

## Certificate of Quality

**Product Name:** MicroScan Gram-positives QC Set/4  
**Lot Number:** 245725

**Product Number:** R4661001  
**Expiration Date:** 2018-09-06  
(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



Quality Assurance Supervisor