

Lipids (HDL-LDL) Calibrator

REF: VT - 004 Lipids (HDL-LDL) Calibrator 5x1 mL

Changes made in the instructions for use are marked as grey.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package.

INTENDED USE

Validity Lipids (HDL-LDL) Calibrator is for use in the calibration of the HDL Direct and LDL Direct Cholesterol assays.

Validity Lipids (HDL-LDL) Calibrator

REF: VT-004

Package: 5x1 mL **Lyophilized**

For use with;

Validity HDL Direct Cholesterol reagent
Validity LDL Direct Cholesterol reagent

CONTENTS / MATERIALS PROVIDED

Validity Lipids (HDL-LDL) Calibrator (REF: VT-004) contains human serum.
Sodium azide (0.09 %) is added as a preservative.

MATERIALS REQUIRED BUT NOT PROVIDED

- Validity HDL Direct Cholesterol Reagents
- Validity LDL Direct Cholesterol Reagents
- Class A volumetric pipette for delivery of 1.0 mL
- Distilled or deionized water meeting specifications equivalent to USP purified water.

STANDARDIZATION

The traceability of the method is verified using Ultra N-geneous HDL Cholesterol Calibrator (REF: VT-004) and N-geneous LDL Cholesterol Calibrator (REF: VT-004)

PRECAUTIONS (General and Users)

IVD For *in Vitro* Diagnostic Use.

Do not use components beyond the expiration date.
Contains sodium azide.
EUH032 Contact with acids liberates very toxic gas.
Do not mix materials from different kit lot numbers.
Human source material.
Calibrator can contain preservatives (as Sodium Azide or others) which total concentration is lower than the limits mentioned in Directive 67/548/ CEE and 88/379 CEE.



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 the presence of HBsAg, HCV, HIV-Ag and antibody to HIV 1/2. 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. Safety Data Sheets are available at www.validity.com.tr or contact your local representative. Emergency Phone Number: In emergency situation please contact the National Poison Solidarity Center (Turkey) for information in Turkish: (114) (24 hours/7 days). Please contact with Validity for information in English: +(90) 212 444 0 892 (Turkey) (8:30-18:30/ except Sundays)

STORAGE AND STABILITY

- Unopened Validity Lipids (HDL-LDL) Calibrator is stable until the expiration date when stored +2 to +8 °C.
- Opened calibrators are stable **2 days** when stored in a dark place +2 to +8°C.
- Validity Lipids (HDL-LDL) Calibrator is stable 30 days when stored -20°C. Reconstitute and store tightly capped in a dark place, kept free of contamination and FROZEN. (Freeze and thaw once only)

PREPARATION OF CALIBRATOR

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.

INDICATIONS OF INSTABILITY OR DETERIORATION

Presence of extreme turbidity or microbial growth may indicate deterioration.

REFERENCES

- Gotto, A.M. Lipoprotein metabolism and the etiology of hyperlipidemia. Hospital Practice 1988; 23 Suppl:1 4-13.
- Crouse, J.R. et al. Studies of low density lipoprotein molecular weight in human beings with coronary artery disease. J. Lipid Res 1985;26:566
- Burtis CA, Ashwood ER, Bruns DE, editors. Tiets Textbook of Clinical Chemistry and Molecular

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Archem Sağlık Sanayi ve Tic. A.Ş. (With official contract based manufacturing agreement with Validity Sağlık Hiz. San. A.Ş. Company)

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Vali

SYMBOLS

IVD

In Vitro Diagnostic Medical Device

LOT

Lot number

CAL

Calibrator

GTIN

Global Trade Item Number

REF

Reference Number

FOR USE WITH

Identifies products to be used together

PRODUCT OF TURKEY

Product of Turkey



Manufacturer



Expiration date



Temperature limitation



Consult instructions for use



Caution



Sufficient for