Reagent for quantitative in vitro determination of HDL-cholesterol in biological fluids.

**SUMMARY OF TEST**

Blood total cholesterol levels have long been known to be related to coronary heart disease (CHD). In recent years, in addition to total cholesterol, high density lipoprotein cholesterol (HDL-C) has become an important tool used to assess an individual risk of developing CHD since a strong negative relationship between HDL-C concentration and the incidence of CHD was reported. Thus, there has been substantial interest in HDL-C analysis.

**PRINCIPLE OF THE METHOD**

Anti human β-lipoprotein antibody in reagent R1 binds to lipoproteins (LDL, VLDL, and chylomicrons) other than HDL. The antigen-antibody complexes formed block enzyme reactions when reagent R2 is added. Cholesterol esterase and cholesterol oxidase in reagent R2 react only with HDL-C. Hydrogen peroxide produced by the enzyme reactions with HDL-C yields a blue color complex upon oxidative condensation of F-DAOS [N-ethyl-N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxy-4-fluoroaniline, sodium salt] and 4-aminoantipyrine in the presence of peroxidase. By measuring the absorbance of the blue color complex produced, at the optimum wavelength of 593 nm, the HDL-C concentration in the sample can be calculated when compared with the absorbance of the HDL-C Calibrator. It is suggested to perform an internal quality control. For this purpose the following human based control sera are available: QUANTINORM CHEMA with normal or close to normal control values QUANTIPATH CHEMA with pathological control values. If required, a multiparametric, human based calibrator is available: AUTOCAL H.

**TEST PERFORMANCE**

Linearity the method is linear up to 220 mg/dl. If the limit is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Sensitivity/limit of detection (LOD) the limit of detection is 1 mg/dl.

Interferences no interference was observed by the presence of: hemoglobin ≤ 500 mg/dl bilirubin (free) ≤ 50 mg/dl bilirubin (conjugated) ≤ 40 mg/dl ascorbic acid ≤ 50 mg/dl

Precision

<table>
<thead>
<tr>
<th>intra assay (n=10)</th>
<th>mean (mg/dl)</th>
<th>SD (mg/dl)</th>
<th>CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>sample 1</td>
<td>32.1</td>
<td>0.18</td>
<td>0.55</td>
</tr>
<tr>
<td>sample 2</td>
<td>88.9</td>
<td>0.61</td>
<td>0.68</td>
</tr>
</tbody>
</table>

Comparison a comparison between HDL-direct FL and other methods has shown the following results:

<table>
<thead>
<tr>
<th>HDL-C Chema = x</th>
<th>HDL-C competitor = y</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 50</td>
<td></td>
</tr>
<tr>
<td>y = 0.96x + 2.5 mg/dl</td>
<td>r² = 0.998</td>
</tr>
</tbody>
</table>

**EXPECTED VALUES**

Each laboratory should establish appropriate reference intervals related to its population.

**REAGENT PREPARATION**

Use separate reagents ready to use. Stabilize: up to expiration date on label. Keep all components at 2-8°C.

**MATERIAL REQUIRED BUT NOT SUPPLIED**


**PRECAUTIONS**

HDL-C R1: Warning. May cause an allergic skin reaction (H317). Avoid breathing vapours (P261). IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water (P303+P361+P353). If skin irritation or rash occurs: Get medical advice (P333+P313).

HDL-C R2: It is not classified as hazardous.

**SPECIMEN**

Use serum as a specimen. It is recommended to measure HDL-C immediately after collection. Ascorbic acid, bilirubin, and hemoglobin do not have a significant effect on the measurement.