GlycoMark®

Enhancing A1C by revealing hidden glucose peaks

Benefits for Diabetes Management – Personalized Care

Clinically proven 2-week measure of average daily maximum blood glucose[1,2,3]

- Reveals recent deterioration in control not yet visible in A1C[4,5]
- Shows therapy change improvement within 2 weeks [5,6]
- May help motivate patients adhere to therapy, diet and lifestyle changes [5]

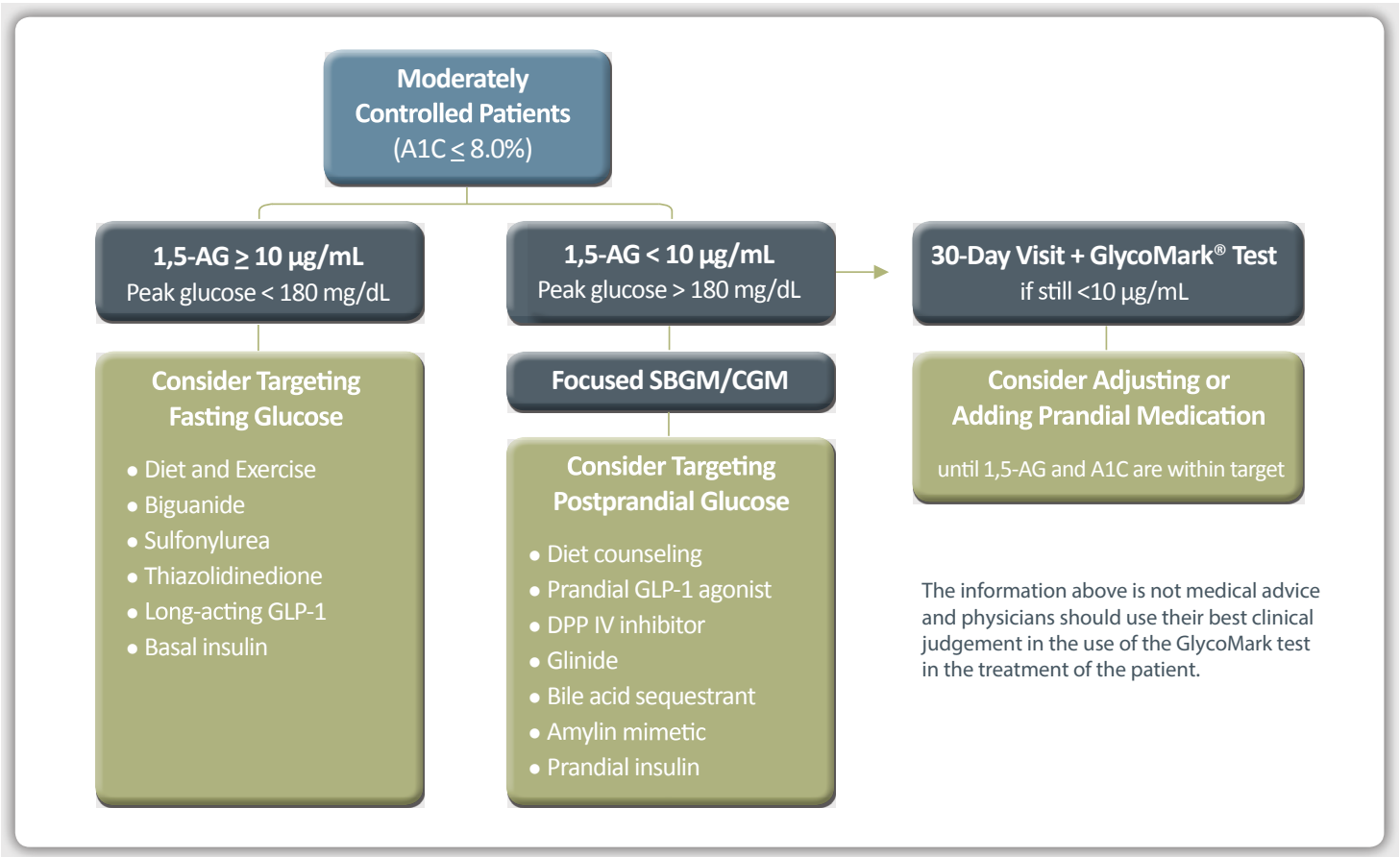
Can help identify patients who may need therapy changes despite a "good" A1C

