

HB410, HB410MB, HB410X

HbA_{1c} Liquid Control

INTENDED USE

The Hemoglobin A1c Liquid Stable 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 HbA1c quantitation. The control is designed for use with the instruments and methodologies as indicated in the value assignment sheet.

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 HbA1c 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 HbA1c occurs slowly (about 0.05%/day) and continuously during the 120-day lifetime of the red cell. Hence the measurement of HbA1c 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 HbA1c is 4% - 6% of total hemoglobin. Each percentage point increase in HbA1c level corresponds to an increase in average blood glucose level of about 30 mg/dL or 1.7 mmol/L. As a general rule HbA1c levels above 10% represent poor diabetic control, whereas values of about 7% are indicative of good control.

REAGENT

The Hemoglobin A1c Liquid Control is prepared from human blood and contains normal hemoglobins, 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 Liquid 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 Liquid Stable Hemoglobin A1c Control with the same precautions used with patient specimens.

STORAGE AND STABILITY

The Hemoglobin A1c Liquid Control will be stable for 30 months from production until the last day of the expiration date shown on the vial when stored unopened at 2° - 8°C.

Once the control is opened; it can be used for 30 days when stored tightly capped at 2° - 8°C. The control should not be frozen or stored uncapped.

PROCEDURE

The Hemoglobin A1c Liquid Control should be used in the same way as patient samples and run in accordance with the instrument manufacturer'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, using instrument manufacturer's reagents, and are specific to this lot of Hemoglobin A1c Liquid 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.

ASSAY VALUES for Hemoglobin A1c

Analyte/Instruments	Units	Level 1 (Normal) Lot No. 4010 Expiry 2008-07		Level 2 (Abnormal) Lot No. 4010 Expiry 2008-07	
		Mean	Expected Range	Mean	Expected Range
Bayer DCA2000	%	5.3	4.2 – 6.4	11.8	9.4 – 14.2
Bio-Rad Variant II	%	5.7	4.6 – 6.8	11.5	9.2 – 13.8
Bayer HealthCare Diagnostics Division, DCA 2000		Bio-Rad Laboratories Pty, Inc. Variant II			

Analyte/Instruments	Units	Level 1 (Normal) Lot No. 4011 Expiry 2009-09		Level 2 (Abnormal) Lot No. 4011 Expiry 2009-09	
		Mean	Expected Range	Mean	Expected Range
Bayer DCA2000	%	6.2	5.0 – 7.4	9.2	7.4 – 11.0
Bayer HealthCare Diagnostics Division, DCA 2000					