

FRUCTOSAMINE CONTROL - LEVEL I (FRUC CONTROL I)

CAT NO. FR2994 **LOT NO.** 538FR
SIZE: 3 x 1 ml **EXPIRY:** 2021-02-28
GTIN: 05055273203127

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 I (3 x 1ml)

MATERIALS REQUIRED BUT NOT PROVIDED

Distilled water
 Volumetric pipette

VALUE ASSIGNMENT

The value of the control was assigned relative to human serum glycated with ¹⁴C -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	201 µmol/l	161 – 241 µmol/l

SIEMENS ENZYMATIC FOR ADVIA® AND ATELICA CH®

	TARGET	RANGE
FRUCTOSAMINE	258 µmol/l	206 – 310 µmol/l

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