ULTRA N-geneous® HDL CHOLESTEROL CALIBRATOR

CATALOGUE NUMBER: 80-6449-00 **SIZE:** 6 x 1 mL

INTENDED USE

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

TEST 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]

WARNINGS AND PRECAUTIONS FOR USE

Contains: Sodium Azide
H302 – Harmful if swallowed.
H412 – Harmful to aquatic life with long lasting effects.
Prevention - P264 – Wash thoroughly after handling.
Avoid release to the environment.
P270 – Do not eat, drink or smoke when using this product.
Response - P314 – Get medical advice/attention if you feel unwell.
If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth.
Disposal – P501 – Dispose of contents/container in accordance with local/regional /national/international regulations.

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. Dispose of in accordance with local, state and federal regulations.
6. Ultra N-geneous® HDL Cholesterol Reagent must be used with Ultra N-geneous® HDL Cholesterol Calibrator.

See Material Safety Data Sheet for additional information.

PRODUCT PREPARATION, STORAGE AND STABILITY

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.

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.

PRODUCT DETERIORATION

Turbidity would indicate deterioration.

DISPOSAL

Product must be disposed of in accordance with all Federal, Provincial, State and local regulations.

ANALYTICAL 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

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

CALIBRATION

The calibrator should be used to analyze patient samples in accordance with the instructions outlined in Sekisui Diagnostics 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 Sekisui Diagnostics Technical Services at 800-565-0265. Outside Canada and the U.S., please contact your local distributor.

Quality Control values should be within the expected range.

SEKISUI DIAGNOSTICS

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Definitions for Symbols

Batch Code

Manufacturer

Consult instructions for use

In vitro diagnostic medical device

Use by
YYYY-MM-DD or YYYY-MM

Catalog number

Temperature limitation

Caution, consult accompanying document

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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