Enhance detection of hyperglycemia with a simple blood test.

The GLYCOMARK® Test

- The only blood test specific to detecting recent hyperglycemia.
- Detects changes in glycemic control within two weeks.
- Independently associated with increased rates of diabetes complications.
- Identifies patients that may benefit from closer diabetes management.
- Complimentary test to A1C, non-fasting, and FDA-cleared.
Detect recent hyperglycemia with the GLYCOMARK test.

The GLYCOMARK test measures 1,5-Anhydroglucitol (1,5-AG), a glucose-like sugar found in most foods.4,5

When blood glucose is well-controlled, glucose and 1,5-AG circulate in the bloodstream, are filtered in the kidneys and reabsorbed by the body. Urinary 1,5-AG is equal to the ingested 1,5-AG.

Circulating 1,5-AG maintained/higher serum concentrations of 1,5-AG

GLYCOMARK Test: Normal

When glucose exceeds the renal threshold (>180 mg/dL†), glycosuria occurs. Glycosuria blocks reabsorption of 1,5-AG. 1,5-AG is excreted in the urine, depleting the serum level.

Circulating 1,5-AG depleted/lower serum concentrations of 1,5-AG

GLYCOMARK Test: Abnormal

A1C reflects an individual’s average blood glucose over the prior two to three months. High and low glucose values are NOT represented with A1C. In fact, the estimated blood glucose range for an A1C of 7% is 123 - 185 mg/dL.3

Nearly 40% of patients in “good control” may have significant postprandial hyperglycemia or glycemic variability.1,2

The body quickly removes and restores 1,5-AG. Changes that improve or worsen glycemic control can be detected within two weeks with the GlycoMark test. A1C takes at least four weeks to show significant change.7,8

The GLYCOMARK test is a specific and more rapid indicator of recent hyperglycemia than A1C.
The GLYCOMARK test reveals hyperglycemic excursions that are not evident with A1C.9

**Patient Case #1**
52 year old female

- A1C 7.4%
- GLYCOMARK 12.4 µg/mL

**Patient Case #2**
49 year old male

- A1C 7.4%
- GLYCOMARK 4.5 µg/mL

**GLYCOMARK Reference Range**

<table>
<thead>
<tr>
<th>Result</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 – 31 µg/mL</td>
<td>GLYCOMARK Normal</td>
</tr>
<tr>
<td>&lt; 10 µg/mL</td>
<td>GLYCOMARK Abnormal</td>
</tr>
</tbody>
</table>

GLYCOMARK results identify recent hyperglycemic excursions that may go undetected and untreated.

Hyperglycemia and low GLYCOMARK are independently associated with significant health risks.

GLYCOMARK correlates with hyperglycemia and glycemic variability as confirmed by continuous glucose monitoring (CGM).9

**Hyperglycemia**

- Hyperglycemia is independently associated with diabetes related complications, which increase patient mortality, morbidity and healthcare costs.

**Abnormal GLYCOMARK**

- Low GLYCOMARK results are strongly associated with higher rates of diabetes related complications, even after adjusting for A1C and other risk factors.11-15

**Diabetes Complications**

- Glycemic variability/hypoglycemia
- Cardiovascular disease/mortality
- Nephropathy
- Cognitive decline
- Macrosomia/high birth weight
- Retinopathy
- Kidney disease

**GlycoMark** is not intended to diagnose, prevent, treat, cure or mitigate these complications.

*Normal GlycoMark results are lower in females than in males.*
Clinical interpretation of GlycoMark test results.

**GlycoMark Test**

- Nonfasting, FDA-cleared blood test
- Reimbursed by federal, state and private payors - CPT Code 84378

**The GlycoMark Test**

- No limits on test frequency
- Collect one (1) SST or EDTA plasma tube

**GlycoMark** is easy to order and available through most reference labs. Contact your local representative or visit our website, www.GlycoMark.com

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**Example: GlycoMark 12**

- **Yes**
  - **Normal**
  - No evidence of significant recent hyperglycemia and/or glycemic variability.

- **No**
  - **Abnormal**
  - Consistent with significant recent hyperglycemia/glycemic variability.
  - Consider fasting glucose, structured SMBG and/or CGM to determine hyperglycemic patterns.

**Example: GlycoMark 3 → 11**

- **Higher**
  - Improving Glycemic Control
  - Future A1C may trend lower.
  - Suggests recent good behavior/compliance with treatment program.

- **Lower**
  - Worsening Glycemic Control
  - Future A1C may trend higher.
  - Suggests non-compliance with treatment program or other factors.

**Example: GlycoMark 12 → 5**

- **Normal**
  - Example: GlycoMark 12
  - Normal result compared to prior?
    - Higher
      - Improving Glycemic Control
        - Future A1C may trend lower.
        - Suggests recent good behavior/compliance with treatment program.
    - Lower
      - Worsening Glycemic Control
        - Future A1C may trend higher.
        - Suggests non-compliance with treatment program or other factors.

- **Abnormal**
  - Example: GlycoMark 5
  - Abnormal result within reference range?
    - Yes
      - Normal
        - No evidence of significant recent hyperglycemia and/or glycemic variability.
    - No
      - Abnormal
        - Consistent with significant recent hyperglycemia/glycemic variability.
        - Consider fasting glucose, structured SMBG and/or CGM to determine hyperglycemic patterns.

**A1C compared to GlycoMark result**

- **A1C At Goal** <7%
  - Concordant
    - Good control.
  - Discordant
    - Prior poor control, recent improvement.
    - Fewer hyperglycemic excursions.

- **A1C Above Goal** ≥7%
  - Concordant
    - Good control.
  - Discordant
    - Prior poor control, recent improvement.
    - Fewer hyperglycemic excursions.

**GlycoMark Normal** 10 – 31 μg/mL

**GlycoMark Abnormal** <10 μg/mL

**Discordant**
- Prior good control, recent worsening. Experiencing hyperglycemic excursions, most likely postprandial.
- Prior poor control, recent improvement.
  - Fewer hyperglycemic excursions.

**Concordant**
- Good control.
- Poor control.

The lower the GlycoMark result, the more severe the hyperglycemia.

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The information contained herein is not medical, diagnostic or treatment advice for any particular patient. Physicians should use their clinical judgment and experience when deciding how to diagnose and treat patients and in the use of the GlycoMark test in the treatment of the patient. Please refer to the GlycoMark product insert for more information.

The GlycoMark test is FDA cleared for professional use to provide quantitative measurement of 1,5-anhydroglucitol (1,5-AG) in serum or plasma. The GlycoMark test is intended for intermediate-term monitoring of glycemic control in patients with diabetes. It is not intended to be used to identify patients that will experience complications of diabetes or reduce the likelihood of experiencing complications.

The information above contains general reimbursement information only and is not legal advice, nor is it advice about how to code, complete, or submit any claim for payment. Providers have the ultimate responsibility for all aspects of coding and billing.