










Hemoglobin A1c (HbA1c) Standard Set

REF: 356 001 (3 Levels)

Level 1	1 x 2 ml
Level 2	1 x 0.5 ml
Level 3	1 x 0.5 ml

SYMBOLS IN PRODUCT LABELLING

	Authorised Representative		Temperature Limitation
	For in-vitro diagnostic use		Use by/Expiration Date
	Batch Code/Lot number		CAUTION. Consult instructions for use
	Catalogue Number		Manufactured by
	Consult instructions for use		

Intended Use

Accuracy standard for quantitative determination of HbA1c in human blood by turbidimetric immunoassay.

composition

The HbA1c Standard set level 1 is a liquid buffer with preservative :0.095 % sodium azide .the HbA1c standard set level 2 , level 3 are hemolysates prepared from packaged human erythrocytes, lyophilized and stabilized.

Preparation

1. HbA1c Standard Set Level 1 ,ready for use.
- 2.HbA1c Standard Set Level 2 and Level 3,accurately add 0.5 ml of distilled water to dissolve the contents,Gently mix for 10 minutes ,or untill all material has dissolved.

Storage and Stability

The expiry date of the product at +2 to +8 °C is listed on the label.
The reconstituted standard set is stable for 15 days if stored tightly closed at +2 to +8 °C

Procedure

The lyophilized HbA1c standard set will produce a calibration curve that will be stable for at least 1 week on most analyzers.The standards should be treated in the same manner as patient samples regarding the hemolysate procedure.Follow the directions that accompany the instruments and reagent kit used in the assay for specific instruments calibration procedures.

Precautions and Warnings

- 1.For "In Vitro Diagnostic Use"
- 2.All blood doner units comprising the source material used in the manufacture of this product have been tested by approved FDA methods and found to be non-reactive for HBsAg,HCV and anti-HIV 1 & 2. Only nevertheless every product obtained from human body fluides should be handled with appropriate care in accordance with recommended procedures for biohazardous materials since absence of infectious agents can never be proven .

Assigned Values

The values are lot dependent. Actual values are printed on the labels.



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