**SUMMARY OF TEST PROCEDURE**

**Figure 1: Procedure Diagram**

![Diagram of the test procedure](image)

1. **Sample:** 10 µl
2. **R1:** 200 µl
3. **R2:** 50 µl
4. **O.D. Measurement 1:**
   - 0 µl
   - 300 sec.
5. **O.D. Measurement 2:**
   - 600 sec.

**Table 1: Instrument Parameters**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>GSP</th>
<th>Albumin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibration method</td>
<td>2 point linear</td>
<td>2 point linear</td>
</tr>
<tr>
<td>Wavelength</td>
<td>546nm/700nm</td>
<td>600nm/700nm</td>
</tr>
<tr>
<td>Test method</td>
<td>2 point end</td>
<td>1 point end</td>
</tr>
<tr>
<td>Reaction temperature</td>
<td>37°C</td>
<td>37°C</td>
</tr>
<tr>
<td>Slope of reaction</td>
<td>increase</td>
<td>increase</td>
</tr>
<tr>
<td>S/R1/R2 vol.</td>
<td>10/200/50 µl</td>
<td>2/200/µl</td>
</tr>
</tbody>
</table>

*Refer to Figure 1 and the package insert for detail

**INTENDED USE**

**Bioway Chemistry Reagent Series Glycated Albumin Reagent Kit** (the Kit) is intended for in vitro quantitative detection of % Glycated Albumin in human serum on automated clinical chemistry analyzers.

**SUMMARY AND EXPLANATION**

Glycated albumin is formed due to a non-enzymatic Maillard reaction between glucose and amino acid residues of albumin. Literature reports that the measurement of glycated albumin is useful for monitoring diabetic patients and elevated blood glucose levels correlate with increased glycated albumin. Glycated albumin level in serum is a short to medium term indicator of diabetic control (2-3 weeks). Published studies found that glycated albumin test is used to measure glycation gap for diagnosis of complications and nephropathy in diabetic patients. Glycated albumin test is complementary to HbA1c in diagnosis and screening of diabetes. It offers more conclusive and accurate results when both tests are used.

**TEST PRINCIPLES**

The kit is composed of Bioway GSP Assay and Bioway Albumin Assay. The Bioway GSP Assay uses proteinases to digest serum proteins including glycated protein molecules into low molecular weight glycated protein fragments (GPF), and uses Fructosaminase, a microorganism originated amadoriase to catalyze the oxidative degradation of Amadori product GPF to yield protein fragment (PF), glucosone and H₂O₂. The H₂O₂ released is measured by a colorimetric Trinder reaction. The absorbance at 546nm is proportional to the concentration of GSP expressed in µmol/L.

\[
\text{GSP} \xrightarrow{\text{Proteinases}} \text{Glycated protein fragments (GPF)}
\]

\[
\text{GPF} \xrightarrow{\text{Fructosaminase}} \text{PF} + \text{Glucosone} + \text{H}_2\text{O}_2
\]

\[
\text{H}_2\text{O}_2 + \text{TOOS} + 4\text{-AAP} \xrightarrow{\text{Peroxidase}} \text{Color} + \text{H}_2\text{O}
\]

The Bioway Albumin Assay is based on the dye-binding properties of serum albumin with bromocresol green (BCG) (a triphenylmethane family dye). The absorbance of BCG at 630 nm increases with binding to albumin, and is proportional to the albumin concentration present. The albumin concentration is expressed in g/dL.

**MATERIALS PROVIDED**

**Reagents:**

- **GSP**
  - R1: Tris-HCl buffer, 4-AA, Enzymes, stabilizers
  - R2: Tris-HCl buffer, enzymes, TOOS, HRP, Geneticin, and stabilizers.

- **Albumin**
  - R1: Bromocresol green buffer

**MATERIALS NEEDED BUT NOT PROVIDED**

1. Automated chemistry analyzer.
2. GA calibrator set (available for purchase) and control set (available for purchase).

**INSTRUMENT**

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

**STORAGE AND STABILITY**

Store the reagents at 2-8°C. Avoid direct sunlight. The Kit is stable until expiration date when stored properly. Reagents are stable for 1 month at 2-8°C after opening.

**PRECAUTIONS**

1. The Kit is for in vitro diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Do not mix and use different lots of reagents.
5. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
6. Reagents contain preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

**SPECIMEN COLLECTION AND HANDLING**

Follow standard laboratory procedures to collect serum samples. It is recommended to perform test immediately after sample collection to avoid hemolysis. If the test cannot be done immediately, store sample at 2-8°C for up to 2 weeks or at -80°C for up to 3 month. Avoid repeated freezing and thawing.
**Bioway Chemistry Reagent Series**

**Glycated Albumin Reagent Kit**

*Detection of Cardiac Glycated Albumin in Human Serum on Chemistry Analyzers*

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**TEST PROCEDURE (see Figure 1)**

**Calibration:** 2 level calibrator set available for purchase for GSP and Albumin (separate calibrators). Recommend using Bioway calibrators for optimal results. Use linear calibration method.

**Test procedure:** The % Glycated Albumin is determined by assaying the Bioway GSP Assay and the Albumin Assay on two separate channels. See Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

**GSP**

1. Add 10 µl of sample and 200 µl of R1; mix well and incubate at 37°C for 300 seconds.
2. Take optical density measurement OD 1 right before addition of R2 at 300 sec.
3. Add 50 µl of R2, mix well and incubate at 37°C for another 300 seconds.
4. Take optical density measurement OD 2.
5. Calculate ΔOD = OD2 - OD1

**Albumin**

1. Add 2 µl of sample and 200 µl of R1; mix well and incubate at 37°C for 60 seconds.
2. Take optical density measurement OD 1.

**RESULT**

The % Galycated Albumin is calculated as indicated below:

\[
\%\ GA = \frac{GSP\ (\mu mol/L) \times 0.182 + 1.97}{Albumin\ (g/dL)} + 2.9
\]

**EXPECTED VALUES**

10.4% ~ 15.7%.

It is recommended for each laboratory to establish its own expected values.

**QUALITY CONTROL**

Using Bioway control (available for purchase) is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

**LIMITATIONS**

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. The test result from the Kit should not be used as the only basis for definite diagnosis.
3. Roche fructosamine calibrators and controls may not be compatible with Bioway GA Assay.
4. Do not use the % GA equation with other assays.
5. Do not use other albumin assay with % GA equation without validation.

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**PERFORMANCE CHARACTERISTICS**

**Linearity:** 6.4% ~ 63.3% GA

**Method comparison:** 315 serum samples compared with Lucica® GA-L method on Hitachi 917, R²=0.9746

**Precision:** Within Run: CV≤10%; Run-to-Run: CV≤10%

**Interference:** GSP: no interference detected for: ascorbic acid (5 mg/dL), bilirubin (7.5 mg/dL), glucose (2400 mg/dL), Hemoglobin (200mg/dL), Uric Acid (35mg/dL) and Triglyceride (2000mg/dL)

Albumin: no interference detected for: hemoglobin (300mg/dL), bilirubin (10.2 mg/dL), and triglyceride (1020 mg/dL).

**REFERENCES**


Not Intended for Sale in the United States.