



PROVEN DIAGNOSTIC PERFORMANCE

CERTIFICATE OF ANALYSIS

Product: C. DIFF QUIK CHEK COMPLETE\* Catalog: T30550C
Lot: 0224014 Expiration: 2026/01/01
Date of Manufacture: 2024/02/06

Biological components and specifications:
All components meet individual release criteria.

Table with 4 columns: Description, Product #, Lot #, Exp. Date. Rows include Conjugate, Diluent, Membrane Device, Positive Control, Membrane Substrate, Wash Buffer, Pipettes, Product Insert, and Instructional Card.

Kit functionality:

The C. DIFF QUIK CHEK COMPLETE\* test has been tested and released to meet the criteria detailed below:

- Positive Control = Visible Control Line and Visible Antigen and Toxin Test Lines
Negative Control (Diluent) = Visible Control Line and No Visible Test Lines
Toxin A (Lot # 0723406 ) = Visible Control Line and Visible Toxin Test Line at >= 0.63 ng/mL
Toxin B (Lot # 0822346 ) = Visible Control Line and Visible Toxin Test Line at >= 0.16 ng/mL
rGDH (Lot # 0323172 ) = Visible Control Line and Visible Antigen Test Line at >= 0.8 ng/mL

Ingredients of animal origin are sourced from countries/areas with no-risk or low-risk status for bovine spongiform encephalopathy (BSE).

This product has been manufactured in accordance with the requirements of the TECHLAB, Inc. Quality Management System. TECHLAB performs quality control and release testing of all in vitro diagnostic test kits manufactured and released for sale.

Logan Hollyfield 4/11/2024
Quality Assurance Representative/Date

Revision: 01-13-2023