

# **Certificate of Quality**

**Product Name:** Vitek 2 GP 21342 QC Set/9 **Lot Number:** 264156 **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:                          | <b>Gram Reaction:</b>  | 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<br>Staphylococcus sciuri<br>Streptococcus thermophilus<br>Enterococcus saccharolyticus | 49619<br>29061<br>19258<br>43076 | Gram Positive Cocci<br>Gram Positive Cocci<br>Gram Positive Cocci<br>Gram Positive Cocci | Vitek 2 GP<br>Vitek 2 GP<br>Vitek 2 GP<br>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