



## Glycated Serum Protein (GSP) LiquiColor® Procedure No. 2350

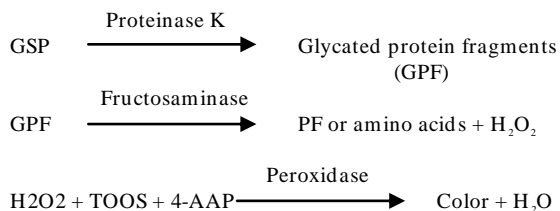
### Intended Use

Stanbio Glycated Serum Protein (GSP) Assay in conjunction with Stanbio Glycated Serum Protein calibrator, are intended for the quantitative determination of glycated serum proteins (GSP; glycated albumin; fructosamine) in serum. The measurement of glycated serum proteins is useful for monitoring diabetic patients. For *in-vitro* diagnostic use only.

### Summary and Principle<sup>1, 2</sup>

Fructosamine is formed due to a non-enzymatic Maillard reaction between glucose and amino acid residues of proteins. In diabetic patients, elevated blood glucose levels correlate with increased fructosamine formation. Glycated serum proteins (GSP; glycated albumins; fructosamine) are a medium term indicator of diabetic control (2-3 weeks).

The Stanbio Glycated Serum Protein Assay uses proteinase K to digest GSP into low molecular weight glycated protein fragments (GPF), and uses a specific fructosaminase™, a microorganism originated amadoriase to catalyze the oxidative degradation of Amadori product GPF to yield PF or amino acids, gluconone and H<sub>2</sub>O<sub>2</sub>. The H<sub>2</sub>O<sub>2</sub> released is measured by a colorimetric Trinder end-point reaction. The absorbance at 546-600 nm is proportional to the concentration of glycated serum proteins.



### Reagents – Working Solutions

GSP Reagent (R1): Enzyme/ substrate reagent containing Good's Buffer, 4-AA, enzymes, and stabilizers

GSP Color Reagent (R2): Enzyme/ substrate reagent containing Good's Buffer, enzymes, TOOS, HRP, Geneticin, and stabilizers.

### Precautions

1. Specimens and reagents containing human sourced materials should be handled as if potentially infectious, using safe laboratory procedures such as those outlined in Biosafety in

Microbiological and Biomedical Laboratories (HHS Publication Number [CDC] 93-8395).

2. As with any diagnostic test procedure, results should be interpreted considering all other test results and the clinical status of the patient.

3. Avoid swallowing and contact with skin or mucous membranes.

4. Additional safety information concerning storage and handling of this product is provided within the Material Safety Data Sheet for this product.

### Reagent Preparation

Stanbio's Glycated Serum Protein (GSP) Assay reagents are liquid stable, ready to use reagents.

### Reagent Storage and Stability

The reagents are stable when stored at 2-8°C until the expiration date on the label. Do not mix reagents of different lots. **DO NOT FREEZE.** The Reagent is stable for at least 4 weeks on-board with refrigeration at 2-8°C.

### Materials Provided

Please refer to the "Reagents – Working Solutions" Section.

### Materials Required But Not Provided

Any instrument with temperature control of 37 ± 0.5°C that is capable of reading absorbance at 546-600 nm may be used.

The Stanbio GSP Calibrator Set (REF 2360-401) and Stanbio GSP Control Set (REF 2370-401) are sold separately.

### Specimen Collection and Preparation<sup>3</sup>

Use fresh patient serum samples. Serum should be separated from cells immediately after collection.

### Sample Stability<sup>3</sup>

Samples can be stored at 2-8°C for 2 weeks or at -20°C for up to 4 weeks. Per CLSI guideline, it is the responsibility of the individual laboratory to use all available references and/ or its own studies to determine specific specimen stability criteria for its laboratory.

### Interference

The following interfering substances produce less than 10% deviation when tested at the indicated concentrations.

Interference	Concentration
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

### Test Scheme for Chemistry Analyzer

GSP should be measured according to specific application parameters for specific chemistry analyzers. Applications are available upon request.

Application questions about the Stanbio GSP Assay should be addressed to Stanbio Technical Support.

