

GLYCATED SERUM PROTEIN (GSP) ASSAY (GLYCATED ALBUMIN)

Dual Vial Liquid Stable

Diazyme's Glycated Serum Protein (GSP; Glycated Albumin) Assay is specific for glycated serum proteins which virtually eliminates the interferences that can impact the accuracy of conventional fructosamine methods. GSP serves as a 2-3 week indicator of average blood glucose, closing the information gap between daily blood glucose testing and HbA1c assays. Studies have shown that GSP can be reliably used in medical conditions which impact red blood cell life span and decrease the accuracy of HbA1c measurements. The reagent, controls and calibrators are all liquid stable and offer the added convenience of instrument specific packaging for many Beckman, Roche and Siemens analyzers.

DIAZYME GLYCATED SERUM PROTEIN ASSAY ADVANTAGES

- Diazyme's method eliminates the inaccuracies caused by non-glycated protein reducing substances which interfere with the NBT fructosamine method
- Diazyme's GSP test utilizes the specificity of fructosylamino oxidase to eliminate significant interferences
- Diazyme's enzymatic method is more reliable and specific than the older non-enzymatic fructosamine NBT method
- User friendly instrument specific packaging options available
- A wide range of instrument parameters are offered for facilitating and simplifying implementation

REGULATORY STATUS

510(k) Cleared  Health Canada Registered

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Beckman**
- Synchron
- AU Series
- **Roche**
- Hitachi
- **Siemens**
- Dimension



GLYCATED SERUM PROTEIN

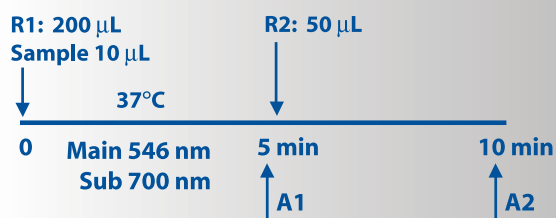
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ASSAY SPECIFICATIONS

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
Linear Range	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

Parameter questions for Glycated Serum Protein Assay should be addressed to Diazyme technical support. Please call 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	200 mg/dL

GA REFERENCE RANGE

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.

DIAZYME LABORATORIES

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