Trinity Biotech

Tri-stat Liquid Controls Kit

REF 03-06-0011 CONT 1 x 1000µL Level I Control, 1 x 1000µL Level II Control

TRINITY BIOTECH
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LOT 7530

2018-07-31

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2°C - 8°C

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

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05-02-0040

INTENDED USE

The Tri-stat Liquid Controls Kit is intended for use as a quality control material to monitor the performance of laboratory testing procedures for HbA1c quantitation. The control is designed for use with Boronate Affinity-based assays. For in vitro diagnostic use only. IVD

CAUTION: Use only Trinity Biotech supplied Tri-stat Liquid Controls Kit (REF: 03-06-0011) for performance verification. Other control materials are not compatible and may not be used.

REF 03-06-0011 LOT 7530

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 HbA1c measurement. Many factors can affect the performance of the assay. In order to ensure the accuracy and precision of this assay, high quality Control material should be used. The Trinity Biotech Tri-stat Liquid Controls Kit was 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 ensures the test reagents are working properly, that the Trinity Biotech Tri-stat 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 Tri-stat Reagent Kits and with each new lot of Reagent Kits
- To train and confirm performance acceptability for new analysts
- When results do not match the patient's clinical condition or symptoms

The Tri-stat Liquid Controls Kit should be tested frequently, and at least daily, to verify instrument and assay performance. The Tri-stat Liquid Controls Kit should be run with every new reagent kit, new instrument, and prior to use after periods of storage. Run Tri-stat Liquid Controls Kit and repeat sample blood test if there are any questions about a test result.

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

- Proper storage and handling of reagent 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

The Tri-stat test employs a patented two phase optical assay. The reagent tube contains boronate affinity gel. A finger stick or venous blood sample is collected with a capillary and added to the reagent tube. In the instrument, the sample is mixed with the suspended gel particles, releasing HbA1c from the red blood cells. The HbA1c binds to the gel particles, which settle to the bottom of the reagent tube at the end of the test. Measurement of HbA1c is by fluorescence quenching. After calculations and validation, the HbA1c test value is displayed on the display screen. The assay is linear with HbA1c concentration.

APPEARANCE

Tri-stat Liquid Controls are dark cherry red in color. Do not use if color or appearance has changed.

REAGENTS / COMPONENTS

1 Tri-stat Liquid Low Control (1000 µL), White Cap
1 Tri-stat Liquid High Control (1000 µL), Black Cap
2 Dropper Caps - 1 White Cap for Tri-stat Liquid Low Control
- 1 Black Cap for Tri-stat Liquid High Control
1 Package insert

This kit contains two vials. There is one vial of Low Control (White Cap) and one vial of High Control (Black Cap). The Tri-stat Liquid Controls Kit is ready for use, without any additional preparation.

STORAGE AND STABILITY

2°C - 8°C	Tri-stat Liquid Controls Kit is ready to use with no additional preparation required. Refrigerate at 2°C - 8° C (36°F - 46° F) when not in use. Do not allow to freeze. Tri-stat Liquid Controls cannot be used once frozen. Opened Tri-stat Liquid Control vials are stable for 30 days, when properly stored. Unopened Tri-stat Liquid Controls are stable until the expiration date, when properly stored.
15°C - 28°C	Before using, allow to warm to room temperature 15°C - 28°C (59°F - 82°F).
	DO NOT USE after the expiration date.

REF 03-06-0011 LOT 7530

PRECAUTIONS

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.

CAUTION: For *In Vitro* Diagnostic IVD Use ONLY

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

TEST PROCEDURE

The Tri-stat Liquid Controls Kit should be used in the same way as patient samples. Both the Tri-stat Liquid Controls Kit and patient samples can be run at the same time.

1. Open the kit containing the Low and High Tri-stat Liquid Controls and droppers.
2. Replace the white cap on the Low Tri-stat Liquid Control with the white dropper cap, and the black cap on the High Tri-stat Liquid Control vial with the black dropper cap.
3. The Package Insert contained in each kit contains detailed instructions for running the Tri-stat Liquid Controls. The Tri-stat Quick Reference Guide can also be used as a reference.
4. If the Tri-stat Liquid Control result IS within the acceptance range stated on the Package Insert, the Tri-stat analyzer can be used to test patient samples.
5. If the Tri-stat Liquid Control result IS NOT within the acceptance range:
   a) Check the Expiration Date of the Tri-stat Liquid Controls Kit
   b) Check that the color has not changed (indication of storage issues)
   c) Ensure sample is not clinging to the outside of the ICC.
   d) Ensure there are no air spaces/ bubbles in the ICC
   e) Re-run the Tri-stat Liquid Control Test.

If the Tri-stat Liquid Control result is not acceptable do not use the Tri-stat analyzer for testing.

RESULTS AND INTERPRETATION OF RESULTS

These Trinity Biotech Tri-stat Liquid Control materials have been assigned values utilizing NGSP and/or IFCC primary HbA1c reference materials. According to these reference materials, the Trinity Biotech Tri-Stat system has been assigned a system- and methodology-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.

Trinity Biotech Tri-stat Liquid Control Kit LOT 7530					EXP 2018-07-31		
		Control Level I LOT 7531			Control Level II LOT 7532		
	Units	$\bar{x}$	RNG		$\bar{x}$	RNG	
Trinity Biotech Tri-stat							
HbA1c (NGSP)[6]	%	6.9	6.2	7.6	11.2	10.1	12.3
HbA1c (IFCC)[7]	S.I.*	52	44	60	99	87	111
S.I.* units (*Système Internationale*) = mmol HbA1c/mol Hb							

Users of other methods should determine their own values.

$\bar{x}$ Mean Value · RNG Range of Acceptable Values

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.

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
03-06-0011	Kit, Tri-stat Liquid Controls	1 x 1000 µL Control I 1 x 1000 µL Control II

Rev J 2017-06-05
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