DIABETES

BioReference LABORATORIES an **OPKO** Health Company

THE PATH TO MANAGING AND MONITORING HYPERGLYCEMIA

Nearly 40 percent of diabetes patients in "good control" have significant glycemic variability, and routinely assessing patients' glycemic variability is challenging. Hemoglobin A1c (HbA1c) glucose levels can vary widely among patients, and fasting and infrequent finger-stick glucose tests often miss glucose peaks at their durations. The GlycoMark^{*} test from BioReference can reveal differences in glycemic variability, so you can safely provide personalized care and manage your patients' diabetes therapy to reach glucose goals.

What is GlycoMark?

GlycoMark[®]

GlycoMark is a non-fasting blood test that measures 1,5 anhydroglucitol (1,5-AG), a specific indicator of hyperglycemic episodes and glycemic variability. The test provides an indication of whether a patient has had recent hyperglycemic episodes, and the results are related to the average daily maximum glucose level over a one-to-two week period.

What is Glycemic Variability?

Glycemic variability is characterized by variable hyperglycemia and hypoglycemia. Patients may have undetected glycemic variability because the glucose highs and lows offset each other, producing an average HbA1c level that suggests good control. Glycemic variability has been shown to be associated with higher rates of repeat cardiovascular events, retinopathy in type 2 diabetes, and an increased risk of microvascular complications.

Why GlycoMark?

- Provides unique information not obtainable with other tests, enabling more informed diabetes treatment
- Identifies hyperglycemic excursions that may not be evident from HbA1c or glucose measurements

- Related to amount of time glucose exceeds the renal threshold (generally >180 mg/dL)
- Reveals recent deterioration in glucose control
- Shows improvements and effectiveness in therapy changes within two to four weeks (faster than HbA1c)
- Measures and positively reinforces adherence to dietary and lifestyle changes
- FDA-cleared for intermediate-term monitoring of glycemic control in people with diabetes

Interpretation of Results

Abnormal 1,5-AG levels (less than 10 mcg/mL) suggest significant glycemic variability within the last one-to-two weeks, which may have occurred in the fasting state, postprandial state or both. An increasing in 1,5-AG level from the previous result reflects progression towards glycemic control. A decreasing 1,5-AG level from the previous result reflects change away from glycemic control.

GlycoMark values have an inverse relationship to blood glucose, so as blood glucose decreases, the GlycoMark value increases. The chart below compares GlycoMark values with the corresponding estimated average peak glucose (eAPG) level.



Providing Personalized Care

Different patterns of glucose control may indicate the need for different therapy approaches. In the sample below, Susan and John have identical HbA1c values. Susan has a lower GlycoMark value and higher post-meal glucose peaks, while John has a higher Glycomark level and high glucose levels overall.

Sample Results	Sample Treatment Considerations
Susan Type 2 Diabetes HbA1c: 7.4% <i>GlycoMark: 3.4</i> Average Max Glucose: 237 Results Interpretation: Likelihood that patient is having very frequent glycemic excursions over 200 mg/dL	 Assess for unusual recent issues that may be causing hyperglycemia (i.e., illness, vacation, stopped diabetes medication, steroid injection, etc.) Have patient self-test pre and post-meal blood glucose by fingerstick or continuous glucose monitoring system to assess meal patterns After identifying meal-related hyperglycemia, consider diet counseling and/or prandial medications Repeat monthly testing to check the effectiveness of treatment plan until GlycoMark value returns to normal (above 10 mcg/mL)
John Type 2 Diabetes HbA1c: 7.4% <i>GlycoMark:</i> 15.1 Average Max Glucose: 175 Results Interpretation: Likelihood that patient is rarely having glycemic excursions over 200 mg/dL	 Although peak blood sugars appear well-controlled, assess why baseline blood sugars overall are high Consider increasing or adding medication to address baseline glucose control to achieve a target goal of A1C < 7% Institute a diet and exercise plan Re-test HbA1c and GlycoMark in 60-90 days to check that HbA1c < 7% and that GlycoMark value remains above 10 mcg/mL

*The information above is not intended to be used as medical advice. Physicians should use clinical judgment in the use of the GlycoMark test and in the treatment of the patient.

