

Certificate of Analysis - Certified Reference Material

thermo scientific

Thermo Scientific™ Trademark™
Product Number R4601971
Product Name E. coli ATCC 35218 PK/5
Lot Number 242629
Usage Decision Accepted (OK)
Expiration Date 2026-09-09

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

The identity, purity, and authenticity of the Licensed Products are exclusively the responsibility of Remel Inc. and not ATCC. The ATCC Licensed Derivative Emblem, the ATCC Licensed Derivative Word mark, and the ATCC Catalog Marks are trademarks of ATCC.

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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: 242629-1 (Qualified Duplicate)
Card Type: GN Bar Code: 2412977103336817 Testing Instrument: 00000B4D4CA6 (01783)
Setup Technologist: Amanda Wood(awood)

Bionumber: 0405610450026601

Organism Quantity:

Selected Organism: Escherichia coli

Comments:	

McFarland:

Identification Information	Card: GN	Lot Number: 2412977103	Expires: Jan 20, 2026 12:00 CST
	Status: Final	Analysis Time: 2.60 hours	Completed: Apr 9, 2025 17:38 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	-			

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

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

bioMérieux Customer: 1011208
System #: 504538

Thermo Fisher Scientific
Laboratory Report

Autoprint
Report Version: 1 of 1

Isolate: 242629-1 (Qualified Duplicate)
Card Type: GN Bar Code: 2412977103336817 Testing Instrument: 00000B4D4CA6 (01783)
Setup Technologist: Amanda Wood(awood)

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: 242629-1 (Qualified Duplicate)
Card Type: AST-GN93 Bar Code: 6833098403269336 Testing Instrument: 00000B4D4CA6 (01783)
Setup Technologist: Amanda Wood(awood)

Organism Quantity: Selected Organism: *Escherichia coli*

Comments:	

McFarland:

Identification Information	
Organism Origin	Technologist
Selected Organism	Escherichia coli
	Entered: Apr 9, 2025 15:03 CDT By: awood
Analysis Messages:	

McFarland:

Susceptibility Information	Card: AST-GN93	Lot Number: 6833098403	Expires: May 21, 2026 13:00 CDT
	Status: Final	Analysis Time: 7.48 hours	Completed: Apr 9, 2025 22:31 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			

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

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System #: 504538

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Laboratory Report

Autoprint
Report Version: 1 of 1

Isolate: 242629-1 (Qualified Duplicate)

Card Type: AST-GN93 Bar Code: 6833098403269336 Testing Instrument: 00000B4D4CA6 (01783)

Setup Technologist: Amanda Wood(awood)

Organism Quantity:

Selected Organism: Escherichia coli

Action	Name (User ID)	Date/Time	Comment
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