[Intended use]
Quantitative measurement of high-density lipoprotein cholesterol in plasma or serum.
For in vitro diagnostic use only.

[Principle of the measurement]
10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE HDL-C-PIIID. The sample is uniformly distributed on the spreading layer. The chylomicron, very low density lipoprotein (VLDL) and low density lipoprotein (LDL) react with the dextran sulfate to form insoluble complexes. On the other hand, high density lipoprotein (HDL) dissociates into protein and lipid (cholesterol component) upon the reaction with the surfactant. The cholesterol esters in the lipids are converted into cholesterols by cholesterol esterase (CHE). The generated cholesterols and endogenous cholesterols are oxidized by cholesterol oxidase (COD) to form hydrogen peroxide. Peroxidase (POD) reacts with the hydrogen peroxide to initiate the coupling reaction between the 4-aminoantipyrine and DAOS forming a blue color dye. The reaction scheme is as shown below.

PLasma or Serum → Dextran sulfate, Mg²⁺ → HDL (soluble) + LDL, VLDL, Chylomicron (insoluble)
HDL Surfactant
Cholesterol + Cholesterol ester + Protein
Cholesterol ester + H₂O → Cholesterol + Fatty acid
Cholesterol + O₂ → COD, H₂O₂ + Cholesterol esterase
4-Aminoantipyrine + DAOS + 2H₂O₂ → Blue color dye + 4H₂O

[Sample requirements]
1. After collecting blood sample immediate measurement is recommended.
2. For plasma, heparin can be used as the anticoagulant. When using heparin, less than 50 units of heparin should be used per 1 mL of whole blood. Do not use EDTA salt, sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.
5. Sample of high neutral fat (over 5.6 mmol/L) may be highly measured.

[Procedure]
1. Read in the new QC-card when you switch to a new box of slides.
2. Set slides on FUJI DRI-CHEM ANALYZER.
3. Set a sample tube in the specified sample rack.
4. Input a sequence No. and a sample ID if appropriate.
5. Press the “START” key to initiate testing.

CAUTION: Use immediately after opening the individual package.
For further details of operation procedure, consult “INSTRUCTION MANUAL” for FUJI DRI-CHEM ANALYZER.

[Internal quality control]
The accuracy and precision of this product can be evaluated with FUJI DRI-CHEM CONTROL QP-L.
1. Measure FUJI DRI-CHEM CONTROL QP-L in the same way as patient samples.
2. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L, investigate the cause.

[Traceability of calibrators and control materials]
HDL-cholesterol...ReCCS (CHT)
ReCCS: Reference Material Institute for Clinical Chemistry Standards

[Performance characteristics]
1. Dynamic range

<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>10–110 mg/dL (0.26–2.84 mmol/L)</td>
<td>Within ± 8 mg/dL (Within ± 0.10 mmol/L)</td>
</tr>
</tbody>
</table>

2. Accuracy

<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>10–40 mg/dL (0.26–1.03 mmol/L)</td>
<td>SD ± 4 mg/dL (SD ± 0.10 mmol/L)</td>
</tr>
<tr>
<td>40–110 mg/dL (1.03–2.84 mmol/L)</td>
<td>CV ± 10 %</td>
</tr>
</tbody>
</table>

3. Precision

<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
<td>40–110 mg/dL (1.03–2.84 mmol/L)</td>
<td>CV ± 10 %</td>
</tr>
</tbody>
</table>

4. Correlation
Correlation was evaluated between HDL homogenous method and FUJI DRI-CHEM system. HDL homogenous method was performed on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

<table>
<thead>
<tr>
<th>n</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>85</td>
<td>0.966</td>
<td>1.7</td>
</tr>
<tr>
<td>Plasma</td>
<td>63</td>
<td>0.973</td>
<td>1.3</td>
</tr>
</tbody>
</table>

[Warnings and precautions]
1. Storage: This product must be stored between 2–8 °C (35.6–46.4 °F) before warmed up to room temperature before opening the individual packages.
2. Handle all patient samples, control serum and used tips carefully as biohazardous samples.
3. Do not touch the membrane in the center of the slide.
4. Set slides on FUJI DRI-CHEM ANALYZER.
5. Avoid using plasma or serum with precipitate such as fibrin.
6. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.
7. Sample of high neutral fat (over 5.6 mmol/L) may be highly measured.

[Limitation of the examination procedure]
The clinical diagnosis must be made by the doctor in charge based on the measured results in the light of clinical symptoms and other test results.

Known interfering substances
(1) No significant effect was observed to the following concentration for each substance.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbic acid</td>
<td>10 mg/dL (0.57 mmol/L)</td>
<td>No effect</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>20 mg/dL (340 μmol/L)</td>
<td>Minor effect</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>2000 mg/L</td>
<td>No effect</td>
</tr>
<tr>
<td>Total protein</td>
<td>40–95 g/L</td>
<td>No effect</td>
</tr>
<tr>
<td>Uric acid</td>
<td>9 mg/dL (0.54 mmol/L)</td>
<td>No effect</td>
</tr>
</tbody>
</table>

(2) Dobutamine hydrochloride(cardiotonic reagent) and dopamine hydrochloride(cardiotonic reagent) give minus bias. These results are representative:

- Test condition may have some influence on your results.
- Interferences from other substances are not predictable.

[Limitation of the examination procedure]
Female | 40–71 mg/dL (1.03–1.84 mmol/L) |
|---|---|

As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals.

[Additional special equipment]
Analyzer:
FUJI DRI-CHEM ANALYZER

Other implements:
FUJI DRI-CHEM QC CARD (attached)
FUJI DRI-CHEM CLEAN TIPS or FUJI DRI-CHEM AUTO TIPS
FUJI HEPARIN/PLAIN TUBE

[Storage and shelf life]
1. Storage: This product must be stored between 2–8 °C (35.6–46.4 °F) before use.
2. Expiry date is printed on the carton.

CAUTION: Do not use expired slides.

[Warnings and precautions]
1. Only the required number of slides should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
2. Do not touch the membrane in the center of the slide.
3. A new slide must be used for each measurement. Do not reuse.
4. Handle all patient samples, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
5. Used slides are categorized as infectious waste. Make sure to dispose them according to the Waste Disposal Law and other related regulations, in accordance with the proper method of disposal, such as incineration, melting, burial or disposal.
6. Because it is highly sensitive to light, as soon as the slide is taken out of its package, it should be set in the cartridge with the slide weight placed on the top of it.
7. Keep QC card away from magnetic material.
8. Do not use the slide if the individual package is damaged.
[Symbols]

- **Do not touch the center part of the slide.**
- **Warmed up to room temperature before opening the individual packages.**
- **SLIDE CODE**
- **Do not reuse**
- **Lot number**
- **Use by**
- **Contains sufficient for <n> tests**
- **Temperature limitation**
- **Consult instructions for use**
- **In vitro diagnostic medical devices**
- **Manufacturer**
- **Authorized representative in the European Community**

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