



Closer Diabetes Monitoring

**GLYCOMARK™ CALIBRATION STANDARD**  
For use with the GlycoMark™ Test

For in vitro diagnostic use

**Intended Use**

The GlycoMark™ Calibration Standard is to be used with the GlycoMark™ test.

The GlycoMark™ test provides quantitative measurement of 1,5-anhydroglucitol (1,5AG) 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 Calibration Standard contains 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 standard should not be used if flocculation occurs.
4. Do not use the standard past its expiration dating.
5. The standard is 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 standard.
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)**

Calibration Standard – 3 vials, 5 mL each

- 1,5AG: 50 µg/mL
- Sodium azide: 1.0 mg/ml
- Water

**Materials Required But Not Supplied**

- GlycoMark™ Kit Reagents – Catalog No. (Small) NK-8300, (Large) NK-8310
- 2-level GlycoMark™ control set – Catalog No. NK-8330
- Saline reagent blank (0.9% physiological saline)
- Automated chemistry analyzer, Roche/Hitachi 917 (Roche Diagnostics Corporation, Indianapolis, IN), or other appropriate open systems

**Procedure**

Refer to the GlycoMark™ kit reagents package insert for details.

**Calibration Standard Storage and Stability**

The GlycoMark™ calibration standard is stable at refrigerated temperature (2-8°C) until the expiration date noted on the outer box. Opened vials are stable for one month if stored at refrigerated temperature (2-8°C).

**Limitations**

- Instrument settings and parameters may change from instrument to instrument. Please contact Tomen America, 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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