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 fructosaminase™ 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
  - Modular P
- **Siemens**
  - Dimension

Diazyme Glycated Serum Protein Assay

- 1 x 45 mL
- 1 x 14 mL

www.diazyme.com
ASSAY SPECIFICATIONS

<table>
<thead>
<tr>
<th>Method</th>
<th>Colorimetric Trinder End-point Reaction</th>
</tr>
</thead>
</table>
| Sample Type & Volume | • Serum  
Sample Volume 10 μL |
| Method Correlation | N = 65  
y-intercept = 14.57  
Slope = 0.9542  
R² = 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*

R1: 200 μL  
Sample 10 μL

R2: 50 μL

37°C

0  
Main 546 nm  
Sub 700 nm

5 min A1  
10 min A2

*Analyzer Dependent

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

ASSAY PRECISION

Within-Run

<table>
<thead>
<tr>
<th></th>
<th>Control Level 1</th>
<th>Control Level 2</th>
<th>Serum Level 1</th>
<th>Serum Level 2</th>
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<tbody>
<tr>
<td>N</td>
<td>80</td>
<td>80</td>
<td>80</td>
<td>80</td>
</tr>
<tr>
<td>Mean (μmol/L)</td>
<td>204</td>
<td>751</td>
<td>251</td>
<td>373</td>
</tr>
<tr>
<td>SD (μmol/L)</td>
<td>2.2</td>
<td>4.9</td>
<td>1.9</td>
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<tr>
<td>CV (%)</td>
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Within-Laboratory

<table>
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<th>Control Level 1</th>
<th>Control Level 2</th>
<th>Serum Level 1</th>
<th>Serum Level 2</th>
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<td>5.6</td>
<td>3.2</td>
<td>3.7</td>
</tr>
<tr>
<td>CV (%)</td>
<td>1.2%</td>
<td>0.7%</td>
<td>1.3%</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

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. 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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