

Laboratory Specifications

Regulatory Items	
Date of 510(k) clearance	22 September 2003 [510(k) Document Number K031604]
Intended Use	The GlycoMark test provides quantitative measurement of 1,5-anhydroglucitol (1,5-AG) in serum or plasma. The test is for professional use, and is indicated for the intermediate term monitoring of glycemic control in people with diabetes.
Expected Values	
Reference Range	10.7-32.0 µg/mL (males), 6.8-29.3 µg/mL (females)
Assay Specifications	
Calibration	2-point calibration using GlycoMark Calibration Standard (NK-8320) and saline reagent blank.
Quality Control	Per laboratory procedure using GlycoMark Controls (NK-8330)
Saline Reagent Blank	0.9% NaCl in deionized water
Sample Diluent	None
Measurement Type	Kinetic, 5 min read (t = 10 min reading minus t = 5 minute reading)
Measurement Wavelengths	546 nm, 700 nm
Sample Type	Serum or plasma
Reagent, Calibrator and Control Storage Temperature	2-8 °C
Closed-vial Stability	Until expiration date printed on container
Open-vial stability	One month
Chemistry Analyzers and Estimated Efficiencies*	
Abbott Architect C8000	100 tests
Alfa Wassermann ACE Alera	150
Bayer/JOEL Advia BM1650	150
Beckman Coulter DxC 800	90
Beckman Coulter Synchron CX5	120
Beckman Coulter Synchron LX20	90
BioLis 24i	120
Dade Dimension	75
Horiba ABX Pentra 400	113
Olympus AU 400	100
Olympus AU 480, 640, 680, 5400	120
Olympus AU 2700	100
Olympus AU 5800	150
Ortho Vitros 5600	120
Roche Cobas Mira	100
Roche Cobas c501 (6000)	180
Roche Integra	113
Roche Hitachi 917	150
Roche Hitachi 7600S, 7700, P Module	120
Roche P 800, P Module, 7700	100

* The GlycoMark test can be run on any open-channel chemistry analyzer. The estimated instrument efficiency is based on the volume of GlycoMark reagents supplied divided by the volume used in the assay, minus 10% to account for quality controls, calibration and waste. Factors that can decrease efficiency include instrument-specific parameters such as pipetting parameters and dead volume, and the frequency of quality control and calibration.

