

HDL/LDL Cholesterol Calibrator

1.0 INTENDED USE

This product is intended for the calibration of HDL/LDL Cholesterol (Direct) assay in serum or plasma. For in vitro diagnostic use only.

2.0 BACKGROUND

2.1 METHOD AND HISTORY

Plasma lipoproteins are spherical particles that contain varying amounts of cholesterol, triglycerides, phospholipids and proteins. The phospholipid, free cholesterol and protein constitute the outer surface of the lipoprotein particle, while the inner core contains mostly esterified cholesterol and triglycerides. These particles serve to solubilize and transport cholesterol and triglycerides in the bloodstream.

The relative proportions of protein and lipid determine the density of these plasma lipoproteins and provide a basis on which to begin their classification (6.1). The classes are: very low-density lipoproteins (VLDL), low density lipoproteins (LDL) and high density lipoproteins (HDL). Numerous clinical studies have shown that the different lipoprotein classes have varied effects (6.2-6.4). The studies all point to LDL cholesterol as the key factor in the pathogenesis of arteriosclerosis and coronary artery disease (CAD)(6.2-6.8), while HDL cholesterol has often been observed to have a protective effect. Even within the normal range of total cholesterol concentrations, an increase in LDL cholesterol can occur with an associated risk for CAD(6.4).

3.0 MATERIALS

Catalog No. 80195/80196 (1 X 2 ml)

3.1 REACTIVE INGREDIENTS

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

NOTE: The HDL/LDL cholesterol values are traceable to the reference method (β -quantification) for determination of HDL/LDL Cholesterol.

3.2 WARNINGS AND PRECAUTIONS

3.2.1 For In Vitro diagnostic use. Avoid ingestion. Good laboratory and safety practices are advisable.

3.2.2 Do not pipette by mouth. In case of skin contact, flush affected areas with copious amount of water. Get immediate medical attention for eye contact or if ingested. Refer to Material Safety Data Sheet for any hazard or safety information.

3.2.3 Do not use the calibrator after the expiration date printed on the kit.

3.2.4 WARNING: Human source material. Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by a FDA-approved method and found nonreactive 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.

3.3 PREPARATION OF CALIBRATOR

Reconstitute lyophilized serum calibrator with 2 ml of reagent grade water. Close the vial and let stand for 5 minutes. Dissolve the contents of the vial by swirling gently, avoiding the formation of foam. Do not shake.

3.4 STORAGE AND STABILITY

Unopened calibrator is stable at 2-8°C until the expiration date on the kit label. After reconstitution, calibrator is stable for 2 weeks at 2-8°C. Reconstituted stability of the calibrator may be extended by aliquoting and freezing the reconstituted calibrator preparation at -80°C.

3.5 INDICATIONS OF INSTABILITY OR DETERIORATION

Presence of extreme turbidity or growth may indicate deterioration.

4.0 CALIBRATION

The calibrator should be run with patient samples in accordance with the instructions outlined in King Diagnostics HDL/LDL Cholesterol reagent package inserts. The value of the calibrator was assigned by procedures traceable to the National Reference System for Cholesterol (NRS/CHOL). Calibration materials have concentrations around the medical decision level. Refer to the instrument manufacturer's recommendation for specific calibration protocol and frequency. For additional assistance please contact King Diagnostics technical service department at 1-800-262-8655.

5.0 EXPECTED VALUES

The following NCEP recommendations for patient classifications are suggested for the prevention and management of coronary heart disease(6.8).

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

The range of expected values for serum HDL Cholesterol is (6.9):

Males: 30-70mg/dl
Females: 30-85mg/dl

6.0 REFERENCES

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