



Trinity Biotech

Certificate of Analysis

Lot Number: 7260 **Manufacture Date:** 2017-08-08 **Shelf-Life/Expiration Date:** 2018-08-31

Product Name: HbA1c (GHb) Controls Kit, 400µl (Levels I & II)

REF: 01-04-0015

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 # 7260									
Units		Control Level I Lot # 7261				Control Level II Lot # 7262			
		$\bar{x}$	RNG			$\bar{x}$	RNG		
Premier Hb9210									
HbA1c (NGSP)	%	6.0	5.7	-	6.3	10.4	9.8	-	11.0
HbA1c (IFCC)	S.I.*	42	39	-	45	90	83	-	97
PDQ									
HbA1c (NGSP)	%	6.0	5.7	-	6.3	10.2	9.6	-	10.8
HbA1c (IFCC)	S.I.*	42	39	-	45	88	81	-	95
Ultra2									
HbA1c (NGSP)	%	6.1	5.8	-	6.4	10.5	9.9	-	11.1
HbA1c (IFCC)	S.I.*	43	40	-	46	91	84	-	98
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:

9/8/2017

09/08/17