FRUCTOSAMINE

Kinetic Fixed Time
Colorimetric Determination
Nitroblue Tetrezolium Method in Serum

4 x 30 ml **REF CP03-120**

For quality control:
2 x 1 ml FRUCTOSAMINE Controlserum N + P **REF 7510**

PRINCIPLE

The colorimetric test is based on the glucose capacity to reduce nitrotetrazolium blue to formazan in an alkaline medium, when glucose is bound to protein aminic groups with a stable ketoaminic bond (fructosamine). A purple color develops, whose intensity is proportional to the protein glycation degree and therefore to fructosamine concentration. The measurement is done against a calibrator.

REAGENTS

Kit composition:	REF CP03-120	Quantity
REAGENT 1 Carbonate buffer pH 10,2	**CP03-120R1l**	**4 x 30 ml**
REAGENT 2 (pre-dosed) Nitroblue-tetrazolium Uricase	**CP03-120R2**	**4 vials**
CALIBRATOR (lyo)	**CP03-120C**	**1 vial**

STABILITY: store at 2-8°C and protect from light to keep reagents stable up to the expiration date.

PREPARATION OF WORKING SOLUTION

Pour the contents of a vial of Reagent 1 with a vial of Reagent 2. Shake gently until complete powder dissolution. Incubate for 30 minutes at room temperature before use.
WARNING: The working solution tends to turn violet as time passes by. Discard the working reagent when the initial absorbance values against distilled water is equal or higher than 0.350 at 550 nm.
STABILITY: 5 days at 2-8°C protected from light.

RECONSTITUTION OF CALIBRATOR

Reconstitute the vial with exactly 1 ml of distilled water.
Shake accurately and incubate for 30 minutes at room temperature.
The calibrator value in µmol/L is written on the vial label and may be different for each lot.
STABILITY: 5 days at 2-8°C.

SAMPLE

Non hemolized serum, heparinized or EDTA plasma.
STABILITY: 3 days at 15-25°C, 2 weeks at 2-8°C, 2 months at -20°C.

MANUAL ASSAY PROCEDURE

Wavelength:	550 nm
Optical path:	1 cm
Reading:	against distilled water
Temperature:	37°C
Method:	kinetic fixed time
Reaction time:	reading after 10 and 15 minutes
Linearity:	1000 µmol/L

Let the working reagent reach 20-25°C before the analysis. Do not incubate at 37°C for too long.

Pipette into test tubes or cuvettes labeled as it follows:
B/R: blank reagent, S: sample, Cal: calibrator:

	B/R	S	CAL
Working reagent	1000 µl	1000 µl	1000 µl
Calibrator	---	---	50 µl
Sample	---	50 µl	---
Distilled water	50 µl	---	---

Mix accurately and incubate at 37°C. After exactly 10 minutes, read the blank reagent (A1), the sample and the calibrator absorbencies against distilled water. After exactly 5 minutes of incubation, read again the blank reagent (A2), the sample and the calibrator absorbencies against distilled water.

CALCULATION

Calculate the absorbance differences for the blank reagent, the sample and the calibrator: ΔA = A2 - A1

$$\text{Fructosamine (µmol/L)} = \frac{\Delta AS - \Delta AB/R}{\Delta ACal - \Delta AB/R} \times \text{calibrator concentration}$$

REFERENCE VALUES

Non diabetic individuals: up to 285 µmol/L

PERFORMANCE CHARACTERISTICS

Linearity: up to 1000 µmol/L.
For higher values, dilute the sample 1:2 with saline solution and multiply the result by 2.

Within run precision:

	Level 1	Level 2
Average (µmol/L)	150	430
DS	1.22	6.01
CV %	0.81	1.40

Between run precision:

	Level 1	Level 2
Average (µmol/L)	145	485
DS	1.76	16.05
CV %	1.21	3.30

Interferences: states of altered protein metabolism can influence the fructosamine defination. Up to 2 mg/dl of bilirubin does not interfere. Up to 100 mg/dl of hemoglobin does not interfere. Up to 3 mg/dl of ascorbic acid does not interfere. Uric acid and lipemia do not interfere.

Correlation: Far kit to define fructosamine shows a correlation coefficient of 0.98 in comparison to another kit available on the market.

NOTES

1. Refer to MSDS.
2. In hydremic conditions (for example pregnancy), it is advisable to relate fructosamines to proteins by the following formula:
   $$\text{Rel. fructosamine (µmol/L)} = \frac{\text{fructos. def. value x 7.2 (in µmol/L)}}{\text{total proteins def. value (in g/dl)}}$$
3. Each laboratory should define its own reference values.
4. Reaction volumes can be proportionally varied without change in calculation.
5. Disposal waste according to local laws.
6. Chemistry analyzer parameters are available.

WARNINGS AND PRECAUTIONS

The reagents may contain non-reactive components and various preservatives. Contact with the skin and ingestion should be avoided. Use the normal precautions expected with correct behavior in laboratory.

REFERENCE

1. Johnson R.N., Metcalf P.A., Baker J.R.: Clin.Chim.Acta 127,87-95 (1983);
2. Smid E., Ferencz A., Fodor M.: Clin.Chim.Acta 156215-220 (1986)
3. Schleicher E.D., Vogt B.W.: Clin.Chem 36, 136-139 (1990).

MANUFACTURER

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KEY SYMBOLS

IVD	In Vitro diagnostic medical device
LOT	batch number
REF	catalogue number
	temperature limits
	use by
	caution
	consult accompanying documents

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