Fructosamine Assay Kit (FRUC)

Method: NBT

Cat .No.	Size	Instrument
GB9122T	R1: 1×60 ml R2: 1×20 ml	For Hitachi 7060/7150 & Shimadzu CL7200/8000
GS9123T	R1: 1×60 ml R2: 1×20 ml	For Hitachi 7170 & OlympusAU640/400/600
GB9122T/B	R1: 3×60 ml R2: 3×20 ml	For Hitachi 7060/7150 & Shimadzu CL7200/8000
GS9123T/B	R1: 3×60 ml R2: 3×20 ml	For Hitachi 7170 & Olympus AU640/400/600

INTENDED USE
For the *in vitro* quantitative determination of fructosamine in serum.

CLINICAL SIGNIFICANCE
The fructosamine are formed in blood from glucose present therein. The carbonyl group of the glucose reacts with free protein amino residues causing the formation of Schiff's base. The half life time of the fructosamine is 17-20 days. So fructosamine determination is suitable for a long-term (1-3 weeks) monitoring of sugar metabolism for patients with diabetes, especially with type Ⅱ diabetes mellitus, and also suitable for drug efficacy monitoring.

ASSAY PRINCIPLES[1]
The serum's fructosamine is one kind of macromolecule alkone amines compounds. It can make nitrotetrazolium blue chloride reduced to formazan under the alkalinity condition. The quantity of the formazan is direct proportional to the fructosamine concentration. The color measured at 540 nm (530-550 nm), is directly propo-rtional to the fructosamine concentration.

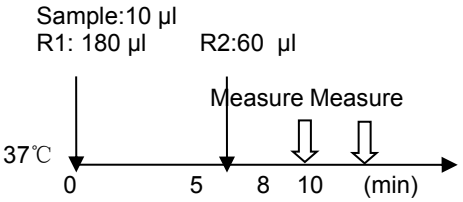
SAMPLE COLLECTION AND PREPARATION
Serum samples.
Use fresh patient serum.
Samples are stable for a week at 2-8℃, or for 6 months at -20℃.

REAGENT COMPOSITION

Contents	Concentration
Reagent 1 (R1)	
Carbonate buffer	0.1mol/L
Detergent	1.0%
Preservative	0.05%
Reagent 2 (R2)	
Carbonate	0.1 mol/L
Nitrotetrazolium blue chloride	0.5 mmol/L

STABILITY AND PREPARATION OF REAGENTS
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
The fructosamine assay kit reagents are stable for 1 month after opening and kept at 2-8℃.

ASSAY PROCEDURE
Test Procedure for Analyzers (HITACHI 7170/917)
Assay Mode: FIXED
Wave Length (main/sub): 546 nm/700 nm



1. Mix 10 µl sample with 180 µl R1 and incubate at 37 ℃ for 5 minutes.
2. Add 60 µl R2 into cuvette, mix and incubate at 37℃ for 3 minutes. Read initial absorbance A1.
3. Incubate at 37 ℃ for 2 minutes. Read initial absorbance A2.
4. Calculate absorbance change ΔA=A2-A1.

CALCULATION
$$\text{Concentration} = \frac{\Delta A_{sample}}{\Delta A_{calibrator}} \times \text{Calibrator value}$$

MATERIALS REQUIRED BUT NOT provided
Gcell Fructosamine Control (Cat .No. GQ-FRUC).

CALIBRATION
Recommend that this assay should be calibrated using Gcell calibrator (Cat .No. GC-FRUC).

QUALITY CONTROL
For quality control, use FRUC control as daily quality control sera and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE
Serum: ≤ 286 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.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY
The method is linear up to 1000 µmol/L. Sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor.

PRECISION
Repeated measurements using the same serum samples 10 times, the measured values of the coefficient of variation (CV) should be ≤ 10%

Inter Assay Precision
Consecutive three batches kit difference between the

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812
Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn
CE Revised 01DEC11 version 1102

grant shall be ≤ 10%.

INTERFERENCE

A Reagent blank may be performed by replacing sample or standard with double deionized water. The following analyze were tested up to the levels indicated and found not to interfere:

Hemoglobin:	2000 mg/dl
Intralipid:	2000 mg/dl
Bilirubin:	30 mg/dl
Ascorbic acid:	10 mg/dl

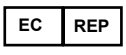
SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Howey JEA, Browning MCK, Fraser CG. Assay of serum fructosamine that minimizes standardization and matrix problems: Use to assess components of biological va-riation. Clin Chem 1987; 33: 269-272.

INDEX OF SYMBOLS

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
	Authorized Representative in the European Company

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn