N BIO - FRUCTOSAMINE

(NBT method)

KIT NAME	KIT SIZE	CAT. NO
N BIO - Fructosamine	1 x 16 ml	DFRU01016M

GENUINE BIOSYSTEM

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 efficiancy monitoring.

METHOD PRINCIPLE

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 proportional to the fructosamine concentration.

KIT CONTENTS

Reagent Name	DFRU01016M
R1 Fru Reagent	1 x 12 ml
R2 Fru Reagent	1 x 4 ml

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 546nm
-Thermostat at 37°C
-General Laboratory equipment

SPECIMEN

Use fresh 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.

Wavelength	546 nm
Temperature	37°C
Cuvette	1 cm

Pipette into the cuvette:

Reagent	Calibrator (C)	Test (T)
R1 Reagent	750 µl	750 µl
R2 Reagent	250 µl	250 µl
Mix well and incubater at 37 C for 5 mins, than add		
R3 Calibrator	40 µl	-
Sample	-	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 ΔA (A2-A1) for test and calibrator.

CALCULATION

$$\text{Fructosamine activity umol/L} = \frac{\Delta A(T)}{\Delta A(C)} \times \text{Calibrator concentration}$$

REFERENCE VALUES

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.

WASTE MANAGEMENT

Please refer to local legal requirements.

Specificity /Interfearnces:

Repeated measurement using the same serum sample for 10 times, the measured values of the co-efficient 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 requirement.

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 Balnk
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)
Standard Concentration	Refer Calibrator vial
Units	µmol/L
Factor	-----
Reaction Slope	Increasing
Linearity	1000 µmol / L

IVD CE

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