

Certificate of Analysis - Certified Reference Material

thermo**scientific**

Thermo ScientificTM TrademarkTM

Product Number

R4608250

Product Name

S. agalactiae Gp B ATCC 13813 PK/5

Lot Number

157501

Usage Decision

Accepted (OK)

Expiration Date

2026-02-12

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 GP	94	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

Comments:

McFarland:						
Identification Information	Card:	GP	Lot Number:	2422830403	Expires:	Aug 26, 2025 13:00 CDT
	Status:	Final	Analysis Time:	4.85 hours	Completed:	Aug 20, 2024 16:52 CDT
Organism Origin	VITEK 2					
Selected Organism	94% Probability Streptococcus agalactiae					
	Bionumber: 031454365733471			Confidence: Very good identification		
Analysis Organisms and Tests to Separate:						
Analysis Messages:						
Contraindicating Typical Biopattern(s)						
Streptococcus agalactiae BGAL(21),AGLU(86),						

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	+															

bioMérieux Customer: 1011208
System #: 504538

Thermo Fisher Scientific
Laboratory Report

Autoprint
Report Version: 1 of 1

Isolate: 157501-1 (To be reviewed)
Card Type: GP Bar Code: 2422830403172852 Testing Instrument: 00000B4D4CA6 (01783)
Setup Technologist: Amanda Wood(awood)

Bionumber: 031454365733471

Organism Quantity:

Selected Organism: Streptococcus agalactiae

Action	Name (User ID)	Date/Time	Comment
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