



## Certificate of Analysis

**Product Name:** Tri-stat Reagent Kit (30); (60); (90)

**REF:** 03-06-0070; 03-06-0071; 03-06-0072

**Lot Number:** 8414 (1U)

**Production Date:** 2018-04-04

**Expiration Date:** 2019-08-31

**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:

4/16/2018