

thermo**scientific**

Certificate of Analysis - Accredited Reference Material

Thermo ScientificTM TrademarkTM

Product Number

R4717000

Product Name

S. pyogenes ATCC 19615 Q+ KT/100 TST

Lot Number

249242

Usage Decision

Accepted (OK)

Expiration Date

2026-09-15

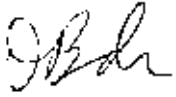
This product has been manufactured, processed and packaged in accordance with Quality Systems Regulation, 21 CFR Part 820. The results were derived from a representative sample of the batch and were obtained at the time of release. Refer to the enclosed product insert for instructions, intended use, 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	2 (Current preserved state)
Delivery	<100 CFU/0.1 mL

S. pyogenes ATCC 19615 Q+ KT/100 TST	Results	Specification
>85% Identification on Vitek 2C GP	96	85 - 100
>95% Identification on MicroSEQ		95 - 100
CFU Mean	41	-
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: 249242-1 (To be reviewed)
Card Type: GP Bar Code: 2423129403243468 Testing Instrument: 00000B4D4CA6 (01783)
Setup Technologist: Amanda Wood(awood)

Bionumber: 051432360331231

Organism Quantity:

Selected Organism: Streptococcus pyogenes

Comments:	

McFarland:

Identification Information	Card:	GP	Lot Number:	2423129403	Expires:	Jun 21, 2026 13:00 CDT
	Status:	Final	Analysis Time:	5.85 hours	Completed:	Mar 21, 2025 17:02 CDT
Organism Origin	VITEK 2					
Selected Organism	96% Probability Streptococcus pyogenes					
	Bionumber: 051432360331231			Confidence: Excellent identification		
Analysis Organisms and Tests to Separate:						
Analysis Messages:						
Contraindicating Typical Biopattern(s)						
Streptococcus pyogenes NC6.5(14),						

Biochemical Details																	
2	AMY	-	4	PIPLC	-	5	dXYL	-	8	ADH1	+	9	BGAL	-	11	AGLU	(+)
13	APPA	+	14	CDEX	-	15	AspA	-	16	BGAR	-	17	AMAN	-	19	PHOS	+
20	LeuA	+	23	ProA	(+)	24	BGURr	-	25	AGAL	-	26	PyrA	+	27	BGUR	-
28	AlaA	+	29	TyrA	+	30	dSOR	-	31	URE	-	32	POLYB	+	37	dGAL	+
38	dRIB	-	39	ILATk	-	42	LAC	-	44	NAG	+	45	dMAL	+	46	BACI	-
47	NOVO	+	50	NC6.5	+	52	dMAN	-	53	dMNE	+	54	MBdG	-	56	PUL	-
57	dRAF	-	58	O129R	+	59	SAL	-	60	SAC	+	62	dTRE	+	63	ADH2s	-
64	OPTO	+															

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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