

# N-geneous® LDL-ST CHOLESTEROL CALIBRATOR

## INTENDED USE

For calibration of the N-geneous® LDL-ST Cholesterol assay.

## SUMMARY AND PRINCIPLE

See the N-geneous® LDL-ST Cholesterol Reagent package insert.

## REAGENTS

### Composition

The N-geneous® LDL-ST Cholesterol Calibrator contains human serum, containing lipoproteins from the various lipoprotein classes including low-density lipoproteins and sodium azide as preservative (0.1%).

**Note:** The value of the N-geneous® LDL-ST Cholesterol Calibrator was assigned by procedures traceable to the CDC LDL cholesterol reference method.<sup>2</sup>

### Precautions and Warnings

1. For In Vitro Diagnostic Use
2. Do not pipette by mouth.
3. Do not use the calibrator after the expiration date printed on the label.
4. **Warning:** Human source material. Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for HBsAg, HCV, HIV 1&2 and HIV-1 Antigen. Because no known test method can offer complete assurance that Hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, all human-based products should be handled in accordance with good laboratory practices using appropriate precautions.<sup>1</sup>
5. **Caution:** Contains sodium azide, which may react with lead and copper plumbing to form potentially explosive metal azides. On disposal, flush drain with large volume of water to prevent buildup.

### Preparation

Allow the vial of calibrator to equilibrate to room temperature before reconstitution. Reconstitute each vial with 1.0 mL of distilled or deionized water (or equivalent) using a Class A volumetric pipette. Replace the cap/stopper and allow to stand for 5 minutes at room temperature. Dissolve the contents of the vial by swirling gently to avoid the formation of foam.

DO NOT SHAKE.

### Storage and Stability

Unopened calibrator is stable until the expiration date printed on the label when stored at 2-8°C.

Once reconstituted, the calibrator is stable up to 2 weeks at 2-8°C.

Reconstituted stability of the calibrator may be extended by aliquotting and freezing the reconstituted calibrator at -80°C.

Freeze only once.

### Indications of Deterioration

Inability to recover control values.  
Presence of turbidity.

## PROCEDURE

### Assay

See the N-geneous® LDL-ST Reagent package insert.

### Materials Provided

Description	Configuration	Catalog Number
N-geneous® LDL-ST Calibrator	3 x 1 mL	80-5666-02

### Materials Required but not Provided

Description	Configuration	Catalog Number
N-geneous® LDL-ST Cholesterol Reagent 1	1 x 30 mL	80-5727-02
N-geneous® LDL-ST Cholesterol Reagent 2	1 x 10 mL	80-5729-02
N-geneous® LDL-ST Cholesterol Reagent 1	1 x 250 mL	80-5665-01
N-geneous® LDL-ST Cholesterol Reagent 2	1 x 80 mL	80-5714-00

1. Class A volumetric pipettes.
2. Distilled, deionized, Type II water or equivalent.

### Calibration

The value of the N-geneous® LDL-ST Cholesterol Calibrator, found on the vial label, was assigned by procedures traceable to the CDC LDL cholesterol reference method.<sup>2</sup> Refer to the instrument manufacturer's recommendation for calibration frequency. If assistance is required, please contact Genzyme Technical Marketing at 1-800-332-1042.

Quality Control values should be within the expected range.

## REFERENCES

1. Centers for Disease Control/National Institutes of Health Manual, "Biosafety in Microbiological and Biomedical Laboratories,"(1988).
2. National Reference System for Cholesterol. CRMLN LDL Cholesterol Protocol, May 2004.

Refer to the N-geneous® LDL-ST Cholesterol Reagent package insert for additional references.

Manufactured by:



**Genzyme Corporation**

One Kendall Square  
Cambridge, MA  
02139-1562  
USA

Tel: 1-800-332-1042  
Fax: 1-617-252-7759

**[www.genzymediagnostics.com](http://www.genzymediagnostics.com)**

80-5666-20-02

**Genzyme Diagnostics**

50 Gibson Drive  
Kings Hill, West Malling  
KENT ME19 4AF  
United Kingdom

Tel: (+44) (0)1732-220022  
Fax: (+44) (0)1732-220024

4/05

N-geneous® is a registered trademark of Genzyme Corporation.