

The GLYCOMARK® Test

A simple adjunctive blood test for detecting recent hyperglycemic excursions.



| TESTS | RESULT |
|------------------------------|--------------|
| <i>Comp. Metabolic Panel</i> | |
| Glucose, Serum | 91 |
| GlycoMark | 4.3 L |
| HbA1c | 6.3 H |
| GlycoMark(R) (1,5 AG) | |
| GlycoMark(TM) is intende | |

Hyperglycemia

Hyperglycemia leads to diabetic vascular complications.¹ Each 1% reduction in A1C can decrease the risk of microvascular complications by 37% and the risk of any diabetes-related complication or death by 21%.¹ However, nearly 40% of patients in “good control” may have significant postprandial hyperglycemia or glycemic variability.^{2,3}

Traditional Tests for Diabetes

Getting patients to ADA goals[†] for glucose and A1C can be challenging:

- ▲ A periodic finger stick glucose is not always reliably timed or performed, and may yield inaccurate results.^{4,5}
- ▲ A quarterly or bi-annual A1C is a glucose average - making it difficult to detect glycemic variability and incapable of detecting recent hyperglycemia.⁶

The GLYCOMARK Test

The GLYCOMARK test is an adjunctive test and specific indicator of recent glycemic variability and hyperglycemic excursions.⁶ An abnormal GLYCOMARK test result indicates significant hyperglycemia and/or glycemic variability occurring in the fasting state, postprandial or both, and is independently associated with diabetes complications.⁷⁻¹¹

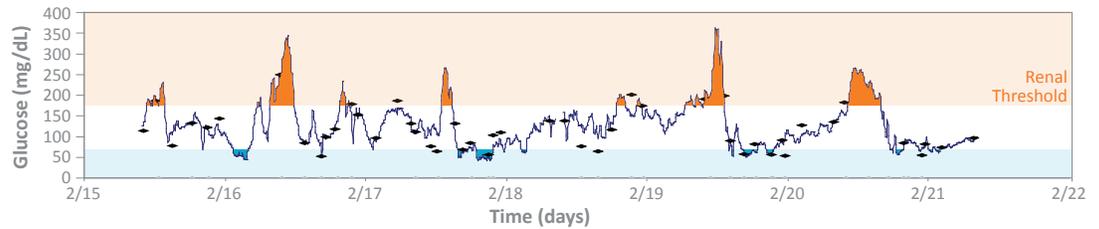
| | Glucose | A1C | GLYCOMARK |
|--|--------------------------|-------------------------------|---|
| Glucose detection | Actual | Average | Glycemic variability, hyperglycemic excursions (fasting, postprandial, or both) |
| Timeframe | Current At blood draw | Long term Prior 2-3 months | Recent/intermediate Prior 1-2 weeks |
| Independently associated with outcomes | ✓ | ✓ | ✓ |
| Specific to recent hyperglycemia and glycemic excursions | | | ✓ |

Which Patient Needs Improved Glycemic Control?¹²

Patient Case #1

52 year old female

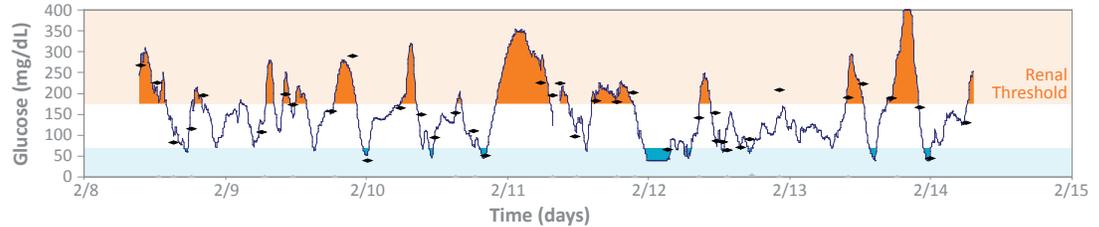
A1C 7.4%
GLYCOMARK 12.4 µg/mL



Patient Case #2

49 year old male

A1C 7.4%
GLYCOMARK 4.5 µg/mL



The GLYCOMARK Test provides additional information to help identify patients that may benefit from closer diabetes management, including continuous glucose monitoring or treatment modifications.

Result Interpretation

Result¹³

10 - 31 µg/mL[‡]

< 10 µg/mL[‡]

Interpretation

GLYCOMARK Normal

GLYCOMARK Abnormal

- ▲ ABNORMAL - represents significant hyperglycemia and/or glycemic variability (fasting, postprandial or both).
- ▲ INCREASING or DECREASING - reveals changes in glycemic control associated with treatment programs (improving or worsening glycemic control).

Refer to the GLYCOMARK Test Interpretation Guide for additional information.

Test Specifications

Patients to Test: Patients diagnosed with diabetes
Test Performed: GLYCOMARK Test / 1,5-Anhydroglucitol
Regulatory: FDA cleared, CE Marked
Patient Prep: Fasting or 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

For more information, contact your local representative or visit our website, www.GLYCOMARK.com, to access educational materials and videos.



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

[‡]Normal GLYCOMARK results are, on average, lower in females than in males.

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.

¹Stratton IM, et al. BMJ. 2000 Aug 12;321(7258):405-12. ²Erlinger TP, Brancati FL. Diabetes Care. 2001 Oct;24(10):1734-8. ³Bonora E, et al. Diabetologia. 2006 May;49(5):846-54. ⁴Erbach M, et al. J Diabetes Sci Technol. 2016;10:1161-1168. ⁵Klonoff DC, et al. J Diabetes Sci Technol. 2011;5:1529-1548. ⁶American Diabetes Association. Diabetes Care 2015 Jan; 38(Supplement 1): S33-S40. ⁷Selvin E, et al. Diabetes 2016;65:201-208. ⁸Selvin E, et al. Clin Chem. 2014 Nov; 60(11): 1409-1418. ⁹Lee AK, et al. Diabetes Care 2017 Dec; 40(12): 1661-1667. ¹⁰Rawlings AM, et al. Diabetes Care 2017 Jul; 40(7): 879-886. ¹¹Nowak N, et al. Diabetologia 2013 Apr; 56(4): 709-713. ¹²Dungan KM, et al. Diabetes Care 2006 Jun; 29(6): 1214-1219. ¹³GLYCOMARK Test Product Package Insert, Revision G, 2017.



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