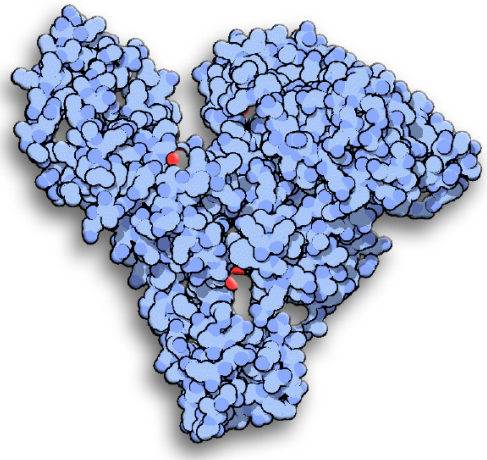


Serum Albumin Molecule

GlycoGap®

ENZYMATIC GLYCATED SERUM PROTEIN (GLYCATED ALBUMIN) ASSAY KIT

DUAL VIAL LIQUID STABLE

510(k) Cleared CE

DIAZYME'S GLYCATED ALBUMIN BRIDGES THE GAP IN DIABETES TESTING

The GlycoGap® test serves as an intermediate term indicator of average blood glucose for the past 2-3 weeks, which closes the existing information gap between daily blood glucose testing and the 2-3 month snapshot provided by HbA1c testing. The American Diabetes Association recommends using HbA1c to screen and diagnose diabetes. However, HbA1c alone may not accurately reflect serum glucose concentrations in all patients with diabetes. There is an ongoing debate about the interpretation of HbA1c levels in black persons and the possible need for race based cut points.

THE GLYCATION GAP

The difference between the actual measured HbA1c concentration and the predicted HbA1c from glycated serum protein is called the glycation gap. The glycation gap information provided by measuring HbA1c and Glycated Serum Protein (GSP) together offers improved diagnostic accuracy by more reliably predicting complications of diabetes including nephropathy and retinopathy than HbA1c alone.

MORE SPECIFIC AND ACCURATE THAN NBT FRUCTOSAMINE

The enzymatic assay is more specific for glycated serum protein than the old NBT based Fructosamine assay which is significantly interfered by endogenous reducing substances such as thiol groups, NADH, and ascorbate. Studies showed that only about half of the reducing activity (Fructosamine) was due to specific non-enzymatic glycation of proteins, and the remaining unspecific activity varied from serum to serum. The NBT based Fructosamine assay is therefore of limited specificity for the exact measurement of glycated proteins in serum.

ENZYMATIC SPECIFICITY AND ACCURACY

The Diazyme Glycogap® uses Proteinase K to digest serum proteins and utilizes Diazyme's proprietary Fructosaminase™ which is specific for ketoamines. The enzymatic method is more reliable because it does not have the inaccuracies caused by non-glycated protein reducing substances seen with the NBT method. This helps to ensure a level of accuracy and reliability that is not possible with the older method.

GLYCOGAP® IS AN AID TO DIABETIC MONITORING WHERE HbA1c IS OF LIMITED VALUE

Especially useful for monitoring patients with the following conditions

- Hemodialysis or peritoneal dialysis
- Gestational diabetes (diabetic pregnancy)
- Hemolytic anemia or blood loss
- Rapid evaluation of effectiveness of diet, activity or medication adjustments
- Complementary to HbA1c in diagnosis and screening of diabetes. It offers more conclusive and accurate results when both tests are used.

DIAZYME

DIAZYME

GlycoGap®

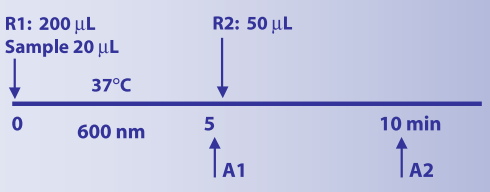
Enzymatic Glycated Serum Protein (Glycated Albumin) Assay Kit

Dual Vial Liquid Stable

Enzymatic Glycated Serum Protein (Glycated Albumin)

Method	Enzymatic
Correlation to Predicate Method	N = 65 r^2 = 0.9966 Slope = 0.9542 Intercept = 14.567 Range of values = 60 - 1249 µmol/L GSP
Linearity	0.0 to 1578.7 µmol/L GSP
Dynamic Range	21.0 – 1354.0 µmol/L
On-Board Stability *	Four weeks
Calibration Interval *	Seven days
Calibration	Two point Sold separately
Sample Type	Serum
Sample Size	20 µL

Assay Procedure



Bridges the Gap in Diabetes Monitoring

- Provides superior specificity and accuracy compared to fructosamine assays (NBT method) for monitoring and assessment of short-term to medium-term (past 2-3 week period) average blood glucose levels.
- Complementary to HbA1c in diagnosis and screening of diabetes. It offers more conclusive and accurate results when both HbA1c and GSP are used together.

Ideal for Glycation Gap Determinations

- Studies suggest that combining GSP results with HbA1c measurements provides a better assessment of long term risk of diabetic complications.

Convenient

- Liquid stable with a wide variety of instrument parameters for most open clinical chemistry systems

Precision per NCCLS – EP-5

Within-Run Precision

	Control Level 1	Control Level 2	Serum Level 1	Serum Level 2
N	80	80	80	80
Mean (µmol/L)	204	751	251	373
SD (µmol/L)	2.2	4.9	1.9	2.4
CV (%)	1.1%	0.7%	0.8%	0.6%

Within-Laboratory Precision

	Control Level 1	Control Level 2	Serum Level 1	Serum Level 2
N	80	80	80	80
Mean (µmol/L)	204	751	251	373
SD (µmol/L)	2.4	5.6	3.2	3.7
CV (%)	1.2%	0.7%	1.3%	1.0%

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