FRUCTOSAMINE CONTROL - LEVEL 1 (FRUC CONTROL 1)

CAT NO. FR2994
SIZE: 3 x 1 ml
GTIN: 05055273203127
LOT NO. 595FR
EXPIRY: 2023-09-28

INTENDED USE
This product is intended for *in vitro* use in the quality control of the Randox Liquid Fructosamine assay on clinical chemistry systems.

SAFETY PRECAUTIONS AND WARNINGS
Human source material, from which this product is derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV1 & HIV2) antibody, Hepatitis B surface antigen (HBsAg) and the Hepatitis C Virus (HCV) antibody and found to be **NON-REACTIVE**.
However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting disease.
For *in vitro* diagnostic use only.

STORAGE AND STABILITY
Unopened Fructosamine Control is stable until the expiry date printed on the product label, when stored between +2°C and +8°C.
Once reconstituted the components of the serum are stable for 28 days at +2°C to +8°C, and 1 month at –20°C when frozen once.

PREPARATION FOR USE
Open the vial carefully, avoiding any loss of the material and reconstitute with 1 ml of distilled water. Replace the rubber stopper; close the vial and leave to stand for 30 minutes before use. Ensure that all traces of dry material are dissolved by swirling gently.

MATERIALS PROVIDED
Fructosamine Control - Level 1 (3 x1 ml)

MATERIALS REQUIRED BUT NOT PROVIDED
Distilled water
Volumetric pipette

VALUE ASSIGNMENT
Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

The value of the control was assigned relative to human serum glycated with ^{14}C -glucose and is the mean of at least 30 replicate determinations, using various clinical chemistry systems in a single laboratory.

RANDOX ENZYMATIC METHOD

	TARGET	RANGE
FRUCTOSAMINE	253 µmol/l	202 – 304 µmol/l

SIEMENS ENZYMATIC FOR ADVIA® AND ATELLICA CH®

	TARGET	RANGE
FRUCTOSAMINE	239 µmol/l	191 - 287 µmol/l

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