Trinity Biotech

HbA1c (GHb) Controls

REF 01-04-0015 CON 1 x 400 µL Level I Control
1 x 400 µL Level II Control

Pour d'autres langues
Für andere Sprachen
Para otras lenguas
Per le altre lingue
Dla innych języków
Para outras línguas
Για τις άλλες λώσσες
För andra språk
For andre språk

www.trinitybiotech.com

INTENDED USE

The Hemoglobin A1c Control is intended for use as a quality control material to monitor the precision of laboratory testing procedures for HbA1c quantitation. For *in vitro* diagnostic use only. IVD

SUMMARY AND EXPLANATION OF THE TEST

Recognition of the usefulness of HbA1c in the control of diabetes has led to a substantial demand for its measurement by clinical laboratories.[1,2,3,4,5] Reliable use of the data generated necessitates good accuracy and precision in the Hemoglobin A1c measurement. Factors such as pH, ionic strength, temperature, dilution and column equilibration can affect the performance of the assay. In order to assure the accuracy and precision of this assay, high quality Control material should be used. The Trinity Biotech HbA1c (GHb) Controls were developed to assist with these requirements.

Good laboratory practice provides a system of management controls to ensure the consistency and reliability of analytical results (e.g., standard operating procedures, uniform sample collection and handling practices, performance training of personnel, statistical evaluation of control results, proper storage of test kits and controls, a permanent record of control results, etc.). Use of external control samples assures the test reagents are working properly, that the Trinity Biotech Affinity Hemoglobin A1c analyzer is calibrated properly, and that the operator has performed the test correctly. If the controls do not perform as expected (i.e., within given acceptance ranges), review the instructions for use to see if the test was performed correctly; repeat the test or contact Trinity Biotech Technical Service before testing patient samples.

The staff at each laboratory site will benefit by establishing a quality assurance plan, based on their institution's policies. Run quality control specimens, for example, under the following conditions:

- At regular intervals determined by the laboratory procedures
- With each new shipment of reagents and with each new lot of reagents
- Each time a calibration is performed
- To train and confirm performance acceptability for new analysts
- When results do not match the patient's clinical condition or symptoms

Good laboratory practices include a well-designed and implemented quality control process. These practices, for example, may involve:

- Proper storage and handling of reagents kits
- Careful sample collection and handling procedures
- Training of testing personnel
- Routine review of sample and control results
- Periodic quality system reviews
- Retention of quality control testing records

If the problem cannot be corrected, or the reason for an out-of-limits result cannot be determined, contact Trinity Biotech or the Trinity Biotech Distributor nearest you.

PRINCIPAL OF THE PROCEDURE

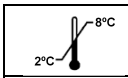
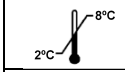
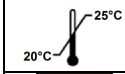
Utilizing the principles of boronate affinity and high-performance liquid chromatography (HPLC), the assay separates and quantitates Glycated Hemoglobin in whole blood and hemolysates of whole blood. Glycated Hemoglobin is separated from non-Glycated Hemoglobin which is then quantitated with an HbA1c result generated based on that ratio.

REAGENTS / COMPONENTS

1 vial lyophilized Trinity Biotech HbA1c (GHb) Level I Control
1 vial lyophilized Trinity Biotech HbA1c (GHb) Level II Control
1 Package insert

The Trinity Biotech Level I and Level II HbA1c (GHb) Controls included in the HbA1c (GHb) Kit are prepared from non-diabetic and glycated non-diabetic whole blood. Each sample provides a clear, cherry red hemolysate containing oxyhemoglobin with low and high HbA1c values as indicated in the assay data section. Once reconstituted, each vial's content is 400 µL (microliters) of HbA1c (GHb) Control material.