HIGHLIGHTS AND REFERENCES:

Test Code:	J114-0
Specimen Requirements:	1 SST tube
Storage Requirements:	Refrigerate
Turn-Around-Time:	1 Day
Specimen Stability:	7 days
CPT Code:	84378

Additional Resources:

GlycoMark: http://www.glycomark.com/

American Diabetes Association: http://www.diabetes.org/

REFERENCES:

- 1. Dungan KM, Buse J, Largay J, et al. 1,5-Anhydroglucitol and postprandial hyperglycemia as measured by continuous glucose monitoring system in moderately controlled patients with diabetes. Diabetes Care. June 2006; 29(6): 1214-1219.
- Bonora E, Corrao G, Bagnardi V, Ceriello A, Comaschi M, Montanari P, Meigs JB. Prevalence and correlates of post-prandial hyperglycaemia in a large sample of patients with type 2 diabetes mellitus. Diabetologia. May 2006; 49(5):846-54.
- 3. Standards of medical care in diabetes 2013. Diabetes Care. January 2013; 36(1): S11-S66.
- Wang Y, et al. A study on the association of serum 1,5-anhydroglucitol levels and the hyperglycaemic excursions as measured by continuous glucose monitoring system among people with type 2 diabetes in China. Diabetes Metab Res Rev. 2012; 28: 357–362.
- Stettler C, Stahl M, Allemann S, Diem P, Schmidlin K, Zwahlen M, Riesen W, Keller U, Christ E. Association of 1,5-anhydroglucitol and 2-h postprandial blood glucose in type 2 diabetic patients. Diabetes Care. August 2008; 31(8): 1534-1535 2008.
- Yamanouchi T, Ogata N, Tagaya T, Kawasaki T, Sekino N, Funato H, Akaoka L, Miyashita H. Lancet . Clinical usefulness of serum 1,5-anhydroglucitol in monitoring glycaemic control. June 1996; 347(9014): 1514-8.
- Moses AC, Raskin P, Khutoryansky N. Does serum 1,5-anhydroglucitol establish a relationship between improvements in HbA1c and postprandial glucose excursions? Supportive evidence utilizing the differential effects between biphasic insulin aspart 30 and insulin glargine. Diabetic Medicine. February 2008; 25(2): 200–205.
- McGill, et al. Circulating 1,5-anhydroglucitol levels in adult patients with diabetes reflect longitudinal changes of glycemia: A U.S. trial of the GlycoMark assay. Diabetes Care. August 2004; 27(8): 1859-1865.
- 9. Dungan KM. 1,5-anhydroglucitol (GlycoMark) as a marker of short-term glycemic control and glycemic excursions. Expert Rev Mol Diag. January 2008; 8(1): 9-19.
- 10. Su G, et al., Impact of admission glycemic variability, glucose, and glycosylated hemoglobin on major adverse cardiac events after acute myocardial infarction. Diabetes Care. April 2013; 36(4): 1026-32.
- 11. Kim WJ, Park CY, Park SE, Rhee EJ, Lee WY, Oh KW, Park SW, Kim SW, Park HS, Kim YJ, Song SJ, Ahn HY. Serum 1,5 anhydroglucitol is associated with diabetic retinopathy in Type 2 diabetes. Diabet Med. 2012; 29(9): 1184-90.
- 12. Selvin E, Rawlings AM, Grams M, Klein R, Steffes M, Coresh J. Association of 1,5 anhydroglucitol with diabetes and microvascular conditions. Clin Chem. 2014; 60(11): 1409-18.

GlycoMark is a registered trademark of GlycoMark, Inc. 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 clinical judgment when using the GlycoMark test. For full prescribing information, visit www.glycomark.com



481 Edward H Ross Drive = Elmwood Park, NJ 07407 = 1-800-229-5227 tel = 1-201-791-1941 fax = www.BioReference.com © 2017 BioReference Laboratories, Inc. All rights reserved. 10007 V1 05/17