ORDEN DE INFORMACIÓN

<table>
<thead>
<tr>
<th>REF: HDLD 20</th>
<th>Cont. 1x20 ml</th>
<th>HDLD 40</th>
<th>Cont. 1x40 ml</th>
</tr>
</thead>
</table>

SIGNIFICADO CLÍNICO

HDL particles serve to transport in the blood-stream. HDL is known as “good cholesterol” because high levels are thought to lower the risk of heart disease and coronary artery disease. A low HDL cholesterol level is considered a greater heart disease risk. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPIO

Direct determination of serum HDL (high-density lipoprotein cholesterol) levels without the need for any pre-treatment or centrifugation of the sample. The method depends on the properties of a detergent which solubilizes only the HDL so that HDL-c is released to react with the cholesterol esterase, cholesterol oxidase and chromogens to give colour. The non HDL lipoprotein LDL, VLDL and chylomicrons are inhibited from reacting with the enzymes due to absorption of the detergents on their surfaces. The intensity of the color formed is proportional to the HDL concentration in the sample.

COMPOSICIÓN DEL REAGENTE

<table>
<thead>
<tr>
<th>R1</th>
<th>GOOD pH 7.0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cholesterol oxidase &lt; 1000 U/L</td>
</tr>
<tr>
<td></td>
<td>Peroxidase &lt; 1300 U/L</td>
</tr>
<tr>
<td></td>
<td>Dimethoxyaniline (TOOS) &lt; 1 mM</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>R2</th>
<th>GOOD pH 7.0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cholesterol esterase &lt; 1500 U/L</td>
</tr>
<tr>
<td></td>
<td>4- Amino antipyrine (4-AP) &lt;1 mM</td>
</tr>
<tr>
<td></td>
<td>Detergent &lt;2%</td>
</tr>
<tr>
<td></td>
<td>Ascorbate oxidase &lt;3000 U/L</td>
</tr>
</tbody>
</table>

HDL/LDL CAL

SUSPENSIÓN ESTANDAR, SERUM DESHIDRATADO HUMANO

PRECAUCIONES Y ADVERTENCIAS

HDL/LDL CAL

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV and antibody to HIV (1/2). However handle cautiously as potentially infectious.

COLECCIÓN DE MUESTRAS Y PRESERVAción

Serum or heparinized plasma, free of hemolysis; Anticoagulants containing citrate should not be used. Removed from the blood clot as soon as possible. Stability of the sample: 7 days at 2-8°C.

PREPARACIÓN Y GUARDAR REAGENTE

- R1 and R2: Are ready to use.
- HDL/LDL CAL: Dissolve the contents with distilled water, as mentioned on vial label. Cap vial and mix gently to dissolve contents.
- R1 and R2: Once opened is stable 8 weeks at 2-8°C.
- HDL/LDL CAL: Once reconstituted 1 week at 2-8°C or 5 weeks at -20°C.
- Do not use reagents over the expiration date.
- Sign of reagent deterioration.
- Presence of particles and turbidity.

ADICIONAL DE EQUIPO

- Spectrophotometer or colorimeter measuring at 600 nm.
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

ESTABILIDAD DEL REAGENTE

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not freeze the reagents.

LINEALIDAD

150 mg/dl

PROCEDIMIENTO DE LA PRUEBA

1. Assay conditions:
   - Wavelength: 600 nm
   - Cuvette: 1 cm light path
   - Temperature: 37°C

2. Adjust the instrument to zero with distilled water.

3. Pipette into a cuvette:

<table>
<thead>
<tr>
<th></th>
<th>Blank</th>
<th>Calibrator</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 (μL)</td>
<td>300</td>
<td>300</td>
<td>300</td>
</tr>
<tr>
<td>Calibrator (μL)</td>
<td>4</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sample (μL)</td>
<td>-</td>
<td>-</td>
<td>4</td>
</tr>
</tbody>
</table>

4. Mix and Incubate for 5 min at 37°C.

5. Add: Reagent 2.

6. Read the absorbance (A1) of the samples and calibrator, against the Blank.

7. Read the absorbance (A2) of the samples and calibrator after 5 mins, against the Blank.
8. Calculate the Increase of the absorbance $\Delta A = A_2 - A_1$.

**CALCULATION**

$\Delta A$ Sample

$\Delta A \times \text{Calibrator conc.} = \text{mg/dL of HDLc in the sample}$

$\Delta A$ Calibrator

Conversion factor: $\text{mg/dL} \times 0.0259 = \text{mmol/L}$.

**QUALITY CONTROL**

Control sera are recommended to monitor the performance of assay procedures. If control values are found outside the defined range, check the instrument reagents and calibrator for problems. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

**REFERENCE INTERVAL**

<table>
<thead>
<tr>
<th></th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low risk</td>
<td>&gt; 50 mg/dL</td>
<td>&gt; 60 mg/dL</td>
</tr>
<tr>
<td>Normal risk</td>
<td>35-50 mg/dL</td>
<td>45-60 mg/dL</td>
</tr>
<tr>
<td>High risk</td>
<td>&lt; 35 mg/dL</td>
<td>&lt; 45 mg/dL</td>
</tr>
</tbody>
</table>

These values are for orientation purpose; each laboratory should establish its own reference range.

**PERFORMANCE CHARACTERISTICS**

Measuring range: From detection limit of 2.5 mg/dL to linearity limit of 150 mg/dL. If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L and multiply the result by 2.

**Precision**:

<table>
<thead>
<tr>
<th></th>
<th>Intra-assay</th>
<th>Inter-assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (mg/dL)</td>
<td>32.9</td>
<td>32.8</td>
</tr>
<tr>
<td>SD</td>
<td>0.3</td>
<td>0.4</td>
</tr>
<tr>
<td>CV</td>
<td>0.8</td>
<td>1.3</td>
</tr>
</tbody>
</table>

Sensitivity: 1mg/dL = 0.0016 A.

Accuracy: Results obtained using ACCUCARE reagents (y) did not show systematic difference when compared with other commercial reagents. (x).

The results obtained using 50 samples were the following:

Correction coefficient ($r$): 0.996.

Regression equation: $y = 0.98 + 3.42$ mg/dL.

The results of the performance characteristics depend on the analyzer used.

**INTERFERENCES**

No Interferences were observed to bilirubin T. and D. up to 60 mg/dL, hemoglobin up to 1000 mg/dL or lipaemia up to 1800 mg/dL.

**NOTES**

ACCUCARE has instrument application sheets for several automatic analyzers. Instructions for many of them are available on request.

**BIBLIOGRAPHY**

2. US National Cholesterol Education Program of the National Institutes of Health.