

Certificate of Analysis - Certified Reference Material

thermo**scientific**

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Product Number

R4608250

Product Name

S. agalactiae Gp B ATCC 13813 PK/5

Lot Number

241207

Usage Decision

Accepted (OK)

Expiration Date

2026-09-03

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		85 - 100
>95% Identification on MicroSEQ	100	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

MicroSEQ ID Report



Generated at: 07 Apr 2025 at 09:54:10 CDT

241207

241207	No Mismatch
Streptococcus agalactiae (^ATCC=13813) 100.00	No Mismatch

Specimen : 241207

= 1.0655%