- Average blood glucose for an A1C of 7% can range from 123 - 185 mg/dL;[7] The GlycoMark test identifies patients with more frequent and extreme hyperglycemic excursions, despite similar A1Cs
- Indicates need for more frequent self blood glucose monitoring (SBGM) or continuous glucose monitoring (CGM)

Low 1,5-AG levels have been shown to stratify patients at higher risk of diabetes complications [8,9,10,11,12]

Suggested Personalized Therapy Algorithm[13,14]

When A1C ≤ 8%, the GlycoMark test can identify patients with higher glucose excursions, providing you additional information.[1]



The information above is not medical advice and physicians should use their best clinical judgement in the use of the GlycoMark test in the treatment of the patient.

Sonora Quest Laboratories™
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BBB Business Ethics AWARDS 2011 Winner

PBJ Best Places to Work 2013 WINNER

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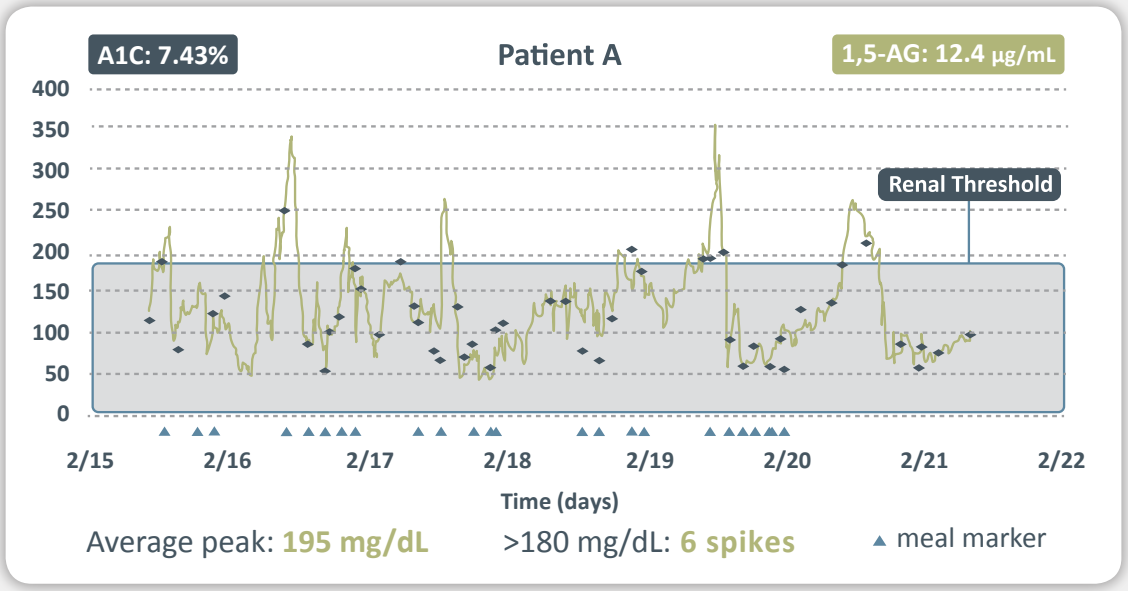
Arizona Governor's Award for Quality 2005 Recipient

What can fingerstick glucose tests miss?

