

Intended Use

The Lipid Control set are assayed Lipid Controls produced from fresh human sera to monitor the accuracy and precision of quantitative lipid determinations of human sera specimens.

Product Description

The Lipid Controls are lyophilized products prepared from fresh human sera enriched with human lipid fractions. Two levels are available to monitor the lipid level of clinical laboratory results.

HDL cholesterol values are provided for the following methods: Dextran Sulfate (50,000MW)¹ and PEG precipitation followed by cholesterol determination², and the manufacturer's autoHDLTM.

LDL cholesterol values have been assigned using the manufacturer's autoLDL cholesterol reagent.

Total Cholesterol values have been assigned using the manufacturer's total cholesterol reagent.³

Triglycerides values have been assigned using the manufacturer's Triglycerides GPO reagent.

Precautions

Human source material. Treat as potentially infectious. Each donor unit used in the preparation of this product has been tested by FDA approved methods and found non-reactive for hepatitis B surface antigen (HBsAg); negative for antibody against human immunodeficient virus (anti-HIV) and for antibody against hepatitis C virus (anti HCV).

Potential bio-hazardous material. No known test method can assure that a product derived from human blood does not contain Hepatitis or HIV virus. It is recommended such samples be handled at the Centers for Disease Control's Bio-Safety Level 2.⁴

Storage

1. Store sealed vials at + 2 °C to + 8 °C until the expiration date.

Procedure

Reconstitute each vial by adding exactly 3.0 ml of distilled / deionized water into each vial. Replace stopper in each vial and allow to stand for 10 minutes. Gently swirl the contents until it is homogenous. Pointe Scientific, Inc. Lipid Controls should be analyzed in the same manner as a patient serum sample.

Product Stability

The lyophilized product is stable until the expiration date when stored at +2 °C to +8 °C.

After reconstitution, controls are stable for:

- ❖ 48 hours + 25 °C
- ❖ 5 days at + 2 °C to + 8 °C
- ❖ 4 weeks at – 20 °C
- ❖ Frozen reconstituted controls should only be thawed once.

Expected Values

The values assigned to each constituent by each method, is derived from multiple analysis on multiple vials representative of the entire lot. The expected range and mean is provided as a reference for the laboratory until it

has established its own mean and standard deviation. The ranges listed were obtained from those suggested by the Health Care Finance Administration as acceptable performance criteria for deviation from a target value.⁵ The indicated value and its assigned range should serve as guidelines in assessing the accuracy of each test method. The values are usually method dependant. Refer to "Assay data" section listed below for the expected results. Make certain that the lot number on the vial matches the lot number on the insert.

Limitations

Results obtained are dependent upon several factors. Erroneous results may occur from reconstitution inaccuracies and technique errors associated with the assay procedure.

References

1. Warnick, G.R., Benderson, J., Albers, J.J., Ballie, E.E., Sexton, B., et al. Dextran Sulfate Mg²⁺ Precipitation Procedure for Quantification of High Density Lipoprotein Cholesterol Clin. Chem. 1982; 28:1379-88.
2. Lopes-Verella, M.F., Stone, P., Ellis, S., et al., Cholesterol Determination in High Density Lipoprotein Separated by Three different methods. Clin. Chem. 19-70; 23:882-890.
3. Duncan, I.W., Mather, A., Cooper, G.R., The Procedure for the Proposed Cholesterol Reference Method, Centers for Disease Control, Clinical Chemistry Division, 1982:75, Atlanta, Georgia.
4. Clinical Laboratory Improvements Amendments 1988, Federal Register, August 28, 1992.
5. National Reference System for Cholesterol, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Atlanta, Georgia.

Assay Data Table

Lot: 420302	Exp.: 2017-05	Exp.: 2017-05	
Analyte	Level 1	Level 2	units
autoHDL	36 ± 13	81 ± 20	mg/dl
autoLDL	187 ± 37	247 ± 62	mg/dl
Cholesterol	292 ± 44	414 ± 62	mg/dl
HDL (Mg/Dex)	27 ± 8	67 ± 10	mg/dl
HDL (PEG)	22 ± 4	34 ± 5	mg/dl
Triglyceride	177 ± 35	338 ± 85	mg/dl

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