

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 & Olympus AU640/400/600 |
| 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 nitrotriazolium 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 proportional to the fructosamine concentration.

SAMPLE COLLECTION AND PREPARATION

Serum samples.

Use fresh patient serum.

Samples are stable for a week at 2-8°C, or for 6 months at -20°C.

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 |
| Nitrotriazolium 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°C.

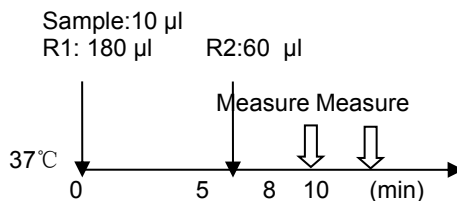
The fructosamine assay kit reagents are stable for 1 month after opening and kept at 2-8°C.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 7170/917)

Assay Mode: FIXED

Wave Length (main/sub): 546 nm/700 nm



- Mix 10 µl sample with 180 µl R1 and incubate at 37 °C for 5 minutes.
- Add 60 µl R2 into cuvette, mix and incubate at 37°C for 3 minutes. Read initial absorbance A1.
- Incubate at 37 °C for 2 minutes. Read initial absorbance A2.
- Calculate absorbance change $\Delta A = A2 - A1$.

CALCULATION

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

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:

- Check instrument settings and light source.
- Check reaction temperature.
- Check expiration date of kit and contents.

NORMAL VALUE

Serum: $\leq 286 \mu\text{mol/L}$

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 $\leq 10\%$

Inter Assay Precision

Consecutive three batches kit difference between the grant shall be $\leq 10\%$.

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 handling 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 variation. 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°C |
|  | Attention:See instruction for use |
|  | Authorized Representative in the European Company |

Manufacture: Beijing Strong Biotechnology, Inc.

Address : No. 15, Yanqi North Second Street, Yanqi Economic Development Area, Huairou District, Beijing 101400, P. R. China

Tel: +86 10 61667168

EC REP :Lotus NL B.V.

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