CE IVD DIALAB

Liquid Reagents – ready to use

FRUCTOSAMINE

NBT

2 Reagents

Diagnostic reagent for quantitative in vitro determination of fructosamine in human serum or plasma on photometric systems

REF Cont.

310144	**4 x 20 ml**	4 x 14 ml	Reagent 1
		4 x 6 ml	Reagent 1a
310140	**2 x 20 ml**	2 x 14 ml	Reagent 1
		2 x 6 ml	Reagent 1a

Additionally offered:

310185	3 x 1 ml	Fructosamine Calibrator
310181	3 x 1 ml	Fructosamine Control N
310182	3 x 1 ml	Fructosamine Control P

TEST PARAMETERS

Method:	colorimetric, kinetic (2-point kinetic), NBT increasing reaction
Wavelength:	546 nm
Temperature:	37°C
Sample:	Serum, heparinized or EDTA plasma
Linearity:	up to 1000 µmol/L
Sensitivity:	The lower limit of detection is 10 µmol/L

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
Reagent 1:	
Nitrotetrazolium-blue	0.57 mmol/L
Sodium cholate	4.9 mmol/L
Potassium chloride	49 mmol/L
Potassium phosphate	49 mmol/L
Uricase (Arthrobacter spec.)	> 2.8 kU/L
Detergent	2.1 %
Reagent 1a:	
Potassium carbonate buffer, pH 10.3	250 mmol/L

REAGENT PREPARATION

Sample Start:
Add the contents of one bottle R1a carefully into one bottle R1 (= working reagent). Mix by swirling gently.
A slight discolouration of R1 does not interfere with the performance of the assay.

REAGENT STABILITY AND STORAGE

Conditions:	protect from light close immediately after use do not freeze the reagents!
Storage:	at 2 – 8 °C
Stability:	up to the expiration date

Stability of working reagent (R1 + R1a):
28 days on board (refrigerated)

SAMPLE STABILITY AND STORAGE

serum, plasma:	at 20 – 25°C	3 days
	at 2 – 8°C	2 weeks
	at -20 °C	2 month

Discard contaminated specimens.
Centrifuge samples containing precipitate before performing the assay.
Avoid repeated freezing and thawing. Mix samples well after thawing.

INTERFERING SUBSTANCES

no interference up to:

ascorbic acid	4 mg/dL (220 mmol/L
bilirubin	5 mg/dL
haemoglobin	500 mg/dL
triglycerides	2000 mg/dL
glucose	900 mg/dL (50 mmol/L)
uric acid	24 mg/dL (1428 µmol/L)

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Sample start

Pipette into test tubes	Blank	Cal.	Sample
Working reagent	1000 µl	1000 µl	1000 µl
Sample or Std./Cal.	-	50 µl	50 µl
Distilled water	50 µl	-	-
Mix, incubate 7 min. at 37°C and read absorbance. Read absorbance again after exactly 1, 2 and 3 min at 37 °C. Determine ΔA/minute.			

CALCULATION

With calibrator

$$\text{Fructosamine [µmol/L]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Cal.}} \times \text{Conc. Cal [µmol/L]}$$

Note [6,12]**:**
In hydraemic states (e.g. during pregnancy) it is recommended to relate fructosamine to total protein using the following formula:

$$\text{Fructosamine}_{\text{corrected for protein}} = \frac{\text{Fructosamine}_{[\mu mol/L]} \times 7.2}{\text{total protein}_{[g/dL]}} \text{ [µmol/L]}$$

Correction for serum albumin is not recommended. Dysproteinemic states may produce erroneous fructosamine values.

REFERENCE RANGE [9,10]

A reference range of 205 to 285 µmol/L for adults without diabetes was determined in a study of 555 apparently healthy persons between the ages of 20 and 60.
In a poorly controlled diabetic patient population, a range of 228 to 563 µmol/L was reported.
A fructosamine concentration above the established expected values is an indicator for hyperglycemia during the preceeding 1-3 weeks or longer.

