

# BQ Kits

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## Glycated Serum Protein Enzymatic Assay

Catalog Number: BQ 005-EADD

### Intended Use

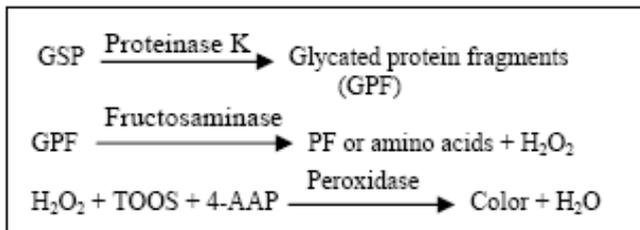
The assay kit is for determination of glycated serum proteins (fructosamine) in human serum.

### Clinical Significance<sup>1</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. Fructosamine is a medium term indicator of diabetic control (2-3 weeks).

### Assay Principle<sup>2</sup>

The BQ Kits assay for glycated serum proteins (GSP) uses Proteinase K to digest GSP into low molecular weight glycated protein fragments (GPF), and uses BQ Kit's specific fructosaminase™, a microorganism originated amadoriase to catalyze the oxidative degradation of Amadori product GPF to yield PF or amino acids, glucosone 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 600 nm is proportional to the concentration of glycated serum proteins (GSP).



### Materials Required But Not Provided

- GSP Calibrator Set: Includes Saline with preservatives for use as calibrator 0 and lyophilized calibrator 1.
- BQ Kits bi-level GSP controls are recommended.

### Reagent Composition

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Reagent	Size
R1	2 x 23 mL
R2	2 x 7.5 mL

**R1:** Enzyme/substrate reagent containing Good's buffer, 4-AA, Enzymes and stabilizers.

**R2:** Enzyme/substrate reagent containing Good's buffer, enzymes, TOOS, HRP, Geneticin, and stabilizers.

### Reagent Preparation

Reagent 1 and Reagent 2 are ready to use. Reagents from different lots should not be interchanged.

### Reagent Stability and Storage

The reagents are stable at 2-8 °C until the expiration date noted on the labels. Reagents are stable for 4 weeks once opened and stored on-board or refrigerated at 2-8 °C.

### Specimen Collection and Handling

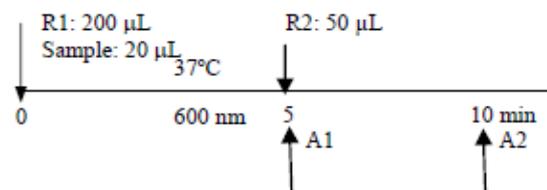
Use fresh patient serum samples. Serum should be separated from cells immediately after collection. Samples can be stored at 2-8 °C for 2 weeks or at -20°C for up to 4 weeks.

### Precautions

- For in vitro diagnostic use.
- 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).
- As with any diagnostic test procedure, results should be interpreted considering all other test results and the clinical status of the patient.
- Avoid swallowing and contact with skin or mucous membranes.

### Assay Procedure

Applications sheets for the use on automated clinical chemistry analyzers are available upon request.



### Calibration

The BQ Kits GSP Assay requires weekly calibration. The GSP Calibrator set includes saline with preservative for use as calibrator 0 and lyophilized calibrator 1. Enter 0 µmol/L for calibrator 0 and calibrator lot specific value provided on the certificate of analysis sheet for calibrator 1 on analyzer to perform calibration. BQ Kits GSP calibrator is intended for use with BQ Kits GSP Assay reagents. The calibrator 1 is in lyophilized form and stable at 2-8 °C until the expiration date noted on the label. Reconstitute lyophilized contents of calibrator 1 with 1ml of distilled water per instruction on certificate of analysis. 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 1 is stable for 14 days when stored at 2-8 °C capped tightly.

### Quality Control

BQ Kits bi-level GSP Controls are recommended to use as daily quality control and can be purchased separately from BQ Kits. Users should follow the appropriate federal, state and local guidelines concerning the running of external quality controls and handling of bio-hazardous material. BQ Kits bi-level GSP controls are in lyophilized form and stable at 2-8°C until the expiration date noted on the label. Reconstitute lyophilized contents of each vial with 1ml of distilled water per instruction on certificate of analysis. 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

Glycated Serum Protein results are reported in µmol/L.

### Reference range

Adults (20-60 years) have a reported normal range of 100 – 285 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.

### Limitations

Roche fructosamine calibrators and controls may not be compatible with BQ Kits Glycated Serum Protein Assay.

## Performance Characteristics

### Accuracy

65 Serum Samples were tested with both BQ Kits GSP assay and predicate method on Hitachi 917. The results are shown below:

	BQ Kits vs. predicate on Hitachi 917
N	65
R <sup>2</sup>	0.9966
Slope	0.9542
Y intercept	14.57

### Precision

The precision of the BQ Kits 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 µmol/L fructosamine, respectively, were tested 2 runs per day in duplicates over 20 working days.

#### Within Run precision

Samples	Control Level 1	Control Level 2	Serum Level 1	Serum Level 1
N	80	80	80	80
Mean (µmol/L)	204	751	251	373
SD (µmol/L)	2.2	4.9	1.9	2.4
CV (%)	1.1%	0.7%	0.8%	0.6%

#### Within Laboratory Precision

Samples	Control Level 1	Control Level 2	Serum Level 1	Serum Level 1
N	80	80	80	80
Mean (µmol/L)	204	751	251	373
SD (µmol/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 BQ Kits GSP assay were determined according to CLSI EP17-A. The LOD was determined to be 7.2 µmol/L and LOQ was 13.0 µmol/L.

### Linearity

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

Analytical measurement range of BQ Kits Glycated Serum Protein Assay is 21.0-1354.0 µmol/L.

### Interferences

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

<u>Interference</u>	<u>Concentration</u>
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

### 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 glycated albumin in biological samples. *Clin. Chim. Acta* 2002; 324: 61-71