

## Intended Use

This product is for the purpose of monitoring accuracy and precision in the quantitative determination of human hemoglobin A1c (HbA<sub>1c</sub>) in blood by automated immunoassay. For *in vitro* diagnostic use only. **Rx Only**

## Summary

Throughout the circulatory life of the red cell, Hemoglobin A1c is formed continuously by the adduction of glucose to the N-terminal of the hemoglobin beta chain. This process, which is non-enzymatic, reflects the average exposure of hemoglobin to glucose over an extended period. In a classical study, Trivelli et al<sup>1</sup> showed Hemoglobin A1c in diabetic subjects to be elevated 2-3 fold over the levels found in normal individuals. Several investigators have recommended that Hemoglobin A1c serve as an indicator of metabolic control of the diabetic, since Hemoglobin A1c levels approach normal values for diabetics in metabolic control.<sup>2,3,4</sup>

Hemoglobin A1c has been defined operationally as the “fast fraction” hemoglobins (HbA<sub>1a</sub>, A<sub>1b</sub>, A<sub>1c</sub>) that elute first during column chromatography with cation-exchange resins. The non-glycosylated hemoglobin, which consists of the bulk of the hemoglobin has been designated HbA<sub>0</sub>. The MedTest Dx procedure utilizes an antigen and antibody reaction to directly determine the concentration of the HbA<sub>1c</sub>.

Controls should be included each time patients are assayed for HbA<sub>1c</sub> to verify that the assay has worked correctly. The mean value of the controls were obtained by assaying representative samples of the entire lot.

## Reagents

The lyophilized HbA<sub>1c</sub> controls are hemolysates prepared from packed human erythrocytes. The controls provide two levels of HbA<sub>1c</sub>, one level in the normal range and the other level in the elevated range. Stabilizers are added to maintain hemoglobin in the reduced state providing complete control of the HbA<sub>1c</sub> procedure.

## Reagent Preparation

Reconstitute vials with 0.5ml deionized water. Gently mix for 10 minutes. Observe for undissolved material. The reconstituted controls may be dispensed in 0.1ml aliquots, sealed tightly and frozen at -20°C.

## Reagent Storage

1. Store controls at 2-8°C. Stable until expiration date if sealed tightly. PROTECT FROM LIGHT AND HEAT.
2. Reconstituted controls retain their assigned values for at least three months if frozen. If not frozen, the reconstituted controls are stable at least one month if stored at 2-8°C and sealed tightly.
3. Do not freeze and thaw more than once.
4. Do not store in a self-defrosting freezer.

## Precautions

1. This product is for *in vitro* diagnostic use only.
2. Although this product has been tested and found non-reactive for Hepatitis B Surface Antigen (HbsAG), HIV-1, HIV-2 and HCV, no known test can offer assurance that products derived from human blood will not transmit disease. Therefore all human serum products and patient specimens should be handled in the same manner as an infectious agent.
3. Do not pipette by mouth. Avoid contact with skin and mucous membranes.

## Procedure

The lyophilized HbA<sub>1c</sub> controls should be assayed in the same manner as blood specimens including the hemolysate procedure. Follow the directions that accompany the instrument, reagent kit used in the assay, and the instrument application instructions for the reagent set.

## Materials Provided

1. Normal level control – Level 1
2. Elevated level control – Level 2

## Materials Required but not Provided

1. Hemoglobin A1c Reagent Set.
2. Pipette capable of accurately delivering 0.5 ml.
3. Deionized water










## Limitations






Things to look for that might cause inaccurate results are improper pipetting, inadequate mixing and poorly calibrated instruments.

## Expected Values

See values listed on vial label. The assayed limits are to be used as a guide in determining the accuracy of the assay procedure. The assay results for the controls should fall within the stated expected range. If they do not, the assay should be repeated, checking closely for the factors mentioned in “Limitations”.

## Symbol Key

 Use by (YYYY-MM-DD)	 Lot and batch code
 Catalog number	 Manufacturer
 <i>In vitro</i> diagnostic medical device	 Temperature limitation
 Consult instructions for use	<b>Rx Only:</b> Prescription Use Only
 CE mark	 Authorized representative in the European Community

 H7541  
-CTL  Manufactured by HORIBA Instruments Incorporated  
5449 Research Drive Canton, MI 48188  2°C  8°C 

Manufactured by HORIBA Instruments Incorporated – Pointe Brand  
5449 Research Drive, Canton, MI 48188

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## Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

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