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

TEST PRINCIPLE

This colorimetric assay is based on the ability of ketoamines to reduce nitro-tetrazolium-blue (NBT) to formazan in an alkaline solution[7]. The rate of formation of formazan is directly proportional to the concentration of fructosamine.
Uric acid interference is eliminated by Uricase and detergent eliminates matrix effects[9].
The rate of reaction is measured photometrically at 546 nm.

PERFORMANCE CHARACTERISTICS

LINEARITY

The test has been developed to determine fructosamine concentrations within a measuring range from 10 µmol/L to 1000 µmol/L. If values exceed this range, samples should be diluted 1+1 with 0.9% NaCl solution (9 g/L) and the results multiplied by 2.

PRECISION (at 37°C)

Intra-assay n = 21	Mean [µmol/L]	SD µmol/L]	CV [%]
Sample 1	288	2.58	0.9
Sample 2	272	1.88	0.7
Sample 3	512	4.12	0.8

Inter-assay n = 21	Mean [µmol/L]	SD [µmol/L]]	CV [%]
Sample 1	296	8.69	2.9
Sample 2	273	3.89	1.4
Sample 3	521	9.01	1.7

METHOD COMPARISON

A comparison of Dialab Fructosamine (y) with a commercially available test (x) using 93 samples (246 – 613 µmol/L) gave following results:
y = 1.019 x – 8.171 µmol/L; r= 0.996.

QUALITY CONTROL

All control sera with fructosamine values determined by this method can be used.
We recommend:

REF	Cont.	
310181	3 x 1 ml	Fructosamine Control N
310182	3 x 1 ml	Fructosamine Control P

CALIBRATION

The assay requires the use of a fructosamine calibrator.
We recommend:

REF	Cont.	
310185	3 x 1 ml	Fructosamine Calibrator

Traceability: This method has been standardized against glycated poly-L-lysine and ^{14}C-glucose.

Two-point calibration is recommended:
S1: 0.9% NaCl
S2: Fructosamine Calibrator

Calibration frequency:

- Every 7 days if reagent bottles are on board the analyser for more than 7 days.
- After reagent bottle change if previous reagent bottles were on board for more than 7 days.
- After reagent lot change
- As required following quality control procedures

AUTOMATION

Special adaptations for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

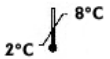
1. Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

1. Armbruster DA. Clin Chem 1987;33:2153-2163
2. Bablok W et al. A Genaral Regressoin Procedure for Method Transformation. J Clin Chem. Clin Biochem 1988;26:783-790
3. Furth AJ. Anal Biochem 1988;175:347-360
4. Glick MR, Ryder KW, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem. 1986;32:470-474
5. Guder WG Narayanan S, Wisser H, Zawta B. List of Analytes Preanalytical Variables. Brochure in : Samples: From the Patient to the Laboratory. Darmstadt: GOT Verlag, 1996.
6. Hanrichs HR, ed. European Fructosamine Workshop. Wien Klein Wochenschr Suppl 1990:180
7. Johnson RN, Metcalf PA, Baker JR, Clin Chim Acta 1983;127:87-95
8. Kennedy, AL, Merimee TJ. Glycosylated serum protein and haemoglobin A1 levels to measure control of glycemia. Ann Intern Med. 1981;95:56-58
9. Kruse-Jarres JD, Jarrausch J, Lehman F Vogt BW, Rietz R Lab Med 1989;13:245-253
10. Melzi d'Eril GV, Bosini T, Solerte SB, Fioravanti M, Ferrari E. Wien Klin Wochenschr Suppl 1990;180:60-63
11. Passing H Pablok W. A New Biometrical Procedure for Testing the Equality of Measurements from Two Different Analytical Methods. J Clin Chem. Clin Biochem 1983;21:709-720
12. Schleicher ED, Olgenmöller B, Wiedenmann E, Gerbitz KD. Clin Chem. 1993;39:625-628
13. Schleicher ED, Vogt BW. Clin Chem. 1990;36:136-139
14. Tahara Y Shima K. Diabetes Care 1995;18:440-447



IVD

DIALAB Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
A – 2351 Wiener Neudorf, Austria
IZ-NÖ Süd, Hondastrasse, Objekt M55
Phone: ++43 (0) 2236 660910-0
Fax: ++43 (0) 2236 660910-30 e-mail: office@dialab.at