Summary
Cholesterol, synthesized by body cells and absorbed with food, is a component of cell membranes and a precursor for steroid hormones and bile acids. Cholesterol is transported in plasma via lipoproteins, complexes between lipids and apolipoproteins. Four lipoprotein classes exist: High density lipoproteins (HDL), low density lipoproteins (LDL), very low density lipoproteins (VLDL) and chylomicrons. These classes show distinct relationships to coronary atherosclerosis. LDL is involved in the cholesterol transport to the peripheral cells, contributing to atherosclerotic plaque formation within the arterial intima and is strongly associated with coronary heart disease (CHD) and related mortality. Even with total cholesterol (TC) within the normal range, an increased concentration of LDL-cholesterol (LDL-C) indicates high risk. HDL-cholesterol (HDL-C) has a protective effect impeding plaque formation and shows an inverse relationship to CHD prevalence. In fact, low HDL-C values constitute an independent risk factor. One of the important functions of HDL involves the physiological removal of cholesterol from peripheral tissues and cells, and transport to the liver. The concept that HDL could protect against CHD primarily originated from epidemiological studies of the healthy population, in particular the Framingham study. In addition to a number of antioxidant effects, HDL also serves as a powerful mediator of the cellular inflammatory and antithrombotic responses. HDL-particles are macromolecule complexes synthesized by liver and intestine and formed from surface components. HDL-particles are released into plasma during lipolysis of lipoproteins rich in triglycerides. Particles consist of an amphipathic lipid monolayer of phospholipids and cholesterol with embedded amphipathic proteins surrounding a core of hydrophobic lipids, mostly cholesteryl esters and triglycerides. HDL-C monitoring is highly relevant in cardiovascular risk assessment. Elevated HDL-C levels usually correlate with decreased cardiovascular risk; whereas reduced concentrations of HDL-C, especially in combination with elevated triglycerides are associated with high risk of atherosclerotic heart disease, even at or below recommended LDL-C goals. Preferred screening tests for dyslipidemia or lipid disorders are TC and HDL-C but the majority of screening guidelines nowadays recommend a full lipid profile including TC, LDL-C, HDL-C and triglycerides. [1-8]

Method
Previous HDL-cholesterol determinations were performed by time-consuming precipitation methods or ultracentrifugation (reference method in combination with cholesterol measurement by Abell-Kendall). However, the direct determination of HDL-cholesterol is used in routine [9]. HDL-c direct FS is a homogeneous method for HDL-cholesterol measurement without centrifugation steps. Block polymer detergents protect LDL, VLDL and chylomicrons in a way that only HDL-cholesterol is selectively determined by an enzymatic cholesterol measurement [10].

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents and protect them from light.

Warnings and Precautions

Materials Required
General laboratory equipment

Storage and Reagent Stability

Reagents
Components and Concentrations
R1: Buffer pH 6.85 20 mmol/L
Peroxidase (POD) ≥ 2000 U/L
N-Ethyl-N-(2-hydroxy-3-sulfopropyl) -3,5-dimethoxyaniline sodium salt (H-DAOS) ≥ 0.7 mmol/L
R2: Buffer pH 8.15 20 mmol/L
Cholesterol esterase (CHE) ≥ 400 U/L
Cholesterol oxidase (CHO) ≥ 700 U/L
Peroxidase (POD) ≥ 15000 U/L
4-Aminoantipyrine ≥ 1.5 mmol/L

Waste Management
Refer to local legal requirements.

Reagent Preparation
The reagent is ready to use.

Materials Required
General laboratory equipment

Specimen
Serum and heparin plasma (Lithium)
Method comparison (n=146)

<table>
<thead>
<tr>
<th>Test Method</th>
<th>Competitor HDL-C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test x</td>
<td>DiDia HDL-c direct FS</td>
</tr>
<tr>
<td>Slope</td>
<td>1.08</td>
</tr>
<tr>
<td>Intercept</td>
<td>–1.05 mg/dL</td>
</tr>
<tr>
<td>Coefficient of correlation</td>
<td>0.987</td>
</tr>
</tbody>
</table>

** according to CLSI document EP17-A2, Vol. 32, No. 8

Reference Range

As follows [15]:

National Cholesterol Education Program (NCEP) guidelines:
- Low HDL-cholesterol (major risk factor for CHD): < 40 mg/dL (≤ 1.04 mmol/L)
- High HDL-cholesterol ("negative" risk factor for CHD): ≥ 60 mg/dL (≥ 1.55 mmol/L)

A number of factors contribute to low HDL-cholesterol levels: e.g. overweight and obesity, smoking, physical inactivity, drugs such as beta-blockers and progestational agents, genetic factors.

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature


* Fluid Stable

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