

Certificate of Analysis - Certified Reference Material

thermo**scientific**

Thermo ScientificTM TrademarkTM

Product Number

R4606500

Product Name

S. epidermidis ATCC 12228 PK/5

Lot Number

241372

Usage Decision

Accepted (OK)

Expiration Date

2026-09-08

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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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



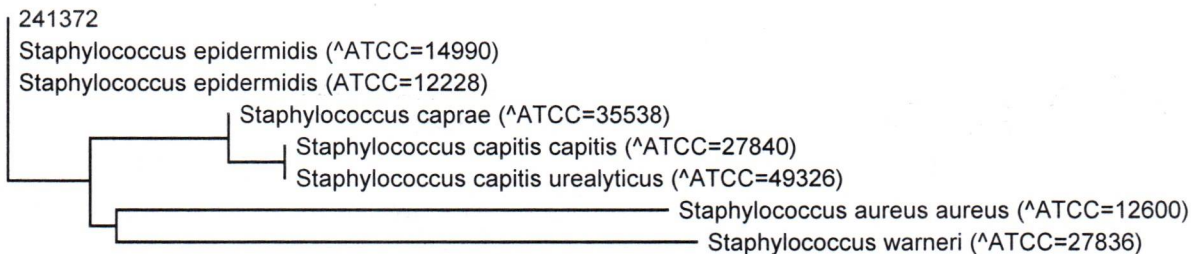
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241372

| | |
|---|-------------|
| 241372 | No Mismatch |
| Staphylococcus epidermidis (^ATCC=14990) 100.00 | No Mismatch |

Specimen : 241372

☐ = 0.4761%



Project Creator: MGonzalez: Maria Bergman-Gonzalez

Printed by: MGonzalez: Maria Bergman-Gonzalez