

Certificate of Analysis

Product Name: TRI-stat Liquid Controls Kit

REF: 03-06-0011

Lot Number: 9270

Production Date: 2018-10-18

Expiration Date: 2019-07-31

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

Storage Requirements: Store liquid material in original container at 2-8°C up to the expiration date. See Package Insert for instructions on usage and stability.

Intended Use: Tri-stat Liquid Controls are intended for the control of the quantitative HbA1c affinity assay on the Tri-stat Analyzer only. No other control materials may be used with the Tri-stat and will not perform correctly. This control may not be used with other systems. For *in vitro* use only.

Method of Analysis: Performance Testing in Comparison to Reference Materials
Standard: HPLC performance validation in comparison to reference standards.
Result:

Product:

Trinity Biotech Tri-stat Liquid Control Kit Lot # 9270									
Units		Control Level I Lot # 9271				Control Level II Lot # 9272			
		☒	☐ RNG			☒	☐ RNG		
Trinity Biotech Tri-stat									
HbA1c (NGSP)	%	6.3	5.6	-	7.0	10.4	9.4	-	11.4
HbA1c (IFCC)	S.I.*	45	38	-	53	90	79	-	101
Trinity Biotech Tri-stat 2									
HbA1c (NGSP)	%	6.9	6.2	-	7.6	11.2	10.1	-	12.3
HbA1c (IFCC)	S.I.*	52	44	-	60	99	87	-	111
S.I.* units (<i>Système Internationale</i>) = mmol HbA1c/mol Hb									

Traceability to International Reference Standards

Standard: Value assignment to NGSP and IFCC reference materials.

Results: Value assignment to NGSP and IFCC reference materials. Meets specification

Testing to Confirm Non-Reactive for Common Pathogens

Standard: Verify test results or confirm certification that source materials have been tested and found non-reactive for common pathogens, including HBsAg, HbC, HIV 1&2, HCV, HTLV I/II, HIV 1&2-RNA, Syphilis, HBV-DNA.

Result: Verified with testing confirmed to be negative/non-reactive for pathogens.

Approval

Quality Manager:



Date: 11/8/2018