ACCU-CAL

MULTICALIBRATOR FOR BIOCHEMISTRY ASSAYS

Introduction

Accu-Cal multicalibrator is intended to be used for the calibration of biochemistry assays on clinical chemistry analyzers.

Multicalibrator Storage, Stability & Handling

Shelf - Life

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

Preparation of Multicalibrator

Lyophilized Accu-Cal multicalibrator should be reconstituted by adding 3.0 ml of distilled or deionized water. Close the vial and dissolve the contents of the vial by swirling gently to avoid the formation of foam. Do not shake. Allow it to stand for 20 minutes before use.

Stability

The components in the reconstituted Accu-Cal are stable for 8 hours at 15 - 25°C or 2 days at 2 - 8°C. Reconstitution stability of the calibrator components may be extended upto 30 days by aliquoting and freezing the reconstituted calibrator preparation at less than -20°C.

Exceptions to stability of the components in the reconstituted Accu-Cal multicalibrator are as below:

1) Stability of Acid Phosphatase & Prostatic Acid Phosphatase:

at 15-25°C - 4 hours

at 2-8°C - 1 day

at -20°C - upto 2 weeks (when frozen once)

2) Stability of Bilirubin (when stored protected from light):

at 15-25°C - 3 hours

at 2-8°C - 8 hours

at -20°C - upto 2 weeks (when frozen once)

3) Stability of UIBC

at 15-25°C - 8 hours

at 2-8°C - 2 days

at -20°C - upto 4 weeks (when frozen once)

Calibration Procedure

The multicalibrator should be used in accordance with the instructions outlined in package insert of specific reagent kit in use. The values of calibrator components are assigned as per the methods mentioned in the value sheet.

Calibrator Values

The concentrations/activities of the calibrator components are as tabulated overleaf

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 calibrator has 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 calibrator after the expiration date printed on the box/vial label.

IVD	In Vitro Diagnostic Use	سا	Date of Manufacturing
(Ii)	Consult Instructions for use	Ω	Use by (YYYY-MM-DD)
REF	Catalogue Number	1	Temperature Limitation
LOT	Batch Code	w	Manufacturer

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