

FRUCTOSAMINE CONTROL - LEVEL 3 (FRUC CONTROL 3)

CAT. NO. FR 2996 **LOT NO.** 539FR
SIZE: 3 x 1 ml **EXPIRY:** 2021-02-28
GTIN: 05055273203134

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 3 (3 x 1 ml)

MATERIALS REQUIRED BUT NOT PROVIDED:

Distilled water
 Volumetric pipette

VALUE ASSIGNMENT:

The control value 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	721 µmol/l	577 – 865 µmol/l

SIEMENS ENZYMATIC FOR ADVIA® AND ATELICA CH®

	TARGET	RANGE
FRUCTOSAMINE	939 µmol/l	751 – 1127 µmol/l

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