



GlycoMark[®]

CPT Code: 84378

Order Code: C155

ABN Requirement: Yes

Synonyms: 1,5-anhydroglucitol

Specimen: Serum or EDTA Plasma

Volume: 1.0 mL

Minimum Volume: 0.5 mL

Preferred Tube Type: Gel-barrier tube (SST, Tiger Top)

Alternate Tube Type: EDTA (Lavender Top)

Collection:

Serum:

1. Collect and label sample according to standard protocols.
2. Gently invert tube 10 times immediately after draw. DO NOT SHAKE.
3. Allow blood to clot 30 minutes.
4. Centrifuge for 10 minutes.

EDTA Plasma:

1. Draw and gently invert 8 to 10 times.
2. Centrifuge for 10 minutes.
3. Pre-squeeze transfer pipet bulb and draw off approximately 2/3 of the upper plasma layer.

Note: *This ensures that the buffy coat and red cells remain undisturbed.*

4. Aliquot plasma into labeled transport tube labeled as "EDTA plasma" and cap tightly. Discard original tube.
5. Store transport tube frozen at -20°C until ready to ship.

Transport: Store serum or EDTA plasma at 2°C to 8°C after collection and ship the same day per packaging instructions provided with the Cleveland HeartLab shipping box.

Stability:

Ambient (15-25°C): not acceptable

Refrigerated (2-8°C): 7 days

Frozen (-20°C): >7 days

Deep Frozen (-70°C): >7 days

Causes for Rejection: Specimens other than serum or EDTA plasma; improper labeling; samples not stored properly; samples older than stability limits

Methodology: Enzymatic Assay

Turn Around Time: 1 to 5 days

Reference Range:

Sex	µg/mL
Males, All Ages	10.7-32.0
Females, All Ages	6.8-29.3

Glycemic control goal for diabetic patients: >10 µg/mL. GlycoMark® reference ranges only apply to individuals without diabetes.

Intended Use: The GlycoMark® test may be performed monthly on individuals with moderately controlled diabetes and HbA1c of 6-8% to detect glucose excursions, and to monitor efficacy of therapy changes in diabetic individuals with high HbA1c (>8%).

Clinical Significance:

- The GlycoMark® test helps identify patients with more frequent and extreme hyperglycemic excursions over the previous 2 week time period, despite similar HbA1c levels, and indicates the need for more frequent self-blood glucose monitoring or continuous glucose monitoring.
- Approximately 40% of individuals with diabetes who are “controlled” for

glucose and HbA1c testing have significant post-prandial glucose variability¹. In fact, the average blood glucose in an individual with an HbA1c of 7% can range from 123 to 185 mg/dL².

- Low levels of 1,5-AG are associated with the presence of diabetes complications. For example, low circulating levels of 1,5-AG are associated with elevated levels of urinary albumin and N-acetylglucosaminidase, both markers of renal damage³.

References

1. Bonora E et al. Prevalence and correlates of post-prandial hyperglycemia in a large sample of patients with type 2 diabetes. *Diabetologia*. 2006; 49: 846-854.
2. Nathan DM et al. Translating the A1C assay into estimated average glucose values. *Diabetes Care*. 2008; 31: 1473-1478.
3. Yamanouchi T et al. Relationship between serum 1,5-anhydroglucitol and urinary excretion of N-acetylglucosaminidase and albumin determined at onset of NIDDM with 3-year follow-up. *Diabetes Care*. 1998; 21: 619-624.

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.