STORAGE AND STABILITY

	**Lyophilized:** Lyophilized vials of Trinity Biotech HbA1c (GHb) Control stored at 2°C – 8°C are stable until the expiration date on the label.
	**Reconstituted:** Once reconstituted, the Trinity Biotech HbA1c (GHb) is stable at 2°C – 8°C for 30 days.
	**Diluted:** Diluted samples of Trinity Biotech HbA1c (GHb) Control are stable for 8 hours at 20°C – 25°C.
	**DO NOT USE** after the expiration date.

PRECAUTIONS

CAUTION: For *In Vitro* Diagnostic IVD Use ONLY

SAFETY GLASSES, GLOVES AND LAB COAT ARE RECOMMENDED WHEN USING THE TRINITY BIOTECH HbA1c (GHb) CONTROLS.

DO NOT USE: If diluted sample turns dark brown.

POTENTIALLY BIOHAZARDOUS MATERIAL

Human sourced materials were used in the manufacturing of this product. This product was found to be non-reactive for hepatitis B surface antigen (HBsAg), antibodies to hepatitis C (HCV), and antibodies to Human Immunodeficiency Viruses (HIV-1 and HIV-2), when tested by FDA cleared methods. No known test method can offer assurance that products derived from human blood will not transmit disease, and material should be handled as such.

PREPARATION PROCEDURE

RECONSTITUTION

1. Tap bottom of vial gently to settle material in vial.
2. Open the vial.
3. Add 400µL of Trinity Biotech Diluent to the vial. Trinity Biotech Diluent REF 01-03-0013 (DIL, 940mL), 01-03-0056 (2DIL, 3.8L), 01-03-0059 (2DIL, 940mL), 01-03-0066 (PDQ DIL), 01-03-0101 (Premier Hb9210™ Sample Diluent, 940 mL), **or** 01-03-0097 (Premier Hb9210™ DIL Reagent, 3.8L). Replace cap. Allow the vial to stand for ten minutes, then rotate gently until completely dissolved.
4. For further dilution, treat the HbA1c (GHb) Control as whole blood.

DILUTIONS

Following instructions below, dilute the reconstituted HbA1c (GHb) Controls using Trinity Biotech Diluent in the same manner required in the assay for a patient sample. The reconstituted HbA1c (GHb) Controls have the same hemoglobin concentration as whole blood.

System/Injector with Injection Volume (µL)	Dilution Ratio	Typical Dilution µL Control : µL Diluent	Vial Type
Premier Hb9210™ (5µL)	1:150	10:1490	Untreated Test Tube
PDQ / PDQ PLUS (10µL)	1:100	20:1980	Untreated PDQ Tube
ultra[2] w/215 (20µL)	1:200	5:995 (or 8:1592)	Shell or Crimp Top

Prior to making each HbA1c (GHb) Control dilution, rotate the HbA1c (GHb) Control vial gently and ensure material is uniformly mixed and in solution.

TEST PROCEDURE

After reconstitution and dilution of the HbA1c (GHb) Control material, it should be analyzed in the same manner as patient samples.

RESULTS AND INTERPRETATION OF RESULTS

These Trinity Biotech HbA1c (GHb) Control materials have been assigned values utilizing NGSP and/or IFCC primary HbA1c reference materials. According to these reference materials, each Trinity Biotech HbA1c system has been assigned a system-specific control range to optimize accuracy. Individual laboratory means should fall within the corresponding acceptable range; however, laboratory means may vary from the listed values during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides. When assayed by the Trinity Biotech HPLC Affinity method, the results on each Trinity Biotech analyzer should fall within these limits:

Trinity Biotech HbA1c (GHb) Control Set Points and Ranges:

Trinity Biotech HbA1c (GHb) Control Kit LOT 6560		EXP 2017-04-30							
		Control Level I LOT 6561				Control Level II LOT 6562			
	Units	$\bar{x}$	RNG			$\bar{x}$	RNG		
Premier Hb9210™									
HbA1c (NGSP)[6]	%	5.9	5.6	-	6.2	10.4	9.8	-	11.0
HbA1c (IFCC)[7]	S.I.*	41	38	-	44	90	83	-	97
PDQ									
HbA1c (NGSP)[6]	%	5.9	5.6	-	6.2	10.2	9.6	-	10.8
HbA1c (IFCC)[7]	S.I.*	41	38	-	44	88	81	-	95
ultra[2]									
HbA1c (NGSP)[6]	%	6.1	5.8	-	6.4	10.7	10.1	-	11.3
HbA1c (IFCC)[7]	S.I.*	43	40	-	46	93	86	-	100

S.I.* units (*Sistème Internationale*) = mmol HbA1c/mol Hb

Users of other methods, including HPLC ion-exchange, should determine their own values.

Premier Hb9210™ Primary Reporting Method Barcodes

Please ensure you scan the relevant barcode set below applicable to your Primary Reporting Method. Note that if you are dual-reporting on the Premier Hb9210™ you do not need to scan the barcodes for the secondary reporting method.

For %HbA1c Values (NGSP/DCCT Referenced)

Premier Hb9210™ HbA1c (GHb) Control Level I Barcode, lot 6561 rrM*:4H*x%4	
Premier Hb9210™ HbA1c (GHb) Control Level II Barcode, lot 6562 PrM_:dA!~8d	

For mmol HbA1c/mol Hb Values (IFCC Referenced)

Premier Hb9210™ HbA1c (GHb) Control Level I Barcode, lot 6561 rrM*:4H*x%4	
Premier Hb9210™ HbA1c (GHb) Control Level II Barcode, lot 6562 PrM_:dA!<8t	

Validation of Assigned Values

The Premier Hb9210™ NGSP & IFCC set points detailed for this HbA1c (GHb) Control kit have been independently verified by the IFCC Network Laboratory of the Queen Beatrix Hospital in Winterswijk, The Netherlands (Dr. Cas Weykamp).

LIMITATIONS

- This product should not be used past the expiration date.
- If there is evidence of microbial contamination, brown color or excessive turbidity in the reconstituted HbA1c (GHb) Control, discard the vial.
- This product is not intended for use as a standard.

	Important Information	Ending or bracketed HbA1c (GHb) Control verifications are recommended with patient specimen testing runs to ensure optimal performance and quality of reported results. Please refer to the system Operator's Manual chapter titled 'Results and Interpretation' for additional information regarding baseline verification and chromatography verification checks.

REFERENCES

1. Trivelli, *New Engl. J. of Med.*, 284, 353, (1971).
2. Gabbay, K.H., *et al., J. Clin. End & Metabl.*, 44, 859, (1977).
3. Dix, D. *et al. Clin. Chem.*, 25, 877, (1979).
4. Abraham, E.D. *Diabetes*, 27, 931, (1978).
5. Goldstein, D.E. *et al. Diabetes,* 31, 70, (1982).
6. Goldstein, D.E. *et al.*, in Methods in Diabetes Research, Vol II, 475-504 (1986).
7. Hoelzel W, *et al.*, Clin.Chem. 2004; 50: 166-174

ORDERING INFORMATION

Catalog No.	Item	Quantity
01-04-0015	Kit, HbA1c (GHb) Controls	1 x 400 µL Control I 1 x 400 µL Control II

Manufactured

European Conformity

EC REP
Authorized Representative

Consult accompanying documents

REF
Product Number

CON
Control

LOT
Lot

IVD
For *In Vitro* Diagnostic use

$\bar{x}$
Mean Value

RNG
Range of Acceptable Values

EXP
Use by YYYY-MM-DD

Caution, consult accompanying documents

8°C / 2°C
Store Lyophilized Material at 2-8ºC

8°C / 2°C
Store Reconstituted Material at 2-8ºC

25°C / 20°C
Store Diluted Material at 20-25ºC

Biohazard

Rev J 04/15

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