Cholesterol FS*

Diagnostic reagent for quantitative in vitro determination of cholesterol in serum or plasma on DiaSys respons® 920

Order Information
Cat. No. 1 1300 99 10 923
4 containers for 200 determinations each

Method
*CHOD-PAP*: enzymatic photometric test

Principle
Determination of cholesterol after enzymatic hydrolysis and oxidation. The colorimetric indicator is quinoneimine which is generated from 4-aminoantipyrine and phenol by hydrogen peroxide under the catalytic action of peroxidase (Trinder’s reaction) [1,2].

\[
\text{Cholesterol ester} + \text{H}_2\text{O} \xrightarrow{\text{CHE}} \text{Cholesterol} + \text{Fatty acid}
\]

\[
2\text{H}_2\text{O} + 4\text{-Aminoantipyrine} + \text{Phenol} \xrightarrow{\text{POD}} \text{Quinoneimine} + 4\text{H}_2\text{O}
\]

Reagent
Components and Concentrations
- Good’s buffer
- pH 6.7
- 50 mmol/L
- Phenol
- 5 mmol/L
- 4-Aminoantipyrine
- 0.3 mmol/L
- Cholesterol esterase
- (CHE)
- ≤200 U/L
- Cholesterol oxidase
- (POD)
- ≥50 U/L
- Peroxidase
- (POD)
- ≥3 kU/L

Storage Instructions and Reagent Stability
The reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. DiaSys responds containers provide protection from light. Do not freeze the reagent!

Warnings and Precautions
1. The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons® 920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
3. In very rare cases, samples of patients with gammopathy might give falsified results [8].
4. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examinations and other findings.
6. For professional use only!

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagent is ready to use. The bottles are placed directly into the reagent rotor.

Specimen
Serum, heparin plasma or EDTA plasma
Stability [3]:
- 7 days at 20 – 25°C
- 7 days at 4 – 8°C
- 3 months at ≤2°C
Discard contaminated specimens. Freeze only once.

Calibrators and Controls
DiaSys TruCal U calibrator is recommended for calibration. The assigned values of the calibrator have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS). For internal quality control DiaSys TruLab N and P or TruLab L controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>TruCal U</th>
<th>5 9100 99 10 063</th>
<th>20 x 3 mL</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>5 9100 99 10 064</td>
<td>6 x 3 mL</td>
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</tr>
<tr>
<td>TruLab N</td>
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<td>20 x 5 mL</td>
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<td>TruLab L Level 1</td>
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<td>3 x 3 mL</td>
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<tr>
<td></td>
<td>5 9030 99 10 065</td>
<td>3 x 3 mL</td>
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</tr>
</tbody>
</table>

Performance Characteristics
- Measuring range up to 750 mg/dL cholesterol (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function...)
- Limit of detection**: 3 mg/dL cholesterol
- On-board stability 4 weeks
- Calibration stability 4 weeks

Interferences < 10% by
- Ascorbate up to 6 mg/dL
- Hemoglobin up to 600 mg/dL
- Bilirubin up to 10 mg/dL
- Lipemia (triglycerides) up to 2000 mg/dL

For further information on interfering substances refer to Young DS [4].

Precision

<table>
<thead>
<tr>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/dL]</td>
<td>132</td>
<td>206</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>1.40</td>
<td>1.16</td>
</tr>
<tr>
<td>Between run (n=20)</td>
<td>1.46</td>
<td>1.13</td>
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</table>

Method comparison (n=110)

<table>
<thead>
<tr>
<th>Test x</th>
<th>DiaSys Cholesterol FS (Hitachi 917)</th>
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</thead>
<tbody>
<tr>
<td>Test y</td>
<td>DiaSys Cholesterol FS (respons 920)</td>
</tr>
<tr>
<td>Slope</td>
<td>0.985</td>
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<tr>
<td>Intercept</td>
<td>0.035 mg/dL</td>
</tr>
<tr>
<td>Coefficient of correlation</td>
<td>0.993</td>
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</table>

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Conversion factor
Cholesterol [mg/dL] x 0.02586 = Cholesterol [mmol/L]

Reference Range [5]
Desirable ≤200 mg/dL (<5.2 mmol/L)
Borderline high risk 200 – 240 mg/dL (5.2 – 6.2 mmol/L)
High risk >240 mg/dL (>6.2 mmol/L)
Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Clinical Interpretation
The European Task Force on Coronary Prevention recommends to lower TC concentration to less than 190 mg/dL (5.0 mmol/L) and LDL-cholesterol to less than 115 mg/dL (3.0 mmol/L) [6].

Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

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* fluid stable
# Cholesterol FS

Application for serum and plasma

<table>
<thead>
<tr>
<th>Test Details</th>
<th>Test Volumes</th>
<th>Reference Ranges</th>
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</thead>
<tbody>
<tr>
<td>Test</td>
<td>CHOL</td>
<td></td>
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<tr>
<td>Report Name</td>
<td>Total Cholesterol</td>
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<tr>
<td>Unit</td>
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<td>Wavelength-Primary</td>
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<tr>
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<td>M2 Start</td>
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<tr>
<td>Control Replicates</td>
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<tr>
<td>Reaction Direction</td>
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<tr>
<td>Prozone Limit %</td>
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</tr>
<tr>
<td>Technical Minimum</td>
<td>3.0</td>
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</tr>
<tr>
<td>Y = ax + b</td>
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<td></td>
</tr>
<tr>
<td>a=</td>
<td>1.0000</td>
<td></td>
</tr>
<tr>
<td>b=</td>
<td>0.0000</td>
<td></td>
</tr>
</tbody>
</table>

* Enter calibrator value.

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>CHOL</td>
<td></td>
</tr>
<tr>
<td>Sample Type</td>
<td>Serum</td>
<td></td>
</tr>
</tbody>
</table>

**Sample Volumes**

- Normal: 2.00 µL
- Increase: 5.00 µL
- Decrease: 2.00 µL
- Standard Volume: 2.00 µL

**Reagent Volumes and Stirrer Speed**

- RGT-1 Volume: 180 µL
- R1 Stirrer Speed: High
- RGT-2 Volume: µL
- R2 Stirrer Speed: 

**Reference Range**

- Category: Male
- Lower Limit: 0.00
- Upper Limit: 200.00

**Sample Types**

- Serum
- Urine
- CSF
- Plasma
- Whole Blood
- Other