CHRONOLAB

CE
IVD

Fructosamine

NBT. Kinetic

Quantitative determination of fructosamine

PACKAGING

Ref.: 101-0378	Cont.: 19 x 3 mL

Store at 2-8ºC

CLINICAL SIGNIFICANCE

Glucose forms stable glycated serum proteins with several plasmatic proteins, mainly, albumin, in covalent union. The determination of fructosamina is based on the measurement of these glycoproteins.
The measurement of fructosamine has utility to know retrospectively (2-3 weeks) the level of glucose concentration in blood.
This test is used for control and monitoring of diabetic patients and not for diagnosis[5,6].
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE OF THE METHOD

Under alkaline conditions the fructosamine or glycated serum proteins reduce a nitro-blue tetrazolium chloride (NBT) salt.
The colour developed is directly proportional to the serum fructosamine concentration[1].

REAGENTS

R 1 Buffer	Carbonate Detergents	200 mmol/L
R 2 Enzymes	Nitrotetrazolium chloride (NBT) Uricase	0.48 mmol/L 3000 U/L
FRUCTOSAMINE CAL	Calibrator lyophilised serum	

Optional (not included in the kit)

Contro-N	Ref.: 101-0252	4 x 5 mL	Lyophilized human control serum
	Ref.: 101-0083	20 x 5 mL	
Contro-P	Ref.: 101-0253	4 x 5 mL	Lyophilized human control serum
	Ref.: 101-0084	20 x 5 mL	

PREPARATION

- **Working reagent (WR):**
  Dissolve (→) 1 tablet of R 2 Enzymes with one vial R 1 Buffer.
  Cap vial and mix gently to dissolve contents.
  The reagent is stable after reconstitution 15 days at 2-8º C or 5 days at room temperature (15-25º C). Protected from light.
- **FRUCTOSAMINE CAL:**
  Dissolve (→) the contents of one vial Calibrator with 1 mL of distilled water. Cap vial and mix gently to dissolve contents.
  The reconstituted calibrator is stable 15 days at 2-8º C or 2 months at -20º C.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8º C, protected from light and contaminations prevented during their use.
Do not use the tablets if appears broken.
Do not use reagents over the expiration date.
Signs of reagent deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 520 ≥ 0.30.

ADDITIONAL EQUIPMENT

- Spectrophotometer or colorimeter measuring at 520 nm.
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

SAMPLES

Serum[1,2]:
Don't use haemolized samples. Separated from cells as rapidly as possible.
Stability of the sample: 7 days at 2-8º C.

PROCEDURE

Notes: CHRONOLAB SYSTEMS has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

1. Assay conditions:
   Wavelength: . . . . . 520 (490-550) nm
   Cuvette: . . . . . 1 cm light path
   Temperature. . . . . 37º C
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

	Blank	Calibrator	Sample
WR (mL)	1.0	1.0	1.0
Calibrator (µL)	--	100	--
Sample (µL)	--	--	100

4. Mix, incubate at 37º C and start stopwatch.
5. Read the absorbance (A_1) of the calibrator and sample exactly after 10 min and after 15 min (A_2) of the sample addition against distilled water.
6. Calculate: $\Delta A = A_2 - A_1$.

CALCULATIONS

$$\frac{(\Delta A)\,\text{Sample}}{(\Delta A)\,\text{Calibrator}} \times \text{Calibrator conc.} = \mu\text{mol/L of fructosamine in the sample}$$

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures.
If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES[1]

In nondiabetic samples: 187 – 287 µmol/L[1,]
These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring range: From *detection limit* of 1 µmol/L to *linearity limit* of 1000 µmol/L.
If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl (9 g/L) and multiply the result by 2.

Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (µmol/L)	217	587	197	552
SD	4.71	8.31	4.20	10.2
CV (%)	2.17	1.41	2.12	1.85

Sensitivity: 1 µmol/L = 00020 A.

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Accuracy: Results obtained using CHRONOLAB reagents (y) did not show systematic differences when compared with other commercial reagents (x).
The results obtained using 50 samples were the following:
Correlation coefficient (r): 0.992
Regression equation: y=0.991x + 1.473
The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Do not interfere: Hemolysis up to 5 g/L, bilirubin up to 20 mg/dL and triglycerides up to 6 gr/L[1,2].
A list of drugs and other interfering substances with fructosamine determination has been reported by Young et. al[3,4].

BIBLIOGRAPHY

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