



Lot Number: 8610 **Manufacture Date:** 2018-06-12 **Shelf-Life/Expiration Date:** 2019-06-30

Product Name: HbA1c (GHb) Controls Kit, 500µl (Levels I & II)

REF: 01-04-0020

Manufactured/Distributed By: Trinity Biotech

Storage Requirements: Store lyophilized material in original container at 2-8°C up to the expiration date. See Package Insert for instructions on storage of reconstituted, aliquot, and diluted materials.

Intended Use: Hemoglobin A1c (HbA1c) Controls are intended for use as a quality control material to monitor the precision of laboratory testing procedures for HbA1c quantitation 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:

Trinity Biotech HbA1c (GHb) Control Kit Lot # 8610									
Units		Control Level I Lot # 8611				Control Level II Lot # 8612			
		$\bar{x}$	RNG			$\bar{x}$	RNG		
Premier Hb9210									
HbA1c (NGSP)	%	5.5	5.2	-	5.8	11.5	10.9	-	12.1
HbA1c (IFCC)	S.I.*	37	34	-	40	102	95	-	109
PDQ									
HbA1c (NGSP)	%	5.4	5.1	-	5.7	11.4	10.8	-	12.0
HbA1c (IFCC)	S.I.*	36	33	-	39	101	94	-	108
Ultra2									
HbA1c (NGSP)	%	5.5	5.2	-	5.8	11.7	11.1	-	12.3
HbA1c (IFCC)	S.I.*	37	34	-	40	104	97	-	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-Reactivity for Common Pathogens

Standard: Verify test results or confirm certification that source material have been tested and found non-reactive for common pathogens, including HBsAG, HIV-1, HIV-2, and HCV.

Results: Testing certification confirmed to be negative/non-reactive for common pathogens.

Approval

Quality Manager:

Date:

7/16/2018

PH 7/16/18
JL