

HB010, HB010MB, HB010X

## HbA<sub>1c</sub> Lyophilized Controls

### INTENDED USE

The Hemoglobin A1c Control kit contains both Normal Level and Abnormal Level Controls. They are intended for use as a quality control material to monitor the precision of laboratory testing procedures for HbA<sub>1c</sub> quantitation.

### SUMMARY AND PRINCIPLE

The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. The two levels of controls allow performance monitoring within the clinical range.

The measurement of HbA<sub>1c</sub> is especially useful in insulin-dependent diabetic patients where blood glucose levels fluctuate widely and where the instantaneous blood glucose does not reflect the averaged situation. The formation of HbA<sub>1c</sub> occurs slowly (about 0.05%/day) and continuously during the 120-day lifetime of the red cell. Hence the measurement of HbA<sub>1c</sub> is useful to physicians as a long-term integral of blood glucose concentration and thus as a measure of the degree of control or self-management by the diabetic patient. The normal range for HbA<sub>1c</sub> is 4% - 6% of total hemoglobin. Each percentage point increase in HbA<sub>1c</sub> level corresponds to an increase in average blood glucose level of about 30 mg/dL or 1.7 mmol/L. As a general rule HbA<sub>1c</sub> levels above 8% represent poor diabetic control, whereas values of about 7% are indicative of good control.

### REAGENT

The Hemoglobin A1c Control is prepared from human blood and contains normal hemoglobin, preservatives and stabilizers. The control is formulated to give enhanced stability.

### LIMITATIONS

The Hemoglobin A1c Control should not be used past the expiration date. If there is evidence of microbial contamination or brown discoloration in the control, discard the vial. The Hemoglobin A1c Control is not intended for use as a standard.

### WARNING AND PRECAUTIONS

#### For *In Vitro* Diagnostic Use.

**WARNING:** THIS PRODUCT CONTAINS A CHEMICAL KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER.

#### **WARNING! POTENTIALLY BIOHAZARDOUS MATERIAL**

Human sourced materials were used in the manufacturing of this product. Each donor unit was tested for hepatitis B surface antigen (HbsAg), antibodies to hepatitis C (HCV), and antibodies to Human Immunodeficiency Viruses (HIV-1 and HIV-2), HIV-1 Antigen and found to be negative.

**CAUTION:** Because no test method can offer complete assurance that HIV, Hepatitis B or C viruses, or other infectious agents are absent, these products should be handled as potentially infectious. Hence handle the Hemoglobin A1c Control with the same precautions used with patient specimens.

### RECONSTITUTION

Each vial is reconstituted by the addition of 250  $\mu$ L of Reconstitution Fluid, 0.09% sodium azide solution. This is done by **adding six (6) drops of reconstitution fluid** to the control, replacing the cap and swirling the vial several times. The control should be allowed to **stand at room temperature for 15 minutes** with intermittent swirling prior to use. This gives a stable hemolysate solution of approximately 14.0 g/dL.

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### **STORAGE AND STABILITY**

The lyophilized Hemoglobin A1c Control will be stable for 3 years from production which is until the last day of the expiration date shown on the vial when stored unopened at 2° - 8°C.

Once the control has been reconstituted; it can be used for 90 days when stored tightly capped at 2° - 8°C. The control should not be frozen or stored uncapped.

### **PROCEDURE**

The Hemoglobin A1c Control should be used the same as patient samples and run in accordance with the instrument's instructions. The controls exhibit column elution profiles comparable to patient whole blood hemolysates.

### **ASSIGNMENT OF VALUES**

The mean values (and range about the mean) printed on this insert were derived from replicate analyses on the Bayer Corporation DCA2000 HbA1c analyzer, and are specific to this lot of Hemoglobin A1c Controls. Individual laboratory means should fall within this range. It is recommended that each laboratory establish its own control limits from day-to-day use of the test. Any result that falls outside the limits established by your laboratory should be investigated.

Lot #	Expiration Date	Normal HbA1c%		Abnormal HbA1c%	
		Mean	Range	Mean	Range
0039	2010-02	5.3	4.2 – 6.4	11.4	9.1 – 13.7
0040	2010-07	5.3	4.2 – 6.4	12.5	10 – 15.0
0042	2010-07	5.3	4.2 – 6.4	12.4	9.9 – 14.9