

Certificate of Analysis - Certified Reference Material

thermo

scientific

Thermo Scientific<sup>TM</sup> Trademark<sup>TM</sup>  
Product Number R4601650  
Product Name C. septicum ATCC 12464 PK/5  
Lot Number 125153  
Usage Decision Accepted (OK)  
Expiration Date 2025-12-03

This product has been manufactured, processed and packaged in accordance with Quality Systems Regulation, 21 CFR Part 820. The results were derived from a representative sample of the batch and were obtained at the time of release. Refer to the enclosed product insert for instructions, intended use, hazard/safety requirements, and storage conditions.

Product Char Results	
Purity	Demonstrates pure growth on applicable media
Viability	Recovered at acceptable level within test period
Passage	3 (Current preserved state)

Microbiological testing	Results	Specification
>85% Identification on Vitek 2C ANC	97	85 - 100
Microscopic Features	Pass	

These tests are performed in accordance with ISO 17025 guidelines. Thermo Fisher Scientific has determined each loop of this reference material to be sufficiently homogeneous for its intended use. Individual products are traceable to a recognized culture collection. Although the Vitek(TM) 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

Signed



Dawn Baker  
QA Manager

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CERT #6559.01

Thermo Fisher Scientific is accredited by A2LA as a registered reference material producer certificate number 6559.01 in accordance with ISO 17034[1].

[1] ISO 17034 First Edition 2016-11-01 General requirements for the competence of reference material producers

Version 1.0



bioMérieux Customer: 1011208

System #: 504538

Last Updated: Jun 28, 2024 08:29 CDT By: MGonzalez

Isolate: 125153-1 (To be reviewed)

Card Type: ANC Bar Code: 2442750503730670 Testing Instrument: 00000B4D4CA6 (01783)

Setup Technologist: Amanda Wood(awood)

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Thermo Fisher Scientific

**Laboratory Report**

Printed by: MGonzalez

Report Version: 2 of 2

Bionumber: 0400003042011

Organism Quantity:

**Selected Organism: Clostridium septicum**

Action	Name (User ID)	Date/Time	Comment
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Installed VITEK 2 Systems Version: 9.02

MIC Interpretation Guideline:

AES Parameter Set Name:

Therapeutic Interpretation Guideline:

AES Parameter Last Modified:

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