**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. Selective chemical precipitation techniques are widely used for the determination of HDL-C such as heparin-manganese, dextran-magnesium, and phosphotungstate-magnesium. However, these techniques require physical separation via centrifugation, which is not suited to large scale lab use. The HDL-direct test eliminates the precipitation procedure by employing a specific antibody, and thus, can be applied on automatic analyzers.

**PRINCIPLE OF THE METHOD**

Anti human 3-lipoprotein antibody in reagent A binds to lipoproteins (LDL, VLDL, and chylomicrons) other than HDL. The antigen-antibody complexes formed block enzyme reactions when reagent B is added. Cholesterol esterase and cholesterol oxidase in reagent B 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.

**KIT COMPONENTS**

For in vitro diagnostic use only.

The components of the kit are stable until expiration date.

Keep away from direct light sources.

For in vitro diagnostic use only.

The components of the kit are stable until expiration date.

Keep away from direct light sources.

**MATERIAL REQUIRED BUT NOT SUPPLIED**


**REAGENT PREPARATION**

Use separate reagents ready to use.

Stability: up to expiration date on labels at 2-8°C.

**PRECAUTIONS**

Labeling: Xi, R43 May cause sensitization by skin contact S20 When using do not eat, drink or smoke. S24 Avoid contact with skin S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S36/37/39 Wear suitable protective clothing, gloves, and eye/face protection. S45 If swallowed, seek medical advice immediately and show this container or label. S56 Dispose of this material and its container at hazardous or special waste collection point.

**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.

**TEST PROCEDURE**

**RESULTS CALCULATION**

serumplasma sample:

HDL-C mg/dl = Ax/As x calibrator value

**EXPECTED VALUES**

Adult male: 35.3 - 79.5 mg/dl

Adult female: 42.0 - 88.0 mg/dl

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

**QUALITY CONTROL AND CALIBRATION**

It is suggested to perform an internal quality control. For this purpose a reliable and compatible human based control sera is needed.

If required, the follow calibrator is available:

- a multiparametric, human based calibrator:

  AT 0030 CH AUTOCAL H 10 x 3 ml

Please contact Customer Care for further information.

**TEST PERFORMANCE**

**REFERENCES**


**WASTE DISPOSAL**

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. Refer to special instructions/safety data sheets.

<table>
<thead>
<tr>
<th>SYMBOLS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVD</td>
</tr>
<tr>
<td>LOT</td>
</tr>
<tr>
<td>REF</td>
</tr>
<tr>
<td>⬤</td>
</tr>
<tr>
<td>☑</td>
</tr>
<tr>
<td>⬤ ⬤</td>
</tr>
<tr>
<td>⬤</td>
</tr>
</tbody>
</table>

**WEB SITE**

http://www.chema.com

**CONTACT**

Via Campania 2/4
60030 Monsano (AN) - ITALY - EU

phone +39 0731 605064
fax +39 0731 605672

e-mail: mail@chema.com

**Chema Diagnostica**

IUS-7.5 UK

rev. 18/10/2013