

Certificate of Quality

Product Name: Vitek 2 AST-GN Set/4
Lot Number: 197131

Product Number: R4652018
Expiration Date: 2026-04-01
(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.

	Strain	Gram Reaction:	Profile:
Escherichia coli	25922	Gram Negative Rod	API 20E
Escherichia coli	35218	Gram Negative Rod	Vitek GN
Pseudomonas aeruginosa	27853	Gram Negative Rod	Vitek GN
Klebsiella pneumoniae	700603	Gram Negative Rod	Vitek GN

CFU/1ml: >10(4) Passage: Kit - All <5

Appearance: Preserved Gel Matrix suspended in inoculating loop
pH: N/A

Signed

Senior Quality Assurance Engineer