



PROVEN DIAGNOSTIC PERFORMANCE

CERTIFICATE OF ANALYSIS

Product: C. DIFF QUIK CHEK COMPLETE®

Catalog: T30525C

Lot: 0125005

Expiration: 2026-10-01

Date of Manufacture: 2025-01-30

Biological components and specifications:

All components meet individual release criteria.

<u>Description</u>	<u>Product #</u>	<u>Lot #</u>	<u>Exp. Date</u>
Conjugate	5038C	1224038	2026-12-01
Diluent	5038D	1024129	2026-10-01
Membrane Device	5038MD	1224039	2026-12-01
Positive Control	5038P	1024131	2026-10-01
Membrane Substrate	MS2	1224040	2028-08-19
Wash Buffer	MW2	1224042	2026-12-01
Pipettes	93-219-00		
Product Insert	91-T525C-02-TL		
Instructional Card	91-525C-02-TL		

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 # 0324136) = Visible Control Line and Visible Toxin Test Line at ≥ 0.16 ng/mL

rGDH (Lot # 0824263) = 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. The results of this testing are documented per the TECHLAB Quality Management System. A Certificate of Analysis is issued for each lot of material tested and passed against required Quality Control release specifications.

Bethany Atike 3/14/2025

Quality Assurance Representative/Date

Revision: 01-13-2023



PROVEN PERFORMANCE IN
GI DISEASE DIAGNOSTICS

Certificate of Origin

August 27, 2021

Legal Manufacturer Name: TECHLAB, Inc.

Product Number(s): T30525C / T30550C

Product Description(s): *C. DIFF QUIK CHEK COMPLETE®*

The product listed above is manufactured in the United States and is labeled as, "Made in the USA" per the Federal Trade Commission (FTC) regulations.

A handwritten signature in black ink, appearing to read "Donna T. Link", written over a horizontal line.

Donna T. Link
Director Regulatory and Compliance
TECHLAB, Inc.