

1,5-ANHYDROGLUCITOL GLYCOMARK® (1,5-AG) ASSAY

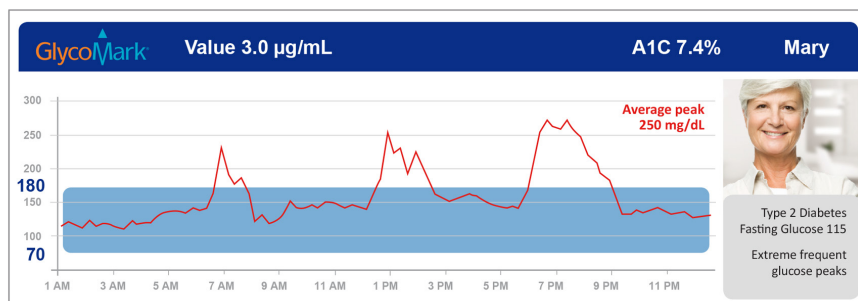
Dual Vial Liquid Stable

GlycoMark (1,5-AG) reflects hyperglycemia above the renal threshold over the preceding 1-2 weeks which is complimentary to HbA1c and Glycated Serum Protein determinations. The test provides a useful, unique perspective of patient's recent hyperglycemic excursions, which may not be evident from standard glycemic markers. This information makes it possible to rapidly identify patients with glycemic variability that may benefit from more frequent self-monitoring of blood glucose (SMBG) or continuous glucose monitoring (CGM).

THE GLYCOMARK (1,5-AG) ASSAY ADVANTAGES

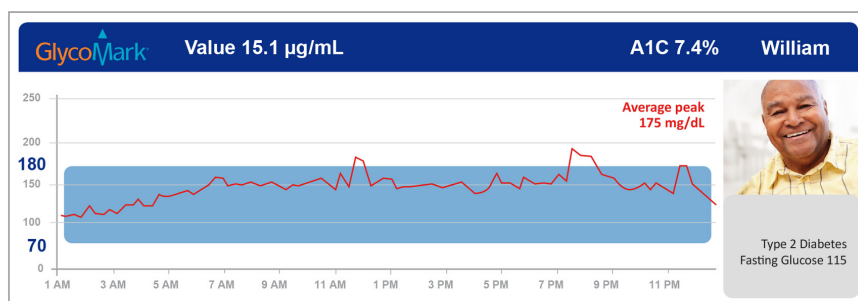
- Reveals recent deterioration in control not yet visible in HbA1c and glycated albumin
- Shows therapy change improvement within 2 weeks
- Can use fasting and non fasting specimens
- There is no ordering frequency limitation so the test can be ordered as needed
- Reimbursed by Medicare, Medicaid, and most private payers

The test is useful for a more informed diabetes treatment, providing unique information not obtainable with other tests.



• Faster than HbA1c at assessing changes in glycemic control to changes in treatment program or patient non-adherence.¹

• Identify hyperglycemic excursions that may not be evident from standard glycemic markers.



• Reflective of glucose levels above the renal threshold (~180 mg/dL).

• Nearly 40% of diabetes patients in "good control" have significant glucose variability.²

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The GlycoMark (1,5-AG) Assay is manufactured by **GlycoMark**

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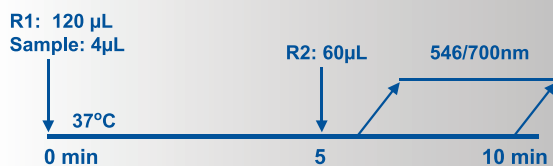
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ASSAY SPECIFICATIONS

Method	Enzymatic
Sample Type	Serum Plasma - EDTA - Heparin - Sodium Fluoride - Sodium Citrate
Sample Volume	4 µL
Analytical Sensitivity	0.2 µg/mL
Linearity	0-50 µg/mL
Calibration Levels	2-Point Calibration
Reagent On-Board Stability	Opened: 30 days at 2-8°C
Interferences	The following substances did not interfere with the GlycoMark (1,5-AG): Hemoglobin: Up to 125 mg/dL Triglycerides: Up to 1153 mg/dL Bilirubin: Up to 40 mg/dL
Regulatory Status	510(k) Cleared CE

GlycoMark (1,5-AG) Assay Procedure*



*Based on Roche Hitachi 917 Parameters

Parameter questions for GlycoMark (1,5-AG) Assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email

support@diazyme.com

1. McGill et al, *Diabetes Care* 2004;27:1859-65
2. Bonora et al, *Diabetologia* 2006;49:846-54
3. Yamanouchi et al, *The Lancet* 1996;347:1514-8

ASSAY PRECISION

Precision studies were performed to evaluate both within-assay and between-assay precision. The summarized results are described below:

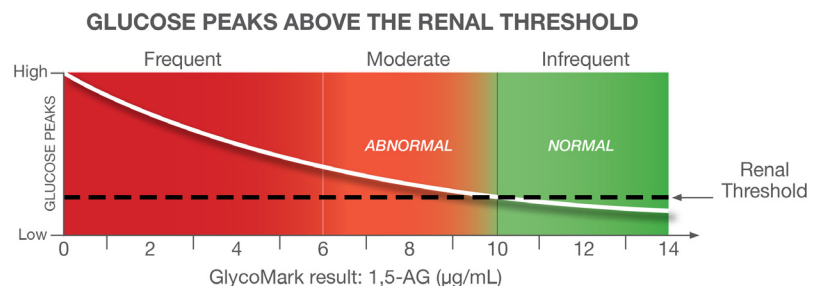
Within-Assay Precision

	Control Low n=20	Control High n=20
Mean µg/mL 1,5-AG	4.63	14.67
Standard Deviation	0.18	0.19
%CV	3.83	1.28

Between-Assay Precision

	Control Low	Control High	Pool 1	Pool 2
Number of replicates	40	40	40	40
Mean µg/mL 1,5-AG	4.70	14.70	19.60	27.00
Standard Deviation	0.18	0.20	0.23	0.21
%CV	3.71	1.35	1.17	0.79

INTERPRETATION OF THE GLYCOMARK (1,5-AG) TEST RESULTS



Abnormal 1,5-AG levels are an indicator of hyperglycemic episodes within the last 1-2 weeks, which may have occurred in the fasting state, post-meal state, or both.³

Changes in 1,5-AG levels reflect progression towards (increasing 1,5-AG) or away from (decreasing 1,5-AG) glyceemic control.³

Test Limitations (See package insert) Low GlycoMark values can occur in Stage 4 or 5 kidney disease, advanced liver disease and during pregnancy. The diabetes drugs acarbose and SGLT2 inhibitors (such as INVOKANA®) cause low values. The Chinese medicines Polygala, Tenuifolia and Senega Syrup may cause high GlycoMark values.

The GlycoMark (1,5-AG) Assay is manufactured by GlycoMark
For additional product information call 888-DIAZYME

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