

Certificate of Analysis - Certified Reference Material

thermo**scientific**

Thermo ScientificTM TrademarkTM

Product Number

R4601219

Product Name

G. stearo**ther**ophilus ATCC 12980 PK/5

Lot Number

205356

Usage Decision

Accepted (OK)

Expiration Date

2026-06-11

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 BCL	93	85 - 100
>95% Identification on MicroSEQ		95 - 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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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

Thermo Fisher Scientific
Laboratory Report

Autoprint
Report Version: 1 of 1

Isolate: 205356-1 (To be reviewed)
Card Type: BCL Bar Code: 2392831203425997 Testing Instrument: 00000B4D4CA6 (01783)
Setup Technologist: Amanda Wood(awood)

Bionumber: 4363111120010010

Organism Quantity:

Selected Organism: Geobacillus stearothermophilus

Comments:	

McFarland:

Identification Information	Card: BCL	Lot Number: 2392831203	Expires: Aug 27, 2025 13:00 CDT
	Status: Final	Analysis Time: 13.87 hours	Completed: Jan 16, 2025 04:52 CST

Organism Origin VITEK 2

Selected Organism 93% Probability **Geobacillus stearothermophilus**
Bionumber: 4363111120010010 Confidence: Very good identification

Analysis Organisms and Tests to Separate:

Analysis Messages:

Contraindicating Typical Biopattern(s)
Geobacillus stearothermophilus APPA(1),GLYG(12),

Biochemical Details																	
1	BXYL	-	3	LysA	-	4	AspA	+	5	LeuA	+	7	PheA	+	8	ProA	-
9	BGAL	-	10	PyrA	+	11	AGAL	+	12	AlaA	+	13	TyrA	+	14	BNAG	-
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	+	22	INO	-	24	MdG	-
25	ELLM	+	26	MdX	-	27	AMAN	-	29	MTE	+	30	GlyA	-	31	dMAN	-
32	dMNE	(-)	34	dMLZ	+	36	NAG	-	37	PLE	-	39	IRHA	-	41	BGLU	-
43	BMAN	-	44	PHC	-	45	PVATE	-	46	AGLU	+	47	dTAG	-	48	dTRE	-
50	INU	-	53	dGLU	-	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	-	59	KAN	-
60	OLD	+	61	ESC	-	62	TTZ	-	63	POLYB I	-						

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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Action	Name (User ID)	Date/Time	Comment
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