



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

**Specifications**

**Microorganism Name:** Clostridioides difficile

**Catalog Number:** 01048

**Lot Number:** 1048-27\*\*

**Reference Number:** ATCC® BAA-1870™\*

**Purity:** Pure

**Passage from Reference:** 3

**Expiration Date:** 2020/3/31

**Release Information:**

**Quality Control Technologist:** Christine Condon

**Release Date:** 2018/5/17

**Performance**

**Macroscopic Features:**

Small to medium, grey with lighter raised center, erose edge, rough

**Microscopic Features:**

Long gram positive straight rods. Spores, when seen, are oval, subterminal (rarely terminal) and swell the cell.

**Medium:**

A/R SBAP

**Method:**

Gram Stain (1)

**ID System:** MALDI-TOF (1)

See attached ID System results document.

**Other Features/ Challenges: Results**

Egg yolk agar: lipase - negative

(1) Indole (DMACA Spot Test): negative

Amanda Kuperus

Quality Control Manager

AUTHORIZED SIGNATURE

**\*\*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 number.

**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.

⚠ 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.



# Bruker Daltonik MALDI Biotyper Classification Results



## Meaning of Score Values

| Range       | Interpretation                      | Symbols | Color  |
|-------------|-------------------------------------|---------|--------|
| 2.00 - 3.00 | High-confidence identification      | (+++)   | green  |
| 1.70 - 1.99 | Low-confidence identification       | (+)     | yellow |
| 0.00 - 1.69 | No Organism Identification Possible | (-)     | red    |

## Meaning of Consistency Categories (A - C)

| Category | Interpretation                                                                                                                                                                                                                                                                                                                 |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (A)      | <b>High consistency:</b> The best match is a high-confidence identification. The second-best match is (1) a high-confidence identification in which the species is identical to the best match, (2) a low-confidence identification in which the species or genus is identical to the best match, or (3) a non-identification. |
| (B)      | <b>Low consistency:</b> The requirements for high consistency are not met. The best match is a high- or low-confidence identification. The second-best match is (1) a high- or low-confidence identification in which the genus is identical to the best match or (2) a non-identification.                                    |
| (C)      | <b>No consistency:</b> The requirements for high or low consistency are not met.                                                                                                                                                                                                                                               |

Sample Name: Clostridioides difficile  
 Sample Description: 01048  
 Sample ID: 1048-27  
 Sample Creation Date/Time: 2018-05-02T14:26:20.355 TB  
 Applied MSP Library(ies): BDAL, Mycobacteria Library (bead method), Filamentous Fungi Library 1.0, Listeria

| Sample Name     | Sample ID | Organism (best match) | Score Value |
|-----------------|-----------|-----------------------|-------------|
| F12<br>(+++)(A) | 1048-27   | Clostridium difficile | 2.31        |

Comments:

N/A