GLYCATED SERUM PROTEIN (GSP)
(GLYCATED ALBUMIN)

- Rapid evaluation of effectiveness of diet, activity or medication adjustments
- A reliable short-term marker of glycemic control Diazyme’s GSP (glycated albumin) test serves as a 2-3 week indicator of average blood glucose
- Diazyme’s GSP (glycated albumin) assay eliminates the inaccuracies of conventional fructosamine methods by utilizing a uniquely specific enzymatic method
- Can be used with confidence in patients with conditions that interfere with the RBC lifespan which may reduce the reliability of HbA1c measurements

DIRECT ENZYMATIC HbA1c

- Fully enzymatic, no latex particle residue to cloud cuvettes and virtually eliminates interference from hemoglobin variants HbS, HbC, HbE
- Directly measures glycated hemoglobin and is resistant to interference from post transcript modifications
- Single channel assay eliminates the need for a dedicated channel for total hemoglobin measurement
- IFCC certified with excellent correlation to Tosoh HPLC and Roche Tina-Quant methods
- The gold standard for measurement of glycemic control over 2-3 months

1,5-ANHYDROGLUCITOL
GLYCOMARK® (1,5-AG)

- GlycoMark (1,5-AG) reflects hyperglycemia above the renal threshold over the preceding 1-2 weeks which is complimentary to HbA1c and Glycated Serum Protein determinations
- The test provides a useful, unique perspective of patient’s recent hyperglycemic excursions, which may not be evident from standard glycemic markers
- This information makes it possible to rapidly identify patients with glycemic variability that may benefit from more frequent self-monitoring of blood glucose (SMBG) or continuous glucose monitoring (CGM)
<table>
<thead>
<tr>
<th>Method</th>
<th>Direct Enzymatic HbA1c</th>
<th>GSP/Glycated Albumin</th>
<th>1,5-Anhydroglucitol GlycoMark* (1,5-AG)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sample Type</strong></td>
<td>Whole Blood (EDTA)</td>
<td>Serum</td>
<td>Serum</td>
</tr>
<tr>
<td><strong>Sample Volume</strong></td>
<td>25 µL</td>
<td>10 µL</td>
<td>4 µL</td>
</tr>
<tr>
<td><strong>Precision</strong></td>
<td>Within-Run Precision ≤ 1.0 CV%</td>
<td>Within-Run Precision ≤ 1.1 CV%</td>
<td>Within-Assay Precision ≤ 3.8%</td>
</tr>
<tr>
<td></td>
<td>Total Precision ≤ 1.8 CV%</td>
<td>Within Laboratory Precision ≤ 1.3 CV%</td>
<td>Between-Assay Precision ≤ 3.71 CV%</td>
</tr>
<tr>
<td><strong>On-Board Stability</strong></td>
<td>Opened: Four weeks at 2-8°C</td>
<td>Opened: Four weeks at 2-8°C</td>
<td>Opened: 30 days at 2-8°C</td>
</tr>
<tr>
<td><strong>Calibration</strong></td>
<td>2-Point Calibration</td>
<td>2-Point Calibration</td>
<td>2-Point Calibration</td>
</tr>
<tr>
<td><strong>Linear Range</strong></td>
<td>4.0% - 12.0% HbA1c</td>
<td>21.0 - 1354.0 µmol/L</td>
<td>0-50 µg/mL</td>
</tr>
<tr>
<td><strong>Instrument Specific Packaging</strong></td>
<td>Beckman - Synchron - AU Series</td>
<td>Universal Packaging</td>
<td>Universal Packaging</td>
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<tr>
<td></td>
<td>Siemens - Dimension</td>
<td>Beckman - AU Series</td>
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<tr>
<td></td>
<td>Roche - Hitachi</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Regulatory Status</strong></td>
<td>• 510 (k) Cleared - CE - Health Canada</td>
<td>• 510 (k) Cleared - CE - Health Canada</td>
<td>• 510 (k) Cleared - CE</td>
</tr>
</tbody>
</table>

* The GlycoMark (1,5-AG) test is only sold in the USA  * Based on Roche Hitachi 917 Parameters

The 1,5-anhydroglucitol GlycoMark (1,5-AG) Assay is manufactured by Diazyme Laboratories

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