thermoscientific

Certificate of Quality

Product Name: MicroScan Gram-positives QC Set/8
Lot Number: 286154
Product Number: R4661001
Expiration Date: 2026-08-20
(YYYY-MM-DD)

This product has been manufactured, processed and packaged in accordance with Quality Systems Regulation, 21 CFR Part 820. Representative samples were tested per Remel Inc., a part of Thermo Fisher Scientific Quality Control specifications and were found to performance criteria for this product.

Purity:
Standardized aliquots of the rehydrated product are inoculated onto nonselective media and examined for pure growth following the appropriate incubation. Selective and Differential media are also tested where applicable.

Viability And Quantification:
Each organism is recovered from the preserved state within the required time frame and at an acceptable level. Passage number is stated as the current preserved state.

Macroscopic And Microscopic Morphology:
Colony morphology is consistent with documented referenced description.
Traditional staining is performed.

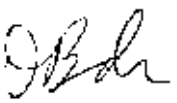
Biochemical Analysis:
Organism exhibits characteristic biochemical and/or enzymatic reactions. Automated and/or conventional testing was performed and results were within established limits. Antimicrobial testing performed where applicable. Results within expected ranges.

Enterococcus faecalis	29212	Gram Positive Cocci	Vitek 2 Compact GP
Micrococcus luteus	49732	Gram Positive Cocci	Vitek 2 Compact GP
Staphylococcus aureus	29213	Gram Positive Cocci	Vitek 2 Compact GP
Streptococcus gallolyticus	49147	Gram Positive Cocci	Vitek 2 Compact GP
Escherichia coli	35218	Gram Negative Rod	Vitek 2 Compact GN
Enterococcus faecalis	51299	Gram Positive Cocci	Vitek 2 Compact GP
Staphylococcus aureus	43300	Gram Positive Cocci	Vitek 2 Compact GP
Staphylococcus aureus	BAA-977	Gram Positive Cocci	Vitek 2 Compact GP

CFU/loop: >10(4)
Passage: Kit - All <5

Appearance: Preserved Gel Matrix suspended in inoculating loop
pH: N/A

Signed



Senior Quality Assurance Engineer