HbA1c Control Material

Packing Insert

【Intend Use】

HbA1c Control Material is intended for the system quality control for accuracy and repeatability.

【Application】

The Control Materials were made from human whole blood. It will compare the measuring results in sample test program with reference range

【Composition】

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

【Packing Specification】

The kit includes Control Material Level 1, Level 2

2×0.1mL

【Expiry Date】

1. Store at 2~8°C, keep in dark place. The Control Material 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.

【Reference Range】

See the reference range on the vial.

【Explanation of QC Results】

The measured QC results should be in reference range. If not, the whole system should be checked, such as the calibrator expiry date, stored condition and system status.

【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:≥2.7g.
3. Accuracy of level 1,level 2:Bias% should be in the range of ± 10%.
4. Intra-assay precision of level 1,level 2:CV≤5%.
5. Inter-assay precision of level 1,level 2:CV≤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 Control Materials 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 Control Materials with the same precautions used with patient specimens

3.Besides the given reference range, laboratories could establish inner QC program according to real condition, and then determined reference range.

4. Use caution in disposing of the materials according to local regulations and law

【Manufacturer】

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