

GLYCATED SERUM PROTEIN ASSAY



Diabetic
Marker

Glycated Serum Protein (GSP) serves as a 2-3 week indicator of average blood glucose, closing the information gap between daily blood glucose and HbA1c monitoring. Studies have shown that GSP can be reliably used in medical conditions which impact red blood cell life span thus decreasing the accuracy of HbA1c measurements.

Diazyme's Glycated Serum Protein Assay is specific for glycated serum proteins and not affected by the interferences that can impact the accuracy of conventional fructosamine dye methods.

DIAZYME GLYCATED SERUM PROTEIN ASSAY ADVANTAGES

- Enzymatic method for the specific and accurate determination of GSP, Glycated Albumin and Fructosamine in serum
- Method eliminates the inaccuracies caused by non-glycated protein reducing substances that interfere with the NBT fructosamine methods
- GSP test utilizes the specificity of fructosaminase™ to eliminate significant interferences
- Liquid stable format requires no reagent preparation
- Wide range of instrument parameters are offered for simplifying implementation

REGULATORY STATUS

510(k) Cleared; EU:  .

Health Canada Registered

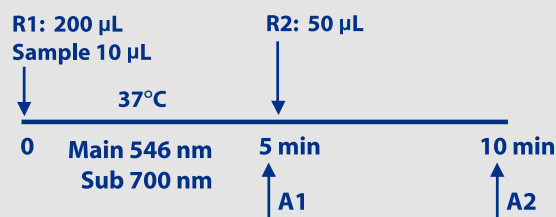
GLYCATED SERUM PROTEIN ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Colorimetric Trinder End-point Reaction
Sample Type & Volume	• Serum Sample Volume 10 µL
Method Correlation	N = 65 y-intercept = 14.57 Slope = 0.9542 R ² = 0.9966
Linearity	21.0 - 1354.0 µmol/L
LOD LOQ	7.2 µmol/L 13.0 µmol/L
Calibration Levels	2-Point Calibration
Reagent On-Board Stability	Opened: 4 weeks when stored at 2-8°C

Glycated Serum Protein Assay Procedure*



*Analyzer Dependent

For a list of validated parameters please contact Diazyme technical support at 858-455-4768 or email support@diazyme.com

1. Abidin D. et al. An Improved Enzymatic Assay for Glycated Serum Protein. Anal. Methods 2013; 5: 2461-2469

ASSAY PRECISION

Within-Run

	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

	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

ASSAY INTERFERENCE

The following interfering substances produce less than 10% deviation when tested at the indicated concentrations.

Ascorbic Acid:	5 mg/dL
Bilirubin:	7.5 mg/dL
Bilirubin (Conjugated):	5 mg/dL
Glucose:	2400 mg/dL
Hemoglobin:	200 mg/dL
Uric Acid:	35 mg/dL
Triglyceride:	2000 mg/dL

GA REFERENCE RANGE

Adults (20-60 years) have a reported normal range of 100-285 µmol/L. In a more recent study, adults (19-65 years) have a reported normal range of 151-300 µmol/L.¹ It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

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