

HbA1c CONTROL

LOW & HIGH

CONTROL FOR HbA1c ASSAY

Introduction

HbA1c Control Low & High are intended to be used for the quality control check during the determination of HbA1c using Accurex HbA1c reagent kit.

Control Storage, Stability & Handling

Shelf - Life

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

Preparation of Control & Stability

Each lyophilized HbA1c control 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. The controls should be treated in the same manner as patient's specimens for the preparation of haemolysate.

Reconstituted HbA1c controls are stable for 30 days at 2° - 8°C.
DO NOT FREEZE.

Control Target & Range Concentration

The target concentration and the range of the control is as follows:

Indications of Deterioration

Presence of extreme turbidity or microbial growth may indicate deterioration.

Precautions & Warnings

1. For *in vitro* diagnostic use.
2. Do not pipette by mouth.
3. Human material used in formulating the controls have been tested and found to be negative for the presence of HBsAg, antibody to 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 controls after the expiration date printed on the box.
5. Sodium azide has been added to the controls 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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