



Certificate of Quality

Product Name: Vitek GPI QC 1 Loop SET/7
Lot Number: 814120

Product Number: R4682010
Expiration Date: 2010-03-31
(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.

		Gram Reaction:	Profile:
Enterococcus faecalis	29212	Gram Positive Cocci	Vitek GPI
Erysipelothrix rhusiopathiae	19414	Gram Positive Rod	Vitek GPI
Enterococcus durans	6056	Gram Positive Cocci	Vitek GPI
Staphylococcus xylosus	29971	Gram Positive Cocci	Vitek GPI
Streptococcus gallolyticus	9809	Gram Positive Cocci	Vitek GPI
Streptococcus equi	9528	Gram Positive Cocci	Vitek GPI
Streptococcus pyogenes	19615	Gram Positive Cocci	Vitek GPI

CFU/loop: >10(4)

Passage: Kit - All <5

Appearance: Preserved Gel Matrix suspended in inoculating loop

pH: N/A

Signed

Quality Control Supervisor