

# Validation of the GLYCOMARK<sup>®</sup> Assay

The GLYCOMARK test is an enzymatic kinetic assay for 1,5-anhydroglucitol which takes approximately 10 minutes in a two-step process. R1 eliminates glucose and R2 measures 1,5-AG.

- **Linearity:** You can establish linearity for your instrument using the 50 µg/ml calibration standard. 50 µg/ml is beyond the upper normal range for 1,5-AG and values less than 10 µg/ml are diagnostic in diabetes; therefore, linearity between 0 and 50 µg/ml is desirable. Intermediate points are not necessary but if you wish you can either dilute the 50 µg/ml standard or use several patient samples with known 1,5-AG values.
- **Precision:** Establish precision using several patient samples in both intra- and inter-runs and determine the CVs from the means and SDs.
- **Accuracy:** For accuracy use the high and low control set from GLYCOMARK, and/or run patient samples and send the sample to another validated reference lab to see the correlation.
- **Proficiency Testing:** The College of American Pathologists (CAP) has just added 1,5-anhydroglucitol to their Proficiency testing survey under the code AG. The 1,5-AG survey can be ordered by calling CAP at (847) 832-7000 and asking for survey AG or by downloading the order form at CAP.org.

## Calibration and Quality Controls with the GLYCOMARK<sup>®</sup> Assay

- **Frequency of Calibration:** The frequency of calibration is instrument dependent. According to users it could be as often as daily for the Alfa Wassermann ACE Alera or hold for two weeks in the case of the Roche Integra.
- **Calibration and Quality Control Use:** The number of uses per calibrator standard depends upon the answer to number 1 above and to the sample volume according to the GlycoMark parameters. You can divide this sample volume into the 15 ml provided in the three calibrator vials (5 ml per vial). The number of available quality control uses is determined by dividing the sample volume into 6 ml (2 ml X 3 per high or low control). Depending upon your SOP you may use one each of the high and low control per run.
- **Expiration Dates:**
  - The calibrator standard and reagent set have an expiration date one year from date of manufacture. The control set has eighteen months from the date of manufacture.
  - Calibrator standard, controls and reagents are stable for thirty days at 2 - 8 C after opening the vials.
- **Cost for Calibration and Controls:** At list price, we have calculated the cost per test on the Hitachi 917 is between 4-6 cents per sample for both calibrator and controls. The efficiency of the analyzer (lower or higher than the Hitachi) would change this cost slightly.

