

Certificate of Analysis - Accredited Reference Material

Thermo Scientific TM Tra	ademark TM
Product Number	R4717016
Product Name	S. aureus ATCC 6538 Q+ KT/100 TST
Lot Number	271778
Usage Decision	Accepted (OK)
Expiration Date	2026-11-26

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. aureus ATCC 6538 Q+ KT/100 TST	Results	Specification					
>85% Identification on Vitek 2C GP >95% Identification on MicroSEQ	99	85 - 100 95 - 100					
CFU Mean	55	-					
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

Abh

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

Thermo Fisher Scientific Laboratory Report

Isolate: 271778-1 (To be reviewed) Card Type: GP Bar Code: 2423163503652977 Testing Instrument: 00000B4D4CA6 (01783) Setup Technologist: Amanda Wood(awood)

Bionumber: 010400062561271 Organism Quantity:

Selected Organism: Staphylococcus aureus

Comments:	
Comments:	

McFarland:									
Identification	Card:	GP	Lot Number:	2423163503	Expires:	Jul 25, 2026 13:00 CDT			
Information	Status: Final		Analysis Time:	4.08 hours	Completed:	Jun 4, 2025 18:45 CDT			
Organism Origin	VITEK 2								
Selected Organism	99% Prot	ability	Staphylococc	us aureus					
	Bionumb	er: 010400062	2561271	Confidence: Excellent identification					
Analysis Organisms and	l Tests to S	eparate:							

Analysis Messages:

Contraindicating Typical Biopattern(s)

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	lLATk	+	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	+															

bioMérieux Customer: 1011208 System #: 504538 Thermo Fisher Scientific Laboratory Report

Autoprint Report Version: 1 of 1

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Action

Name (User ID)

Date/Time

Comment

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

Therapeutic Interpretation Guideline: AES Parameter Last Modified: Page 2 of 2