

Certificate of Analysis - Certified Reference Material

Thermo Scientific ^{TN}	¹ Trademark TM
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 Microscopic Features	97 Pass	85 - 100						

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

Abh

Dawn Baker QA Manager

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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

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)												Printed by: MGonzale Report Version: 2 of 2					
	umber: 040 nism Quan		04201	1		Sele	cted Orga	nism:	Clost	ridium sep	ticur	n					
Com	ments:																
					ANG			McF	arlan	d:							
Identification			Card:	Lot N			2442750503		ires:	Jun 7, 2025 13:00 CDT							
Information				Status:	Analy	Analysis Time:		5.83 hour	hours Completed		pleted:	Jun 21, 2024 17:26 CDT					
Orga	nism Orig	gin		VITEK 2													
Selected Organism				Clostridium septicum Bionumber: 0400003042011 Confidence: Low discrimination													
Ana	lysis Orga	nisms	and	Tests to Se	parat	e:											
Clos Clos	Discrimin tridium sep tridium cha	oticum auvoe	1	SA		AROS	SE(0), SE(90),										
Ana	lysis Mess	ages:															
	t raindicat tridium cha		-	l Biopatter Al		(24),A	ARA(20),										
Bioc	hemical D	etails			a.												
4	dGAL	-	5	LeuA	-	6	ELLM	-	7	PheA	-	8	ProA	-	10	PyrA	+
11	dCEL	-	13	TyrA	-	15	APPA	-	18	dGLU	-	20	dMNE	-	22	dMAL	-
28	SAC	-	30	ARB	-	33	NAG	-	34	BGLUi	-	36	URE	-	37	BGURi	-
39	BGALi	+	41	AARA	+	42	AGALi	-	43	BMAN	-	44	ARG	-	45	PVATE	-

55

62

+

-

_

BNAGi

OPS

56

63

_

+

AMANi

AARAF

Thermo Fisher Scientific

Laboratory Report

53

60

-

+

ESC

IARA

MORPH

54

61

-

BdFUC

dRIB2

AERO

51

59

MTE

PHOS

GRAM

bioMérieux Customer: 1011208

57

64

+

-

AIFUC

dXYL

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) <u>Setup Technologist: Amanda Wood(awood)</u>

Printed by: MGonzalez Report Version: 2 of 2

Bionumber: 0400003042011 Organism Quantity:

Selected Organism: Clostridium septicum

Thermo Fisher Scientific

Action

Name (User ID)

Date/Time

Comment

Installed VITEK 2 Systems Version: 9.02 MIC Interpretation Guideline: AES Parameter Set Name:

Therapeutic Interpretation Guideline: AES Parameter Last Modified: Page 2 of 2