

HbA1c Calibrator

Packing Insert

【Intend Use】

HbA1c Calibrator is intended for the percent determination of HbA1c in human blood using High Performance Liquid Chromatography (HPLC).

【Principle】

Form correspondence between the concentration of HbA1c and the variation of peak area ratio by testing calibrator level 1 and level 2. Establish standard curve to measure the concentration of HbA1c in sample.

【Application】

It's only for use with Lifotronic GH and H series HbA1c system.

【Composition】

1. Calibrator includes hemoglobin from lyophilized whole blood, preservatives and stabilizers.
2. It's traceable to NGSP Ion Exchange Chromatography method.

【Packing Specification】

The kit includes calibrator level 1, level 2
2×0.1mL

【Expiry Date】

1. Store at 2~8°C, keep in dark place. The calibrator is provided in lyophilized form for increased stability
2. Expiry Date, shelf life is 12 months. After resolved, it will be stable for 7 days at -20°C

【Operation Step】

1. Open vial, and place at room temperature for 10~15 minutes.
2. Add 100μL deionized water with pipette to dissolve level 1 and level 2, then stand for 30 minutes.
3. Tighten the vial covers and shake them gently and thoroughly.
4. Then choose suitable centrifuge tubes to dispatch, label and use.

【Limitation of the Procedure】

Refer to the operation guide to use the calibrator. If not, the measured results are not reliable.

【Performance Standard】

1. Appearance: Visual inspection: be red loose dried frozen aquatic products, be red liquid after redissolving .
2. Packing volume of level 1, level 2: $\geq 2.7\text{g}$.
3. Accuracy of level 1, level 2: Bias% should be in the range of $\pm 10\%$.
4. Intra-assay precision of level 1, level 2: $\text{CV} \leq 5\%$.
5. Inter-assay precision of level 1, level 2: $\text{CV} \leq 10\%$.
6. Bio-safety of level 1, level 2: HBsAg, HIV antibody, HCV antibody, TP antibody are negative.

【Precautions/Warnings】

1. For In Vitro Diagnostic Use.
2. Each unit of whole blood used in the manufacturer of the calibrators was tested by CFDA approved methods and found non-reactive for HBsAg, HCV, HIV-1, HIV-2 and TP. No test method can offer complete assurance from infection. In accordance with good laboratory practice, all human source material should be considered potentially infectious; therefore, handle the calibrators with the same precautions used with patient specimens.

【Calibration Referring Value】

See the reference Value on the vial.

【Manufacturer】

Shenzhen Lifotronic Technology Co., Ltd

Add : Unit A, 4th Floor, Building 15, Yijing Estate, No.1008 Songbai Road, Nanshan District, Shenzhen City,
Guangdong Province, 518055, P.R.China

Mail: service@lifotronic.com

【Authorized representative in the European Community】

Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80, 20537 Hamburg, Germany

【Version and Modification Date】

Version: A5

Modification Date: 2018-03-16