

# GLYCATED SERUM PROTEIN (GSP) ASSAY

## Dual Vial Liquid Stable

Diazyme's Glycated Serum Protein (GSP) Assay is specific for glycated serum proteins which eliminates the interferences that can impact the accuracy of conventional fructosamine dye 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

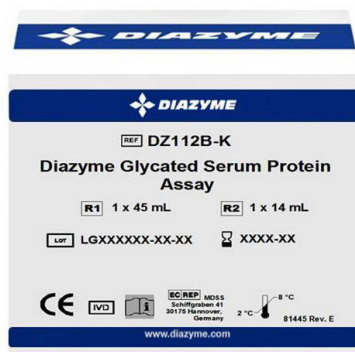
- Diazyme's method eliminates the inaccuracies caused by non-glycated protein reducing substances which interfere with the NBT fructosamine method
- Diazyme's GSP test utilizes the specificity of fructosylamino oxidase to eliminate significant interferences
- Diazyme's enzymatic method is more reliable 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

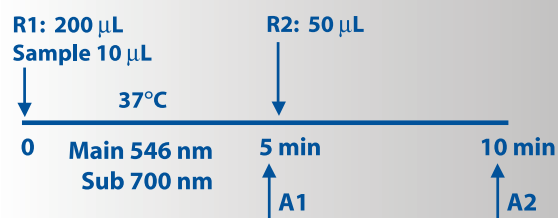
- |                  |                |                  |
|------------------|----------------|------------------|
| • <b>Beckman</b> | • <b>Roche</b> | • <b>Siemens</b> |
| - Synchron       | - Hitachi      | - Dimension      |
| - AU Series      | - Modular P    |                  |



## ASSAY SPECIFICATIONS

<b>Method</b>	Colorimetric Trinder End-point Reaction
<b>Sample Type &amp; Volume</b>	• Serum  Sample Volume 10 µL
<b>Method Correlation</b>	N = 65 y-intercept = 14.57 Slope = 0.9542 R <sup>2</sup> = 0.9966
<b>Linear Range</b>	21.0 - 1354.0 µmol/L
<b>LOD</b> <b>LOQ</b>	7.2 µmol/L 13.0 µmol/L
<b>Calibration Levels</b>	2-Point Calibration
<b>Reagent On-Board Stability</b>	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](mailto: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
<b>N</b>	80	80	80	80
<b>Mean (µmol/L)</b>	204	751	251	373
<b>SD (µmol/L)</b>	2.2	4.9	1.9	2.4
<b>CV (%)</b>	1.1%	0.7%	0.8%	0.6%

### Within-Laboratory

	Control Level 1	Control Level 2	Serum Level 1	Serum Level 2
<b>N</b>	80	80	80	80
<b>Mean (µmol/L)</b>	204	751	251	373
<b>SD (µmol/L)</b>	2.4	5.6	3.2	3.7
<b>CV (%)</b>	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 mmol/L. Adults (19-65 years) have a reported normal range of 151-300 µmol/L.<sup>1</sup> 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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