Trinity Biotech

Certificate of Analysis

Lot Number: 8660 **Manufacture Date:** 2018-06-12 **Shelf-Life/Expiration Date:** 2019-06-30

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 # 8660									
		Control Level I Lot # 8661				**Control Level II Lot # 8662**			
Units		$\bar{x}$	**RNG**			$\bar{x}$	**RNG**		
Premier Hb9210									
HbA1c (NGSP)	%	5.9	5.6	-	6.2	10.6	10.0	-	11.2
HbA1c (IFCC)	S.I.*	41	38	-	44	92	85	-	99
PDQ									
HbA1c (NGSP)	%	5.8	5.5	-	6.1	10.5	9.9	-	11.1
HbA1c (IFCC)	S.I.*	40	37	-	43	91	84	-	98
Ultra2									
HbA1c (NGSP)	%	6.0	5.7	-	6.3	10.9	10.3	-	11.5
HbA1c (IFCC)	S.I.*	42	39	-	45	96	89	-	103
S.I.* units (*Sistème Internationale*) = 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: 7/17/2018

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PH 7/17/18