

Certificate of Analysis - Certified Reference Material

thermo**scientific**

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Product Number

R4601968

Product Name

E. coli ATCC 10536 PK/5

Lot Number

257331

Usage Decision

Accepted (OK)

Expiration Date

2026-10-23

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 GN	99	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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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

Thermo Fisher Scientific  
**Laboratory Report**

Autoprint  
Report Version: 1 of 1

Isolate: 257331-1 (To be reviewed)  
Card Type: GN Bar Code: 2412977103336807 Testing Instrument: 00000B4D4CA6 (01783)  
Setup Technologist: Amanda Wood(awood)

Bionumber: 0405610450026601

Organism Quantity:

**Selected Organism: Escherichia coli**

<b>Comments:</b>	

**McFarland:**

Identification Information	Card: GN	Lot Number: 2412977103	Expires: Jan 20, 2026 12:00 CST
	Status: Final	Analysis Time: 2.92 hours	Completed: May 7, 2025 17:14 CDT
Organism Origin	VITEK 2		
Selected Organism	99% Probability Escherichia coli Bionumber: 0405610450026601 Confidence: Excellent identification		
Analysis Organisms and Tests to Separate:			
Analysis Messages:			
Contraindicating Typical Biopattern(s)			

Biochemical Details																	
2	APPA	-	3	ADO	-	4	PyrA	-	5	IARL	-	7	dCEL	-	9	BGAL	+
10	H2S	-	11	BNAG	-	12	AGLTp	-	13	dGLU	+	14	GGT	-	15	OFF	+
17	BGLU	-	18	dMAL	+	19	dMAN	+	20	dMNE	+	21	BXYL	-	22	BAlap	-
23	ProA	-	26	LIP	-	27	PLE	-	29	TyrA	-	31	URE	-	32	dSOR	+
33	SAC	+	34	dTAG	-	35	dTRE	+	36	CIT	-	37	MNT	-	39	5KG	-
40	ILATk	-	41	AGLU	-	42	SUCT	-	43	NAGA	-	44	AGAL	+	45	PHOS	-
46	GlyA	-	47	ODC	+	48	LDC	+	53	IHISa	-	56	CMT	+	57	BGUR	+
58	O129R	-	59	GGAA	-	61	IMLTa	-	62	ELLM	+	64	ILATa	-			

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**Selected Organism: Escherichia coli**

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: