

Certificate of Quality

Product Name: Vitek 2 GP 21342 QC Set/9 **Lot Number:** 254587 **Product Number:** R4652020 **Expiration Date:** 2026-04-21

(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.

(Organism:	Strain:	Gram Reaction:	Profile:
S	Streptococcus equi ssp zooepidemicus	43079	Gram Positive Cocci	Vitek 2 GP
F	Enterococcus casseliflavus	700327	Gram Positive Cocci	Vitek 2 GP
ŀ	Kocuria kristinae	BAA 752	Gram Positive Cocci	Vitek 2 GP
Ι	Listeria monocytogenes	BAA 751	Gram Positive Rod	Vitek 2 GP
S	Streptococcus pneumoniae	49619	Gram Positive Cocci	Vitek 2 GP
S	Staphylococcus sciuri	29061	Gram Positive Cocci	Vitek 2 GP
S	Streptococcus thermophilus	19258	Gram Positive Cocci	Vitek 2 GP
F	Enterococcus saccharolyticus	43076	Gram Positive Cocci	Vitek 2 GP
S	Staphylococcus saprophyticus	BAA 750	Gram Positive Cocci	Vitek 2 GP
S	Streptococcus pneumoniae Staphylococcus sciuri Streptococcus thermophilus Enterococcus saccharolyticus	49619 29061 19258 43076	Gram Positive Cocci Gram Positive Cocci Gram Positive Cocci Gram Positive Cocci	Vitek 2 GP Vitek 2 GP Vitek 2 GP Vitek 2 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