



Trinity Biotech

Certificate of Analysis

Product Name: TRI-stat Reagent Kit

REF: 03-06-0010

Lot Number: 7678 (1G)

Production Date: 2017-11-28

Expiration Date: 2019-02-28

Manufactured/Distributed By: Trinity Biotech, Kansas City, Missouri, USA

Storage Requirements: Store refrigerated in an upright position at 2-8°C. **DO NOT FREEZE.**
See Package Insert for instructions on usage and stability.

Intended Use: The Tri-stat Reagent Kit for use with Trinity Biotech Tri-stat Analyzer, is a rapid *in vitro* test for measuring the level of glycated haemoglobin (HbA1c) in human blood from finger stick or venous samples.

Method of Analysis:

Control Performance

Standard: No test value outside of controls upper and lower limit on Tri-stat analyzer

Result: Meets specification.

Whole Blood Performance

Standard: No test value outside of controls upper and lower limit on Tri-stat analyzer

Result: Meets specification

Correlation

Standard: No correlation value outside of the lower limit on Tri-stat analyzer ($r^2 > 0.980$)

Result: Meets specification

Key Card Conformance

Standard: Tri-stat analyzer accurately displays the reagent calibration information

Result: Key card is scanned accurately by the Tri-stat analyzer.

Approval

Quality Manager:

Date:

12/7/2017