### Calibration

The Stanbio GSP Calibrator Set (2360-401) includes saline with preservative for use as Calibrator 1 and lyophilized Calibrator 2. Enter 0 mol/ L for Calibrator 1 and Calibrator 2 lot specific value provided on its vial label for Calibrator 2 on analyzer to perform calibration. Stanbio's GSP Calibrator Set is intended for use with Stanbio Glycated Serum Protein Assay reagents (REF 2350-062). Calibrator 2 is in lyophilized form and stable at 2-8°C until the expiration date noted on the label. Reconstitute lyophilized contents of Calibrator 2 with 1 mL of distilled water per the IFU included with the Stanbio GSP Calibrator Set. To ensure complete reconstitution, equilibrate vial at room temperature for 30 minutes with gentle swirling a few times before first use, make sure all the contents are dissolved. Reconstituted Calibrator 2 is stable for 14 days when stored at 2-8°C capped tightly.

#### Calibration Frequency

The Stanbio Glycated Serum Protein Assay requires weekly calibration.

### Quality Control

Stanbio's GSP Control Set (REF 2370-401) is recommended to use as daily quality control and can be purchased separately from Stanbio Laboratory. Users should follow the appropriate federal, state and local guidelines concerning the running of external quality controls and handling of bio-hazardous material. Stanbio's GSP controls are in lyophilized form and stable at 2-8°C until the expiration date noted on their label. Reconstitute lyophilized contents of each vial with 1 ml of distilled water per the IFU included with the Stanbio GSP Control Set. To ensure complete reconstitution, equilibrate vial at room temperature for 30 minutes with gentle swirling a few times before first use, make sure all the contents are dissolved. Reconstituted controls are stable for 14 days when stored at 2-8°C capped tightly.

### Results

Results are printed out in µmol/ L.

### Limitations

Other company's fructosamine calibrators and controls may not be compatible with Stanbio's Glycated Serum Protein assay.

## Reference Range

Adults (19-65 years) have a reported normal range of 151-300  $\mu\text{mol/L}$ .<sup>4</sup> It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

## Analytical Characteristics Accuracy

65 serum samples were tested with both Stanbio GSP assay and predicate method on Hitachi 917. The results are shown below:

Stanbio GSP vs. predicate on Hitachi 917	
N	65
r2	0.9966
slope	0.9542
Y intercept	14.57

## Precision

The precision of the Stanbio GSP Assay was evaluated according to CLSI EP5-A guideline. In the study, two controls and two levels of serum specimens containing about 200, 750, 250 and 375  $\mu\text{mol/L}$  fructosamine, respectively, were tested 2 runs per day in duplicates over 20 working days.

### Within Run Precision

	Control Level 1	Control Level 2	Serum Level 1	Serum Level 2
N	80	80	80	80
Mean ( $\mu\text{mol/L}$ )	204	751	251	373
SD ( $\mu\text{mol/L}$ )	2.2	4.9	1.9	2.4
CV (%)	1.1%	0.7%	0.8%	0.6%

### Total Precision

	Control Level 1	Control Level 2	Serum Level 1	Serum Level 2
N	80	80	80	80
Mean ( $\mu\text{mol/L}$ )	204	751	251	373
SD ( $\mu\text{mol/L}$ )	2.4	5.6	3.2	3.7
CV (%)	1.2%	0.7%	1.3%	1.0%

## Limit of Detection (LOD) and Limit of Quantitation (LOQ)

The LOD and LOQ of the Stanbio GSP Assay were determined according to CLSI EP17-A. The LOD was determined to be 7.2  $\mu\text{mol/L}$  and LOQ was 13.0  $\mu\text{mol/L}$ .

## Linearity

Nine levels of linearity set were prepared by diluting a sample containing 1579  $\mu\text{mol/L}$  Fructosamine with saline according to CLSI EP6-A. The linearity set prepared was analyzed on Hitachi 917 over up to 1354  $\mu\text{mol/L}$ . allowable systematic error (Sea) was 3.5%.

Analytical measurement range of Stanbio's Glycated Serum Protein Assay is 21.0 – 1354.0  $\mu\text{mol/L}$ .

## References

1. Armbuster DA, Fructosamine: Structure, Analysis and Clinical Usefulness. *Clin. Chem.* 1987; 33 (12): 2153-2163.
2. Kouzuma T. *et al.* An Enzymatic Method for the Measurement of Gly-cated Albumin in Biological Samples. *Clin. Chimi. Acta* 2002; 324: 61-71.
3. CLSI. Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline - Fourth Edition. CLSI document H18-A4. Wayne, PA: CLSI; 2010.
4. Abidin D. *et al.* An Improved Enzymatic Assay for Glycated Serum Pro-te-in. *Anal. Methods* 2013; 5: 2461-2469.

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