GlycoMark®

GlycoMark Controls
For use with the GlycoMark Test

CONTROL

For in vitro diagnostic use

IVD

Intended Use
The GlycoMark Controls are to be used with the GlycoMark test.

The GlycoMark test provides quantitative measurement of 1,5-anhydroglucitol (1,5-AG) in serum or plasma. The test is for professional use, and is indicated for the intermediate term monitoring of glycemic control in people with diabetes. Please see the GlycoMark Kit Reagents package insert for full product description.

Warnings and Precautions
1. Directions in the GlycoMark Kit Reagents package insert must be followed for optimal results.
2. The GlycoMark Controls contain 1.0 mg/mL sodium azide as a preservative. Avoid contact by mouth, with the skin, or any mucous membranes. In the case of contact with the standard, immediately wash the affected areas with large amounts of water.
   Sodium azide reacts with lead and copper pipes to generate an explosive metal azide compound. When disposing leftover reagents down a sink, large amounts of water should be used to flush the pipes.
3. The controls should not be used if flocculation or discoloration occur.
4. Do not use the controls past their expiration dating.
5. The controls are to be stored at refrigerated temperatures (2-8˚C). Open vials should also be stored at refrigerated temperatures (2-8˚C).
6. Do not dilute the controls.
7. After GlycoMark analysis, the containers should be discarded in accordance with rules of the facility, and in accordance with local, State, and Federal regulations.

Package Components (Materials Supplied)
Low Control – 3 vials, 2 mL each
- 1,5-AG: ~4.0 to 5.5 µg/mL
- SeraSub®
- Sodium azide: 1.0 mg/mL

High Control – 3 vials, 2 mL each
- 1,5-AG: ~13.0 to 16.0 µg/mL
- SeraSub®
- Sodium azide: 1.0 mg/mL

The control ranges are indicated for every lot of controls – see bottle label. The controls are prepared in a surrogate serum matrix to eliminate the risk of using biohazardous materials.

Materials Required But Not Supplied
- GlycoMark Kit Reagents – REF (Small) NK-8300
- GlycoMark Calibration Standard – REF NK-8320
- Saline reagent blank
- Automated chemistry analyzer, Roche/Hitachi 917 (Roche Diagnostics Corporation, Indianapolis, IN), or other appropriate open systems

Procedure
Bring the controls to room temperature and mix gently to avoid foaming. Controls should be assayed in the same manner as clinical samples. See the GlycoMark Kit Reagents package insert for procedural instructions.

Controls Storage and Stability
The GlycoMark Controls are stable at refrigerated temperatures (2-8˚C) until the expiration date noted on the outer box. Opened vials are stable for one month if stored at refrigerated temperatures (2-8˚C).

Limitations
- Instrument settings and parameters may change from instrument to instrument. Please contact GlycoMark, Inc. for assistance with a particular instrument. Incorrect results may be obtained if incorrect sample volumes or reagent volumes are used.
- As with all diagnostic tests, GlycoMark results should be interpreted along with clinical findings and results from other diagnostic methods.

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EC REP

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