artery disease (CAD) is the key factor in the pathogenesis of arteriosclerosis and coronary heart disease. An increase in LDL cholesterol can occur as a result of elevated triglycerides, which is a risk factor for CAD. Even within the normal range of total cholesterol, HDL cholesterol has often been observed to have a protective effect. Numerous clinical studies have shown that the different lipoprotein classes have varied effects.

The HDL/LDL cholesterol values are traceable to the reference method (β-quantification) for determination of HDL/LDL Cholesterol. The classes include very low-density lipoproteins (VLDL), low density lipoproteins (LDL) and high density lipoproteins (HDL). The relative proportions of protein and lipid determine the density of these plasma lipoproteins and provide a basis on which to begin their classification. The classes are: very low-density lipoproteins (VLDL), low density lipoproteins (LDL) and high density lipoproteins (HDL).

In summary, 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.

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.

Presence of extreme turbidity or growth may indicate deterioration.

CALIBRATION

The calibrator should be run with patient samples in accordance with the instructions outlined in Cliniqa 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.

PROCEDURE

Reconstitute lyophilized serum calibrator with 3 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 and mix intermittently until completely dissolved. Do not shake.

WARNINGS AND PRECAUTIONS

1. Good laboratory safety practices should be followed when handling any laboratory reagent. Refer to a recognized laboratory safety program for additional information. (See GP17-T, Clinical Laboratory Safety; Tentative Guideline (1994), National Committee on Clinical Laboratory Standards, Wayne, PA.)
2. Results should be interpreted considering all other test results and clinical status of the patient.
3. Do not use the calibrator after the expiration date printed on the kit.

REFERENCES

6. The Lipid Research Clinics, Coronary Primary Prevention Trial Results, JAMA, 251 (3) 351-374(1985).
<table>
<thead>
<tr>
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