

HDL Ultra Cholesterol Calibrator

INTENDED USE

For the calibration of the HDL Ultra Cholesterol assay.

SUMMARY

Refer to the HDL Ultra Cholesterol Reagent package insert.

REAGENTS

The HDL Ultra 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 HDL Ultra 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. HDL Ultra Cholesterol Reagent must be used with HDL Ultra 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
HDL Ultra Cholesterol Calibrator	3 x 1 mL	6272-3

Materials Required but not Provided

Description	Configuration	Catalog Number
HDL Ultra Cholesterol Reagent	R1 1 x 60 mL R2 1 x 20 mL	6121
HDL Ultra Cholesterol Reagent	R1 1 x 250 mL R2 1 x 80 mL	6122
HDL Ultra Cholesterol Reagent R1	R1 1 x 750 mL	6123R1
HDL Ultra Cholesterol Reagent R2	R2 1 x 250 mL	6123R2

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 HDL Ultra Cholesterol Reagent package insert. The value of the HDL Ultra 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 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 HDL Ultra Cholesterol Reagent package insert for additional references.

Definitions for Symbols



Catalog number



For *in vitro* diagnostic use



Temperature limitation



Manufactured by



Use by



Batch code



Consult instructions for use



Caution, consult accompanying document

Manufactured by:

genzyme
Diagnostics

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