

# HbA1c 4 LEVEL CALIBRATOR

## CALIBRATOR FOR HbA1c ASSAY

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### Introduction

HbA1c 4 level calibrator is intended to be used for the calibration of HbA1c assay.

### Calibrator Storage, Stability & Handling

#### Shelf - Life

Unopened calibrators are stable when stored at 2° - 8°C until the expiration date printed on the vial label.

#### Preparation of Calibrator & Stability

Each lyophilized HbA1c calibrator should be reconstituted by adding 0.5 ml of distilled or deionized water. Close the vial and dissolve the contents by swirling gently to avoid formation of foam. Do not shake. Allow it to stand for 20 minutes before use.

Reconstituted HbA1c calibrators are stable for 30 days at 2° - 8°C.

**DO NOT FREEZE.**

#### Calibrator Concentration

Concentration of each calibrator is printed on the vial label.

#### Indications of Deterioration

Presence of extreme turbidity or microbial growth may indicate deterioration.

### Components

HbA1c 4 level Calibrators are prepared from packed human erythrocytes.

### Calibration Procedure

The calibrators should be used to analyze patient samples in accordance with the instructions outlined in Accurex HbA1c Reagent package insert by generating a calibration curve. The calibrators should be treated in the same manner as patient's specimens for the preparation of haemolysate.

The values of calibrators are assigned by assaying against the material referenced to NGSP values.

Refer to the instrument manufacturer's recommendation for calibration frequency.

### Precautions & Warnings

1. For *in vitro* diagnostic use.
2. Do not pipette by mouth.
3. Human material used in the preparation of this product has been tested and found non reactive for the presence of HBsAg, HCV and antibody to HIV 1/2. However, all human-based products should still be handled in accordance with good laboratory practices using appropriate precautions to avoid transmission of any infectious diseases.
4. Do not use the calibrators after the expiration date printed on the box.
5. Sodium azide has been added to the calibrators as an antibacterial agent. Sodium azide may react with lead and copper plumbing to form potentially explosive metal azide buildup.

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ISO 13485, ISO 9001 CERTIFIED COMPANY
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