



Lot Number: 8650 **Manufacture Date:** 2018-06-12 **Shelf-Life/Expiration Date:** 2019-06-30

Product Name: HbA1c (GHb) Calibrator Kit, 400µl (Levels 1 & 2)

REF: 01-04-0018

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) Calibrators are intended for the calibration of quantitative HbA1c affinity assays. 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) Calibrator Kit Lot # 8650			
	Units	Calibrator 1 Lot # 8651	Calibrator 2 Lot # 8652
Premier Hb9210			
HbA1c (NGSP)	%	5.2	12.0
HbA1c (IFCC)	mMol HbA1c/Mol Hb	33	108
PDQ			
HbA1c (NGSP)	%	5.2	11.8
HbA1c (IFCC)	mMol HbA1c/Mol Hb	33	105
Ultra2			
HbA1c (NGSP)	%	5.3	12.1
HbA1c (IFCC)	mMol HbA1c/Mol Hb	34	109

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

PH 7/17/18
10/18/18