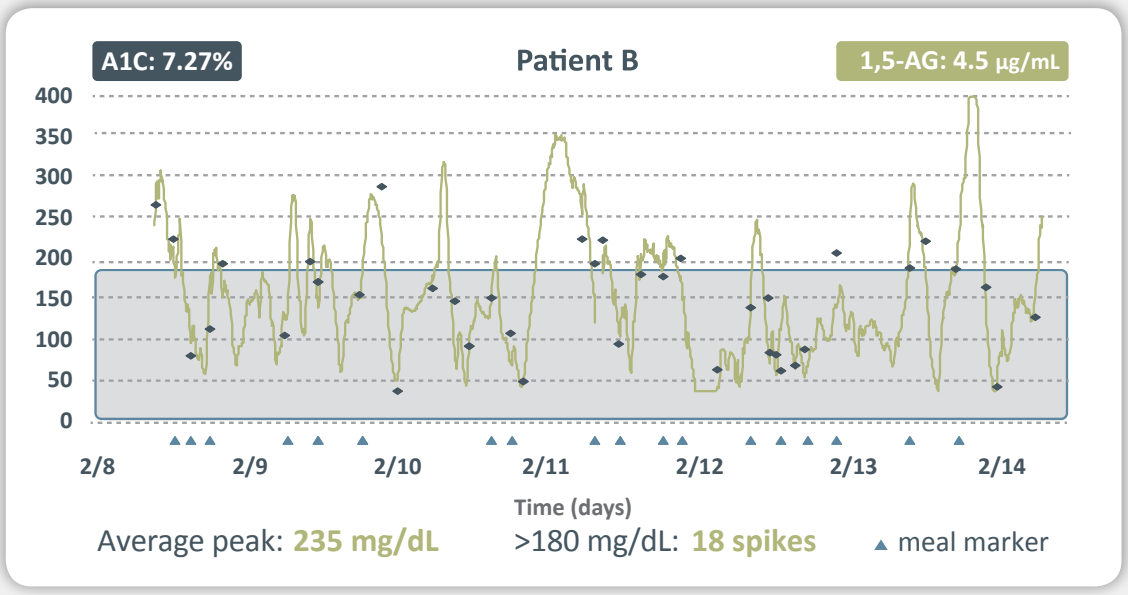
The GlycoMark 1,5-AG test can reveal frequent and significant excursions over the renal threshold of 180 mg/dL with a single non-fasting blood test[1]

Continuous glucose monitor vs ◆ fingerstick glucose tests



While Patient A has a slightly higher A1C value (7.43%), the 1,5-AG value (12.4 µg/mL) indicates that the patient is having fewer excursions with a lower average glucose peak (195 mg/dL) than patient B.[1]

Different GlycoMark values despite similar A1Cs can help focus your attention on patients who need therapy adjustments.



Patient B not only experienced three times as many glycemic spikes as Patient A, but the peaks were significantly higher (235 mg/dL). The lower 1,5-AG value of 4.5 µg/mL indicates a high mean maximum blood glucose.[1]

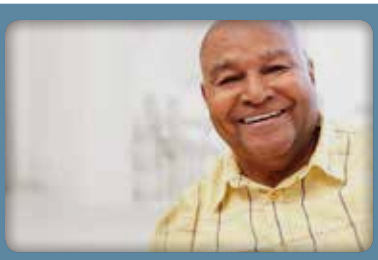
Routinely assessing glycemic variability is challenging

A1C average glucose levels can vary widely between patients, and fasting and infrequent fingerstick glucoses often miss glucose peaks and their durations.

A1C	GlycoMark Value	Estimated Average Peak Glucose[1]
7.9 %	4.4 µg/mL	219 mg/dL
7.8	3.5	235
7.7	6.5	199
7.5	19.6	171
7.4	3.0	250
7.4	15.1	175
7.2	5.7	205
7.2	19.2	171
7.0	2.0	294
7.0	18.1	172
6.8	5.8	204
6.8	20.8	170
6.4	2.3	276
6.4	6.3	200
6.4	16.8	173
6.3	4.3	221
6.3	9.2	187
6.3	10.2	184

