

ULTRA N-geneous® HDL CHOLESTEROL CALIBRATOR

INTENDED USE

For the calibration of the Ultra N-geneous® HDL Cholesterol assay.

SUMMARY

Refer to the Ultra N-geneous® HDL Cholesterol Reagent package insert.

REAGENTS

The Ultra N-geneous® HDL Cholesterol Calibrator is a preparation of lyophilized human serum containing lipoproteins from the various lipoprotein classes including high-density lipoproteins.

Note: The value of the Ultra N-geneous® HDL Cholesterol Calibrator was assigned by procedures traceable to the CDC HDL cholesterol reference method.^{1,2}

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 box.
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 nonreactive 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.
5. **Caution:** Contains sodium azide, which may react with lead and copper plumbing to form potentially explosive metal azides. On disposal, flush drain with a large volume of water to prevent buildup.
6. Ultra N-geneous® HDL Cholesterol Reagent must be used with Ultra N-geneous® HDL Cholesterol Calibrator.

Preparation

Allow the vial of calibrator to equilibrate to room temperature before reconstitution. Lyophilized serum calibrator should be reconstituted by adding 1.0 mL of distilled or deionized water. Close the vial and let stand for 20 minutes. 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 at 2-8°C until the expiration date printed on the vial.

After reconstitution, calibrator is stable for 14 days at 2-8°C. Reconstitution stability of the calibrator may be

extended by aliquotting and freezing the reconstituted calibrator preparation at less than -70°C for up to 4 weeks.

Indications of Deterioration

Presence of turbidity.

PROCEDURE

Materials Provided

Description	Configuration	Catalog Number
Ultra N-geneous® HDL Cholesterol Calibrator	6 x 1 mL	80-6449-00

Materials Required but not Provided

Description	Configuration	Catalog Number
Ultra N-geneous® HDL Cholesterol Reagent 1	250 mL	80-6267-00
Ultra N-geneous® HDL Cholesterol Reagent 2	80 mL	80-6263-00
Ultra N-geneous® HDL Cholesterol Reagent 1	750 mL	80-6283-00
Ultra N-geneous® HDL Cholesterol Reagent 2	250 mL	80-6277-00
Ultra N-geneous® HDL Cholesterol Reagent 1	2 Liter	80-6271-00
Ultra N-geneous® HDL Cholesterol Reagent 2	2 Liter	80-6269-00
Ultra N-geneous® HDL Cholesterol Reagent 1	20 Liter	80-6275-00
Ultra N-geneous® HDL Cholesterol Reagent 2	20 Liter	80-6273-00

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

Calibration

The calibrator should be used to analyze patient samples in accordance with the instructions outlined in Genzyme's Ultra N-geneous® HDL Cholesterol Reagent package insert. The value of the Ultra N-geneous® HDL Cholesterol Calibrator, which can be found on the calibrator vial label, is assigned by procedures traceable to the CDC HDL cholesterol reference method.^{1,2} Refer to the instrument manufacturer's recommendation for calibration frequency. If assistance is required please call Genzyme Technical Marketing at 1-800-332-1042.

Quality Control values should be within the expected range.

REFERENCES

1. National Reference System for Cholesterol. CRMLN HDL Cholesterol Protocol, November 2002.
2. Kimberly MM, Leary ET, Cole TG, Waymack PW. Selection, validation, standardization, and performance of a designated comparison method for HDL-cholesterol for use in the Cholesterol Reference Method Laboratory Network. *Clinical Chemistry* 1999; 45: 1803-12.

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

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