Enhance detection of recent hyperglycemia with a simple blood test.

**The GlycoMark® Test**

- Detects recent hyperglycemia and hyperglycemic excursions.
- Reveals improving or worsening glycemic control for the prior one to two weeks.
- Is independently associated with increased rates of diabetes complications.
- Identifies patients that may benefit from closer diabetes management.
- Is a non-fasting, FDA cleared blood test that complements A1C.
Nearly 40% of patients in “good control” may have significant postprandial hyperglycemia or glycemic variability.\(^1,^2\)

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.\(^3\)

**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.\(^4,^5\)

**Glycemic Control**

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.

- 1,5-AG in food
- 1,5-AG distributed to all organs and tissues
- 1,5-AG reabsorbed by the kidney

No glycosuria, low urinary 1,5-AG excretion

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

**GlycoMark Test: Normal**

**Hyperglycemia**

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

- 1,5-AG in food
- 1,5-AG distributed to all organs and tissues
- Glucose in the kidney blocks 1,5-AG reabsorption

Glycosuria, high urinary 1,5-AG excretion

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

**GlycoMark Test: Abnormal**

\(^1\)The ADA recommends a postprandial blood glucose goal of 180 mg/dL and an A1C of <7%.\(^6\)

**A specific and more rapid indicator of recent changes in glycemic control than A1C.**

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.\(^7,^8\)

**Change in Test Values from Baseline in Response to Improved Glycemic Control\(^8\)**

<table>
<thead>
<tr>
<th>Week</th>
<th>1,5-AG</th>
<th>A1C</th>
<th>Fructosamine</th>
<th>Glucose</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>2</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>4</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>8</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
</tbody>
</table>

**Baseline 9.5% A1C**

\(^*p<0.05\)
The GYCOMARK test reveals hyperglycemic excursions that are not evident with A1C.\(^9\)

**Patient Case #1**
52 year old female, type 1 diabetes

- **A1C 7.4%**
- **GlycoMark 12.4 µg/mL**

**Patient Case #2**
49 year old male, type 2 diabetes

- **A1C 7.3%**
- **GlycoMark 4.5 µg/mL**

**GYCOMARK Reference Range\(^\text{10}\)**

<table>
<thead>
<tr>
<th>Result</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 – 31 µg/mL(^1)</td>
<td>GlycoMark Normal</td>
</tr>
<tr>
<td>&lt; 10 µg/mL(^1)</td>
<td>GlycoMark Abnormal</td>
</tr>
</tbody>
</table>

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

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

- Hyperglycemia is independently associated with diabetes related complications, which increase patient mortality, morbidity and healthcare costs.
- Low GYCOMARK results are strongly associated with higher rates of diabetes related complications, even after adjusting for A1C and other risk factors.\(^11-15\)

**Diabetes Complications**\(^\text{**}\)
- Glycemic variability/hypoglycemia,
- Cardiovascular disease/mortality,
- Nephropathy/kidney disease,
- Macrosomia/high birth weight,
- Cognitive decline,
- Retinopathy

\(^\text{**GlycoMark is not intended to diagnose, prevent, treat, cure or mitigate these complications.}\)
Clinical interpretation of GLYCOMARK test results.

GLYCOMARK result within reference range?

- Yes
  - 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.

GLYCOMARK 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.

A1C compared to GLYCOMARK result

- A1C At Goal <7%
  - Concordant
    - Good control.

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

GLYCOMARK Normal 10 – 31 μg/mL

- Concordant
  - Good control.

GLYCOMARK Abnormal <10 μg/mL

- Discordant
  - Prior good control, recent worsening. Experiencing hyperglycemic excursions, most likely postprandial.

Concordant
- Poor control.

Example: GLYCOMARK 12

Example: GLYCOMARK 3 → 11

Example: GLYCOMARK 12 → 5

Test Specifications

- Patients to Test: Patients diagnosed with diabetes
- Test Performed: GLYCOMARK Test / 1,5-Anhydroglucitol
- Regulatory: FDA cleared, CE Marked
- Patient Prep: Non-fasting
- Specimen: SST or EDTA plasma, 7 days, refrigerated
- Instrument: Most major chemistry platforms
- Send-Out: National and regional laboratories
- Reimbursement: Reimbursed by most federal, state and private payors, CPT Code 84378

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

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

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 diagnose disease or identify patients that will experience complications of diabetes or 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.

**Contact Information**

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