

## FRUCTOSAMINE CONTROL - LEVEL 3 (FRUC CONTROL 3)

**CAT. NO.** FR 2996

**LOT NO.** 550FR

**SIZE:** 3 x 1 ml

**EXPIRY:** 2021-10-28

**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 <sup>14</sup>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	711 µmol/l	569 - 853 µmol/l

#### SIEMENS ENZYMATIC FOR ADVIA® AND ATELLICA CH®

	TARGET	RANGE
FRUCTOSAMINE	871 µmol/l	697 - 1045 µmol/l

EC REP

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16 Nov '20 ne

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