus faecalis and Enterococcus faecium infection in blood culture and swab samples. After DNA isolation, the detection of Enterococcus faecalis and Enterococcus faecium is performed by the amplification of a conserved region of the ddl gene, using specific primers and fluorescent-labelled probes.

E. faecalis & E. faecium

VIASURE *E. faecalis & E. faecium* **Real Time PCR Detection Kit** is designed for the qualitative detection and differentiation of DNA from *Enterococcus faecalis* and *Enterococcus faecium* in blood culture and swab samples, BAS, BAL and sputum specimens by their healthcare professional (HCP).

This test is intended to be used as an aid in the diagnosis of *Enterococcus faecalis* and *Enterococcus faecium* infection in combination with clinical and epidemiological risk factors. DNA is extracted from clinical samples, amplified using real time PCR and detected using fluorescent reporter dye probes specific for *Enterococcus faecalis* and *Enterococcus faecium*.

VIASURE *E. faecalis* & *E. faecium* Real Time PCR Detection Kit contains in each well all the components necessary for real time PCR assay (specific primers/probes, dNTPs, buffer, and polymerase) in a stabilized format, as well as an internal control to verify the correct functioning of the amplification mix.

Analytical sensitivity

VIASURE *E. faecalis* & *E. faecium* **Real Time PCR Detection Kit** has a detection limit of 10 DNA copies per reaction for *Enterococcus faecalis* and *Enterococcus faecium*, with a positive rate of 95%. (Figures 1 and 2)

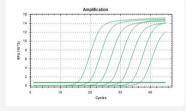


Figure 1.

Dilution series of ddl gene (E. faecalis) (10⁷-10¹ copies/rxn) template run on the CFX96™ Real-Time PCR Detection System (Bio-Rad) (channel HEX).

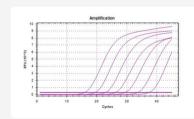


Figure 2.

Dilution series of ddl gene (E. faecium) (10⁷-10¹ copies/rxn) template run on the CFX96TM Real-Time PCR Detection System (Bio-Rad) (channel Cy5).

References - VIASURE E. faecalis & E. faecium Real Time PCR Detection Kit

1 x 8-well strips, low profile	VS-EFF101L
6 x 8-well strips, low profile	VS-EFF106L
12 x 8-well strips, low profile	VS-EFF112L
96-well plate, low profile	VS-EFF113L
4 tubes x 24 reactions	VS-EFF196T
2 x 4-well strips, Rotor-Gene®	VS-EFF101

1 x 8-well strips, high profile	VS-EFF101H
6 x 8-well strips, high profile	VS-EFF106H
12 x 8-well strips, high profile	VS-EFF112H
96-well plate, high profile	VS-EFF113H
9 x 4-well strips, Rotor-Gene®	VS-EFF136
18 x 4-well strips, Rotor-Gene®	VS-EFF172

For more information and use procedure, read the instructions for use included in this product.

certest

Certest Biotec, S.L. Pol. Industrial Río Gállego II · Calle J, N°1 50840, San Mateo de Gállego, Zaragoza (Spain) Tel. (+34) 976 520 354 | viasure@certest.es | **www.certest.es**

Modification rights reserved. All rights reserved. © CerTest Biotec, S.L. The products, services and data set out in this document may suffer changes and/or variations on the texts and pictures shown.