

## Certificate of Analysis - Certified Reference Material

thermo scientific

Thermo Scientific<sup>TM</sup> Trademark<sup>TM</sup>  
**Product Number** R4601971  
**Product Name** E. coli ATCC 35218 PK/5  
**Lot Number** 257334  
**Usage Decision** Accepted (OK)  
**Expiration Date** 2026-10-28

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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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: 257334-1 (To be reviewed)  
Card Type: GN Bar Code: 2413032403022009 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: 2413032403	Expires: Mar 16, 2026 13:00 CDT
	Status: Final	Analysis Time: 2.60 hours	Completed: Jun 11, 2025 17:55 CDT
Organism Origin	VITEK 2		
Selected Organism	99% Probability <b>Escherichia coli</b> 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	-			

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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Autoprint  
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Isolate: 257334-1 (To be reviewed)  
Card Type: GN Bar Code: 2413032403022009 Testing Instrument: 00000B4D4CA6 (01783)  
Setup Technologist: Amanda Wood(awood)

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Bionumber: 0405610450026601

Organism Quantity:

**Selected Organism: Escherichia coli**

Action	Name (User ID)	Date/Time	Comment
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bioMérieux Customer: 1011208  
System #: 504538

Thermo Fisher Scientific  
**Laboratory Report**

Autoprint  
Report Version: 1 of 1

Isolate: 257334-2 (To be reviewed)  
Card Type: AST-GN93 Bar Code: 6833098403269339 Testing Instrument: 00000B4D4CA6 (01783)  
Setup Technologist: Amanda Wood(awood)  
Organism Quantity:                      **Selected Organism: Escherichia coli**

<b>Comments:</b>	

**McFarland:**

Identification Information	
Organism Origin	Technologist
Selected Organism	Escherichia coli
	<b>Entered:</b> Jun 11, 2025 15:17 CDT <b>By:</b> awood
Analysis Messages:	

**McFarland:**

Susceptibility Information	<b>Card:</b> AST-GN93	<b>Lot Number:</b> 6833098403	<b>Expires:</b> May 21, 2026 13:00 CDT
	<b>Status:</b> Final	<b>Analysis Time:</b> 7.73 hours	<b>Completed:</b> Jun 11, 2025 23:03 CDT

Antimicrobial	MIC	Interpretation	Antimicrobial	MIC	Interpretation
ESBL	NEG	-	Ertapenem	<= 0.5	S
Ampicillin	>= 32	R	Meropenem	<= 0.25	S
Ampicillin/Sulbactam	>= 32	R	Amikacin	<= 2	S
Piperacillin/Tazobactam	<= 4	S	Gentamicin	<= 1	S
Cefazolin	<= 4	S	Ciprofloxacin	<= 0.25	S
Ceftazidime	<= 1	S	Tigecycline	<= 0.5	S
Ceftriaxone	<= 1	S	Nitrofurantoin	<= 16	S
Cefepime	<= 1	S	Trimethoprim/ Sulfamethoxazole	<= 20	S
Aztreonam	<= 1	S			

<b>AES Findings:</b>	<b>Last Modified:</b> Mar 21, 2019 14:44 CDT <b>Parameter Set:</b> CLSI+Natural Resistance
<b>Confidence Level:</b>	Consistent

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**Laboratory Report**

Autoprint  
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Card Type: AST-GN93 Bar Code: 6833098403269339 Testing Instrument: 00000B4D4CA6 (01783)  
Setup Technologist: Amanda Wood(awood)  
Organism Quantity: **Selected Organism: Escherichia coli**

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Action	Name (User ID)	Date/Time	Comment
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