

FRUCTOSAMINE Biolis Liquid Reagent (24 Tray)

KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GLC24046	3 x 30 ml	FRUC-R1	2 - 8°C
	3 x 10 ml	FRUC-R2	

INTENDED USE:

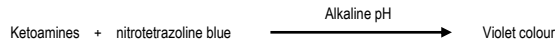
In Vitro Diagnostic reagent pack for the determination of Fructosamine in serum, on Biolis automated analysers.

SUMMARY AND EXPLANATION: ²

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 efficacy monitoring.

PRINCIPLE OF THE TEST: ¹

Ketoamines in an alkaline environment reduce nitrotertrazoline blue. The intensity of the violet colour produced is directly proportional to the fructosamine in the sample.



WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only

Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:

Reagent 1: Colourless Liquid

Reagent 2: Yellow Liquid

Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damaged to the bottle and/or cap, resulting in product leakage and/or contamination: do not use the reagent pack and contact your distributor.

Safety precautions:

This product is not hazardous under EU specifications. Material Safety Data Sheet is available upon request. Reagent contains Sodium azide. Avoid ingestion or contact with skin or mucous membranes. In the case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, immediately seek medical attention.

Handling precautions:

- Protect from direct light, contamination and evaporation.
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

COMPONENT COMPOSITION:

Component	Ingredients	Concentration in Tests
Reagent 1	Carbonate buffer	0.1 mol/L
	Detergent	< 0.2 %
	Preservative	< 0.1 %
Reagent 2	Carbonate	0.1 mol/L
	Nitrotertrazolum blue chloride	> 0.3 mmol/L

REAGENT PREPARATION AND STABILITY:

Reagent 1 & 2 are ready for use. Before use, mix reagent by gently inverting each bottle.

If stored at 2 - 8°C and handled properly, stable until expiry date stated on the label. Once opened, reagents are stable for 4 weeks when stored at 2 - 8°C.

INSTRUMENTS:

This assay is designed to run on Biolis clinical chemistry analysers. Refer to relevant user's manual or Laboratory internal practice for routine maintenance procedures.

TYPE OF SPECIMEN: ^{1, 2}

Use fresh patient serum.

It is recommended to follow CLSI procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sampling container, with proper specimen identification. Plasma/serum should be separated from cells within 2 hours after collection.

Stability: Samples are stable for 7 days at 2-8°C or 6 months at -20°C.

TEST PROCEDURE:

Materials required but not supplied:

Description	Catalogue No.	Description	Catalogue No.
Fructosamine Calibrator	GL9809	Biolis Analyser	N/A
Fructosamine Control Level 1	GL9308	Biolis Consumables	N/A
		General Laboratory Equipment	N/A

Assay procedure:

Refer to relevant user's manual for instructions on instrument start-up, loading components and samples, calibration, sample testing procedures, calculating and reporting results.

Calibration:

Using suitable Calibrator, calibrate the assay:

- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part.
- When Quality Controls are out of range.

Quality Control:

All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with suitable controls. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.

Controls should be assayed:

- Prior to reporting patient results.
- Following any maintenance procedure.
- At some intervals chosen by the laboratory.

CALCULATION:

$$\text{Concentration} = \frac{\Delta A_{\text{sample}}}{\Delta A_{\text{calibrator}}} \times \text{Calibrator Value}$$

EXPECTED VALUES:

Adult in Serum	≤ 286 μmol/L
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Each laboratory should establish its own reference range. Fructosamine results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance evaluation can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:

This assay is linear up to 1000 μmol/l.

For samples with a higher concentration, dilute with 0.9% NaCl and re-assay. Multiply result by the dilution factor.

Interfering substances:

Results of study are as follows. The following analytes were tested up to the levels indicated and found not to interfere:

Ascorbic acid:	Up to 10 mg/dL.
Haemoglobin:	Up to 2000 mg/dL.
Bilirubin:	Up to 30 mg/dL.
Intralipid:	Up to 2000 mg/dL.

Sensitivity:

The Lowest Detectable Level was estimated at 15.4 μmol/L.

Precision:

















Within Run N = 20	Mean	SD	% CV	Between Run N = 20	Mean	SD	% CV
Level 1	260	2.07	0.80	Level 1	265	2.00	0.75
				Level 2	264	1.34	0.51

BIBLIOGRAPHY:

- Burtis CA, Ashwood ER, Tietz Fund. Of Clin. Chem. 5th ed. 30-54,456 and 982.
- Howey 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.


SYMBOLS:

The following symbols are used in the labelling of Glenbio Ltd. systems:

	In Vitro Diagnostics		Catalogue No
	Batch Code		Content
	Reagent		Antibody
	Calibrator		Substrate
	Buffer		CE Mark - Device complies with the Directives 98/79/EC
	Storage temperature		Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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