



# FRUCTOSAMINE LR liquid reagent

REF C3400620 456 Test

CE C3400620A 456 Test  
IVD For in vitro medical device

## Use

Kit for measurement of fructosamine in serum or plasma. Colorimetric method NBT

## Summary

Fructosamine measurements are used to check the average trend of the Glycaemia in latest 2-3 weeks

## Principle

The level of Fructosamine are high in diabetic patients with high levels of haematic glucose. Fructisamine is a short- medium term indicator of the diabetic control, while the determination of haematic glucose is only a short term indicator. It originates from a not enzymatic Maillard reaction between glucose and the aminoacid residuals of proteins.

Chetoamins in alkaline environment reduce nitroretrozoline blue. The intensity of violet colour developed is directly proportional to the fructosamine in the tested sample.

## Reagents

R1	Carbonate buffer	160.0 mmol/l
	NBT	0.38 mmol/l

## Reagent Preparation

Reagents are liquid and ready to use.

## Storage and stability

- Store the kit at 2-8°C.
- After opening, the R1 vial is stable 30 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.

## Precaution in Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). However the reagent should be handled with caution, according to good laboratory practice. Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contact with skin, eyes and mucous membranes.

## Waste Management

Please refer to the local legal requirements.

## Specimen Collection and Preparation

- Serum- Heparinized plasma or EDTA plasma
- Do not use samples with haemolysis.
- The fructosamine is stable in the samples up to 7 days at 2-8°C.

## Note

- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the single vials.

## Procedure

Wavelength  $\lambda$ : 550 nm  
 Working Temperature 37°C  
 Optical path 1 cm  
 Reaction "fixed time"  
 Bring the reagents at 15-25° before use them.

## -- Monoreagent Procedure "sample starter"

	BLANK	STD	SAMPLE
Working Reagent	1000 $\mu$ l	1000 $\mu$ l	1000 $\mu$ l
Sample	--	--	100 $\mu$ l
Standard	--	100 $\mu$ l	--

Mix, then incubate for 5' at 37°C (15-25°C). Measure the absorbance of the sample (EC) and standard (ESTD) against the reagent blank.

## Calculation

$$\text{Fructosamine } [\mu\text{mol/l}] = \text{EC} / \text{ES} \times \text{Conc STD}$$

The reagent performances are related to 37°C, 1 cm and 550 nm.

## Reference Values

Serum or plasma up to 285  $\mu$ mol/l

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

## ANALYTICAL PERFORMANCES

### Linearity

Reaction is linear up to a concentration of 1000  $\mu$ mol/l. Samples with values exceeding 1000  $\mu$ mol/l must be diluted with saline solution. Then multiply the result for diluting factor.

### "Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN ( $\mu$ mol/l)	N = 199.2	P = 428.26
S.D.	N = 2.14	P = 8.50
C.V.%	N = 1.47	P = 1.87

### "Inter-Assay" precision (between-Run)

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN ( $\mu$ mol/l)	N = 199.3	P = 429.41
S.D.	N = 2.40	P = 8.68
C.V.%	N = 1.20	P = 1.82

## Analytical sensitivity

The test sensitivity in terms of detection limit is: 22  $\mu$ mol/l.

## Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor:  $r = 0.98$

$$y = 0.9655x + 28.529$$

## Interferences

No interference was observed by the presence of:

Bilirubin	$\leq$ 20 mg/dl
Triglycerides	$\leq$ 600 mg/dl
Hemoglobin	$\leq$ 100 mg/dl

For a comprehensive review of interfering substances, refer to the publication by Young.

## Quality controls

It's necessary, every time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

## Bibliography

Kaplan, L.A., Pesce, A.J.: "Clinical Chemistry", Bohuon, C. Clin. Chem. Acta 16, 155 (1957). Mann, C.I. and Yoe, J.H., Anal. Chem. 28,202 (1955). Fragay D.A., Casey, Clin. Biochem., 791 (1974). Young D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, DC 5<sup>th</sup> ed.2000.

## Symbols

CE CE Mark (requirement of 98/79 regulation)

IVD in vitro medical device

LOT Batch Code

Use by

Storage temperature limits

Read instruction for use

Gesam Production srl