

Art.-Nr.: KG2994-2993-2996
Ch.-B.: 321FR-320FR-322FR
Inhalt: 3 x 1 ml
Verw. bis: 2011-04

INTENDED USE:

This product is intended for *in vitro* use in quality control of fructosamine assays 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 calibrator is 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 (3 x 1ml)

MATERIALS REQUIRED BUT NOT PROVIDED:

Distilled water

Volumetric pipette

VALUE ASSIGNMENT:

The value of the calibrator 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.

| FRUCTOSAMINE µmol/l | TARGET | RANGE |
|------------------------|--------|-----------|
| Level 1 | 239 | 191 - 287 |
| Level 2 | 414 | 331 - 497 |
| Level 3 | 610 | 488 - 732 |

22 Oct '08