

Certificate of Quality

Product Name:Xpect C. diff Toxin A/B KT/20TSTProduct Number: R24650Lot Number:299133Expiration Date: 2025-11-11

(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 meet performance criteria for this product.

Kit Components	Quantity
Lateral Flow Cassettes	20
Conjugate Reagent 1	1 X 3.6 mL
Conjugate Reagent 2	1 X 3.0 mL
Positive Control	1 X 2 mL
Negative Control	1 X 2 mL
Sample Diluent	1 X 12 mL

Performance Characteristics

Test Item	Specification	Result
Positive Control	Test Line Present	Pass
Negative Control	No Test Line Present	Pass

Microbial Load Evaluation:

Product is evaluated for performance specifications only.

Signed

Senior Quality Assurance Engineer