Lyophilized Calibration Serum

FRUCTOSAMINE CALIBRATOR

Lyophilized calibration serum for the use in tests for the quantitative in vitro determination of fructosamine on photometric systems.

REF Cont.

310185	**3 x 1 ml**	finished kit
310185SV	**1 x 1 ml**	single vial
310185VSV	**1 x 1 ml**	unlabeled single vial (OEM)

COMPOSITION

Lyophilized calibrator based on human serum.

Reactive components:
Human serum with chemical additives and material of biological origin as specified:

Analyte	Origin
Fructosamine	human serum

Non reactive components:
Preservatives and stabilizers

CALIBRATOR PREPARATION

1. Open the vial very carefully, avoiding any loss of the lyophilized material.
2. Add exactly 1 ml of dist. water (inaccurate reconstitution of the control and error in assay technique can cause erroneous results).
3. Close the vial carefully and dissolve the components completely by occasional gently swirling within 30 minutes. Avoid the formation of foam.
4. Leave the solution to stand for at least 60 minutes before use.

CALIBRATOR STABILITY AND STORAGE

Storage: at 2 – 8°C
Stability: until date of expiration

Stability after reconstitution:
at 15 – 25 °C: 7 days
at 2 – 8 °C: 4 weeks

CLOSE IMMEDIATELY AFTER USE
Store calibrator tightly capped when not in use.

LOT SPECIFIC ASSAY DATA

	Fructosamine
Value:	**395 µmol/L**
LOT:	**154330**
Expiry Date:	**2012 / 05**
Values and Expiry Date are LOT specific.	

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use.
2. Exercise the normal precautions required for handling all laboratory reagents.
3. All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.
   However, as no testing method can rule out the potential risk of infection wit absolute certainty, the material should be treated just as carefully as a patient specimen. In the event of exposure the directives of the responsible health authorities should be followed.[1,2]
   Safety data sheet for professional users available on request.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local guidelines.

REFERENCES

1. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register. July 1, 2001;17:260-273.
2. Directive 2000/54/EC. Official Journal of the European Communities No. L262 from October 17, 2000.

2°C 8°C IVD

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