

Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

Specifications

Microorganism Name: Enterococcus faecalis

Catalog Number: 0366 Lot Number: 366-262

Reference Number: ATCC® 29212™*

Purity: Pure

Passage from Reference: 3

Expiration Date: 2018/10/31

Release Information:

Quality Control Technologist: Christine Condon

Amanda Kuperus **Quality Control Manager AUTHORIZED SIGNATURE**

Release Date: 2016/12/9

| Performance | | | | | | |
|---|--|--|--|--|--|--|
| Macroscopic Features: | Medium: | | | | | |
| Small to medium, gray/white, translucent, smooth, circular with entire edge | SBAP | | | | | |
| Microscopic Features: | Method: | | | | | |
| Gram positive ovoid cells, mostly in pairs or short chains | Gram Stain (1) | | | | | |
| ID System: MALDI-TOF | Other Features/ Challenges: Results | | | | | |
| See attached ID System results document. | (1) Catalase (3% Hydrogen Peroxide): negative | | | | | |
| · | (1) Bile Esculin Agar: positive | | | | | |
| | (1) Streptomycin (300 mcg - Disk Susceptibility): 14 - 20 mm | | | | | |
| | (1) Gentamicin (120 mcg - Disk Susceptibility): 16 - 23 mm | | | | | |
| | (1) SXT (1.25/23.75 mcg - Disk Susceptibility): >/= 20 mm | | | | | |
| | BHIA w/Vancomycin (6 mcg/ml): Sensitive | | | | | |
| | Amanl Supers | | | | | |

Disclaimer: The last digit(s) of the lot number appearing on the product label and packing slip are merely a packaging event number. The lot number displayed on this certificate is the actual base lot

Note for Vitek®: Although the Vitek® panel uses many conventional tests, the unique environment of the card, combined with the short incubation period, may produce results that differ from published results obtained by other methods.

A Refer to the enclosed product insert for instructions, intended use and hazard/safety information.

Individual products are traceable to a recognized culture collection.



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- (1) These tests are accredited to ISO/IEC 17025:2005.



TESTING CERT #2655.01

Bruker Daltonik MALDI Biotyper Classification Results



Meaning of Score Values

| Range | Description | Symbols | Color |
|-------------|--|---------|--------|
| 2.300 3.000 | highly probable species identification | (+++) | green |
| 2.000 2.299 | secure genus identification, probable species identification | (++) | green |
| 1.700 1.999 | probable genus identification | (+) | yellow |
| 0.000 1.699 | not reliable identification | (-) | red |

Meaning of Consistency Categories (A - C)

| Category | Description |
|----------|--|
| Α | Species Consistency: The best match was classified as 'green' (see above). Further 'green' matches are of the |
| | same species as the first one. Further 'yellow' matches are at least of the same genus as the first one. |
| В | Genus Consistency: The best match was classified as 'green' or 'yellow' (see above). Further 'green' or 'yellow' |
| | matches have at least the same genus as the first one. The conditions of species consistency are not fulfilled. |
| С | No Consistency: Neither species nor genus consistency (Please check for synonyms of names or microbial |
| | mixture). |

Analyte Name: Enterococcus faecalis

Analyte Description: 0366 Analyte ID: 366-262

Analyte Creation Date/Time: 2016-11-30T17:40:15.960 CC

Applied MSP Library(ies): BDAL, Mycobacteria Library (bead method), Filamentous Fungi Library 1.0, IVD, Listeria

Applied Taxonomy Tree:

| Analyte Name | Analyte ID | Organism (best match) | Score Value |
|-------------------|------------|-----------------------|-------------|
| <u>E12(++)(A)</u> | 366-262 | Enterococcus faecalis | 2.086 |

Comments:

| N/A | | |
|-----|--|--|
| | | |