



Trinity Biotech

Certificate of Analysis

Lot Number: 7350

Manufacture Date: 2017-11-01

Shelf-Life/Expiration Date: 2018-11-30

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 # 7350			
	Units	Calibrator 1 Lot # 7351	Calibrator 2 Lot # 7352
Premier Hb9210			
HbA1c (NGSP)	%	5.2	11.9
HbA1c (IFCC)	mMol HbA1c/Mol Hb	33	107
PDQ			
HbA1c (NGSP)	%	5.1	11.5
HbA1c (IFCC)	mMol HbA1c/Mol Hb	32	102
Ultra2			
HbA1c (NGSP)	%	5.3	12.2
HbA1c (IFCC)	mMol HbA1c/Mol Hb	34	110

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: 12/7/2017

PH 12/7/17