



## Certificate of Quality

**Product Name:** Vitek 2 AST-GP QC SET/7  
**Lot Number:** 674642

**Product Number:** R4652019  
**Expiration Date:** 2009-11-30  
(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 Quality Control specifications and were found to meet 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.

	Strain	Gram Reaction:	Profile:
Enterococcus faecalis	29212	Gram Positive Cocci	Vitek GPI
Enterococcus faecalis	51299	Gram Positive Cocci	Vitek GPI
Escherichia coli	35218	Gram Negative Rod	Vitek GNI +
Staphylococcus aureus	29213	Gram Positive Cocci	Vitek GPI
Streptococcus pneumoniae	49619	Gram Positive Cocci	Vitek GPI

CFU/1ml: >10(4)

Passage: Kit - All <5

Appearance: Preserved Gel Matrix suspended in inoculating loop

pH: N/A

Signed

Quality Control Supervisor