



Certificate of Analysis: Lyophilized Microorganism Specification and Performance Upon Release

**Specifications**

**Microorganism Name:** Mycobacterium kansasii  
**Catalog Number:** 0545  
**Lot Number:** 545-19  
**Reference Number:** ATCC® 12478™\*  
**Purity:** Pure  
**Passage from Reference:** 2

**Expiration Date:** 2019/6/30

**Release Information:**

**Quality Control Technologist:** Kieshia L Negen

**Release Date:** 2017/10/3

**Performance**

**Macroscopic Features:**

At 3 weeks colonies are small, circular, convex and cream. At 4 weeks the colonies are large, circular, low raised, erose edge, pale yellow to dark yellow, rough. The center of the colony may appear opaque while the margin is transparent. As culture ages colonies become larger and darker yellow.

**Microscopic Features:**

Gram positive rods.

**Medium:**

Middlebrook 7H11

**Method:**

Gram Stain (1)

**ID System:** MALDI-TOF

See attached ID System results document.

**Other Features/ Challenges: Results**

- (1) Catalase (3% Hydrogen Peroxide): positive
- (1) Kinyoun Acid Fast Stain: positive

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.



TESTING CERT #2655.01



Meaning of Score Values

| Range       | Interpretation                      | Symbols | Color  |
|-------------|-------------------------------------|---------|--------|
| 1.80 - 3.00 | High-confidence identification      | (+++)   | green  |
| 1.60 - 1.79 | Low-confidence identification       | (+)     | yellow |
| 0.00 - 1.59 | 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: Mycobacterium kansasii  
Sample Description: 0545  
Sample ID: 545-19  
Sample Creation Date/Time: 2017-10-03T14:23:25.280 cs  
Applied MSP Library(ies): Mycobacteria Library (bead method)

| Sample Name    | Sample ID | Organism (best match)  | Score Value |
|----------------|-----------|------------------------|-------------|
| A7<br>(+++)(A) | 545-19    | Mycobacterium kansasii | 1.91        |

Comments:

N/A