DR.FRUCTOSAMINE

DIAGNOSTIC KIT FOR DETERMINATION OF FRUCTOSAMINE ACTIVITY

Genuine Biosystem

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Kit name	Kit size	Cat. No
DR.FRUCTOSAMINE	1 x 15 ml	FRU01DR
DR.FRUCTOSAMINE	1 x 30 ml	FRU02DR

INTRODUCTION

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.

METHOD PRINCIPLE (NBT method)

The serum's fructosamine is one kind of macromolecule alkone amines compounds. It can make nitro blue tetrazolium (NBT method) 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.

REAGENTS

Package

	DR.FRUCTOSAMINE	
R1-Fructosamine Reagent	1 x 11.25 ml	1 x 22.5 ml
R2-Fructosamine Reagent	1 x 3.75 ml	1 x 7.5 ml
R3-Fructosamine Calibrator	1 vial	1 vial

The calibrator value has mentioned in the vial label.

Working reagent preparation and stability

The reagents are ready to use.The reagents when stored at 2-8°C are stable up to expiry date printed on the package. **The assay kit reagents are stable for 1 month after opening and kept at 2-8°C.** The reagents are stable for 7 days on board the analyser at approximately 2-8 °C.

Concentrations in the test

Carbonate buffer	0.1 mmol/L
Detergent	1.0 %
Preservative	0.05 %
Carbonate	0.1 mmol/L
Nitrotetrazolium blue chloride	0.5 mmol/L

Warnings and notes

(i) Products for in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
(ii) Reagents 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.
(iii) 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.
(iv) 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.

ADDITIONAL EQUIPMENT

- automatic analyzer or photometer able to read at 546 nm
- thermostat at 37ºC;
- general laboratory equipment;

SPECIMEN

Use fresh patient serum.
Samples are stable for a week at 2-8 °C or for 6 months at - 20 °C.

PROCEDURE

These reagents may be used both for manual assay and in several automatic analysers.
Applications for them are available on request.

Manual procedure

wavelength	546 nm
temperature	37°C
cuvette	1 cm

Pipette into the cuvette:

	Calibrator (C)	Test (T)
R1 Fructosamine Reagent	750 µl	750 µl
R2 Fructosamine Reagent	250 µl	250 µl
Mix well & incubate for 5 min. at 37ºC, then add		
Calibrator	40 µl	-
Serum	-	40 µl

Mix well and after exactly 180 secs read the absorbance A1 of the Test (T) and Calibrator (C) against reagent blank. In next 120 secs repeat absorbance reading A2 and calculate A (A2-A1) for test and calibrator.

Calculation

Fructosamine activity umol/L = ΔA (T) / ΔA (C) X Calibrator concentration

REFERENCE VALUES

Serum	≤ 286 umol/L

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

PERFORMANCE CHARACTERISTICS

Linearity: up to 1000 umol/L. If the sample activity exceeds 1000 umol/L, dilute sample with 0.9% NaCl and repeat the assay. Multiply the result by the dilution factor.

Specificity / Interferences

Haemoglobin up to 2000 mg/dl, intralipid up to 2000 mg/dl, bilirubin up to 30 mg/dl, ascorbatic acid up to 10 mg/dl do not interfere with the test.

Specificity / Interferences

Reapeated measurement 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 grant shall be ≤ 10%.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Howley 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.

SYSTEM PARAMETERS

Method	**:**	**Fixed Time (2-point)**
Wavelength	**:**	**546 nm**
Zero Setting	**:**	**Reagent Blank**
Temperature Setting	**:**	**37°C**
Incubation Temperature	**:**	**37°C**
Incubation Time	**:**	**----**
Delay time	**:**	**180 secs**
Read time	**:**	**120 secs**
No. of Reading	**:**	**2**
Interval time	**:**	**----**
Sample Volume	**:**	**0.04 ml (40 ul)**
Reagent Volume	**:**	**1.0 ml (1000 ul)**
Calibrator Concentration	**:**	**Refer Calibrator vial**
Units	**:**	**umol/L**
Factor	**:**	**---**
Reaction slope	**:**	**Increasing**
Linearity	**:**	**1000 umol/L**

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