Consider these two patients who look the same clinically

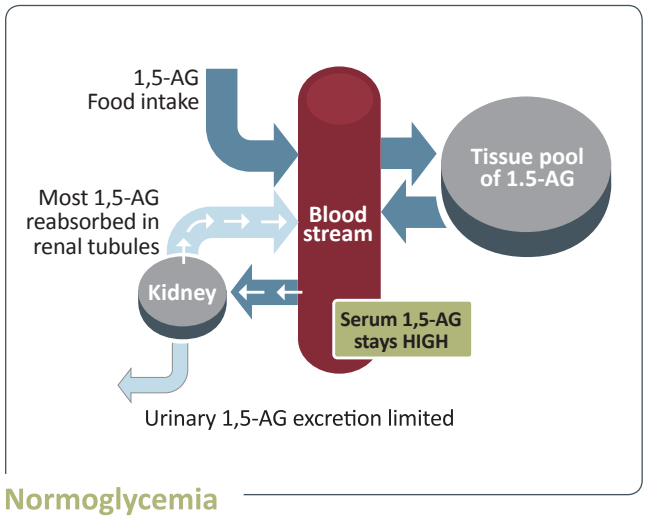
Mary
Type 2 Diabetes
A1C: 7.4%
Fasting Glucose: 115 mg/dL
Medications: Metformin and Sulfonylurea



William
Type 2 Diabetes
A1C: 7.4%
Fasting Glucose: 115 mg/dL
Medications: Metformin and Sulfonylurea

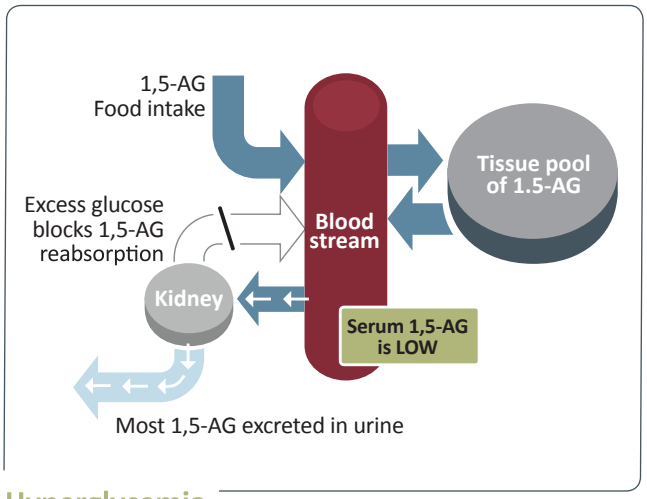
How does the GlycoMark test measure glucose peaks?[17]

The test measures a glucose-like sugar called 1,5-Anhydrogluticol (1,5-AG) found in most foods.



Normoglycemia

- When blood glucose is well-controlled, most 1,5-AG is reabsorbed in the renal proximal tubules, so the serum 1,5-AG level stays high.
- People without diabetes have median 1,5-AG values above 20 µg/mL.



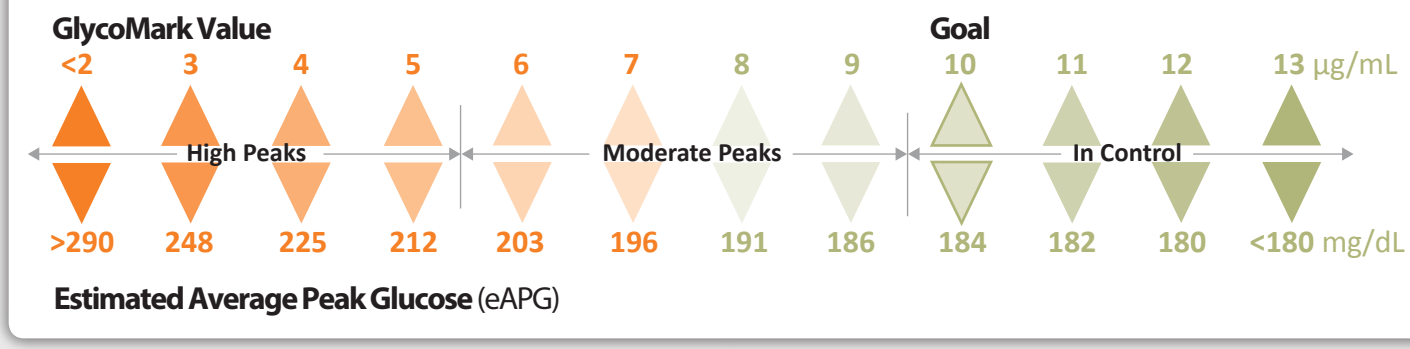
Hyperglycemia

- When hyperglycemia occurs, excess glucose blocks reabsorption of 1,5-AG and it is excreted in the urine.
- Every time blood glucose spikes above 180 mg/dL, the body loses 1,5-AG.
- The more frequent the glucose spikes, the lower the GlycoMark result will typically be.

Interpreting Results[1]

- GlycoMark values <10 µg/mL indicate frequent hyperglycemic excursions over the renal threshold of approximately 180 mg/dL during the past 1-2 weeks
- The lower the GlycoMark value, the higher the mean daily peak glucose, because 1,5-AG is excreted in the urine whenever glucosuria occurs, quickly lowering serum levels

American Diabetes Association Guidelines for 2-hour postmeal blood glucose: <180 mg/dL (AACE <140 mg/dL)[14,15]



Test Limitations[16]

- 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

Ordering GlycoMark Through Sonora Quest Laboratories

Test Name	Test Code	Specimen Requirements	CPT code(s)*
GlycoMark	902757	1 mL refrigerated serum	84378
Hemoglobin A1c with eAG	9230	1 refrigerated EDTA lavender-top tube (1 mL whole blood minimum)	83036
Hemoglobin A1c w/Reflex to GlycoMark (if Hgb A1c 6.5-8%)	904354	**Dedicated tubes as follows:** 1 EDTA lavender-top tube AND 1 serum separator tube Submit both tubes refrigerated	83036; 84378 if reflex is required
Hemoglobin A1c and GlycoMark	802386	**Dedicated tubes as follows:** 1 EDTA lavender-top tube AND 1 serum separator tube Submit both tubes refrigerated	83036; 84378

*The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

The GlycoMark test is FDA-cleared for intermediate monitoring of glucose control in people with diabetes. Components of glycemic monitoring include hyperglycemia and hypoglycemia. The GlycoMark test does not reflect hypoglycemia and is not intended to diagnose any specific diabetes state or disease. Physicians should use their best clinical judgment when using the GlycoMark test. For full prescribing information, visit www.glycomark.com.

[1] Dungan, et all, Diabetes Care 29:1214-1219, 2006; Patent No. US8, 178,312 B2 May 15, 2012; [2] Wang, et al, Diabetes Metab Res Rev 28: 357-362, 2012; [3] Stettler, et al, Diabetes Care 31: 1534-1535, 2008; [4] Yamanouchi, et al, Lancet 347 (9014), June 1996; [5] McGill, et al, Diabetes Care 27: 1859-1865, Aug 2004; [6] Moses, et al, Diabet Med 25, 2008; [7] Nathan, et al, Diabetes Care, Vol 31(8), pp 1473-8, Aug 2008; [8] Yamanouchi, et al, Diabetes Care, Vol 21(4), pp 619-624, 1998. [9] Kim, et al, Diabetic Medicine, DOI: 10.1111/j.1464-5491. Feb 2012; [10] Watanabe, et al, Atherosclerosis, Vol 216(2), pp 477-483, Feb 2011; [11] Hirsch, et al, Presented at Endocrine Society Meeting July 2012; [12] Juraschek, et al (Johns Hopkins), Diabetes Care, August 2012; [13] Modified from Dungan, Expert Rev Mol Diagn 8(1), 2008; [14] AACE 2011 Diabetes Guidelines - Drugs separated into fasting and post-prandial; [15] ADA Standards of Medical Care in Diabetes, Diabetes Care 36(1), Jan 2013; [16] Visit www.glycomark.com for more details; [17] Dungan, et al, Expert Rev Mol Diag 28(1), 2008