

Intended Use

For the calibration of Pointe Scientific's autoHDL™ and autoLDL™ Cholesterol Reagent Set in serum or plasma. For *in vitro* diagnostic use only.

Summary

Lipoproteins are spherical-shaped particles that contain varying amounts of cholesterol, triglycerides, phospholipids and proteins. The phospholipid, free cholesterol and protein make up the outer surface of the lipoprotein particle, while the inner core contains mostly esterified cholesterol and triglyceride. The primary function of these particles is to solubilize and transport cholesterol and triglyceride in the bloodstream.

The relative amounts of the protein and lipid constituents determine the density of the lipoprotein particles and provide a basis for their classification.¹ These classes are: chylomicron, very-low-density lipoprotein (VLDL), low-density lipoprotein (LDL) and high-density lipoprotein (HDL). There have been many clinical studies that have shown that these lipoprotein particles have very distinct and varied effects.²⁻⁴

The studies all point to LDL cholesterol as the key factor in the pathogenesis of atherosclerosis and coronary artery disease (CAD),²⁻⁸ while HDL cholesterol has often been observed to have a protective effect.

The Liquid autoHDL™ and autoLDL™ Cholesterol reagents provide a simple and effective means for determining levels of these analytes. This serum calibrator has been developed to provide accurate calibration of the Liquid autoHDL™ and autoLDL™ Cholesterol reagents.

Reagents

The autoHDL/LDL™ Cholesterol Calibrator is a preparation of lyophilized human serum containing lipoproteins from the various lipoprotein classes including high-density lipoproteins.

NOTE: The LDL cholesterol value is traceable to the reference method (β -quantification) for determination of LDL cholesterol.

Preparation

Reconstitute lyophilized serum calibrator with 3.0ml of reagent grade water. Close the vial and let stand for 5 minutes. Swirl gently, avoiding the formation of foam. Do not shake.

Storage and Stability

When stored at 2-8°C, unopened calibrator is stable until the expiration date printed on the vial. After reconstitution, calibrator is stable for 21 days at 2-8°C. Reconstituted stability of the calibrator may be extended by aliquoting and freezing the reconstituted calibrator preparation at -80°C.

Precautions

1. This calibrator is for *in vitro* diagnostic use.
2. Do not pipette by mouth. In case of skin contact, flush affected areas with copious amounts of water. Get immediate medical attention for eye contact or if ingested. Refer to Material Safety Data Sheet for any hazard or safety information.
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 non-reactive for the presence of HbsAg, HCV, 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.

Deterioration

Presence of extreme turbidity or growth may indicate deterioration.

Materials Provided:

autoHDL/LDL™ Cholesterol Calibrator serum (lyophilized):
1 vial x 3.0 ml reconstituted volume.

Materials required but not provided:

1. Liquid autoHDL™ or, autoLDL™ Cholesterol Reagent Kit.
2. Volumetric pipette (3.0 ml).
3. Distilled or deionized water meeting specifications equivalent to USP purified water.

Calibration:

The calibrator should be run along side patient samples in accordance with the instructions outlined in Pointe Scientific's autoHDL™ or, autoLDL™ Cholesterol Reagent package insert. Calibration materials have concentrations around the medical decision level. Refer to the instrument manufacturer's recommendation for calibration frequency. For additional assistance please contact the manufacturer's Technical Service Department.

Expected Values

The expected values for serum HDL Cholesterol are as follows:⁹

| | |
|----------|-------------|
| Males: | 30-70 mg/dL |
| Females: | 30-85 mg/dL |

According to the NCEP, HDL values greater than or equal to 35 mg/dL are considered desirable and values greater than or equal to 60 mg/dL are considered to offer some protection against coronary heart disease. Values below 35 mg/dL are considered to be a significant independent risk factor for coronary heart disease.⁸

The following NCEP recommendations for patient classifications are suggested for the prevention and management of coronary heart disease.⁸

| <u>LDL Cholesterol</u> | <u>Classification</u> |
|----------------------------------|-----------------------|
| <130 mg/dl (3.36 mmol/L) | Desirable |
| 130-159 mg/dl (3.36-4.11 mmol/L) | Borderline High Risk |
| 160 mg/dl (4.14 mmol/L) | High Risk |

References

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8. Report of the National Cholesterol Education Program Expert Panel of Detection, Evaluation and Treatment of High Blood Cholesterol in Adults, Arch. Intern. Med., 148:36-69 (1988).
9. Tietz, N.W., Clinical Guide to Laboratory Tests, W.B. Saunders Co., Philadelphia, p.256 (1986).

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