Lyophilized Control Serum

# FRUCTOSAMINE CONTROL N
## (Assayed Control Serum Normal)

**Lyophilized control serum for the use in tests for the quantitative in vitro determination of fructosamine in human serum or plasma on photometric systems.**

REF Cont.

| | | |
|---|---|---|
| **310181** | **3 x 1 ml** | finished kit |
| **310181SV** | **1 x 1 ml** | single vial |
| **310181VSV** | **1 x 1 ml** | unlabeled single vial (OEM) |

## COMPOSITION

Lyophilized control serum based on human serum.

Reactive components:
Fructosamine in human serum

Non reactive components:
Preservatives and stabilizers

## CONTROL PREPARATION

1. Open the vial very carefully, avoiding any loss of the lyophilized material.
2. Add exactly 1 ml of distilled/deionized 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. Avoid the formation of foam.
4. Allow the contents to reconstitute over a period of approximately 1 hour.
5. Analyze the control in the same way as a patient sample.

## CONTROL 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

| **Lot: 156783**<br>**Exp: 2012/12** | **Mean**<br>**[µmol/L]** | **Range**<br>**[µmol/L]** |
|---|---|---|
| | 246 | 210 – 282 |
| 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.



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