Diagnostic reagent for quantitative in vitro determination of cholesterol in serum or plasma on DiaSys respons®910

**Order Information**
Cat. No. 1 1300 99 10 923
4 containers for 200 tests 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].

Cholesterol ester + H₂O → Cholesterol + Fatty acid

Cholesterol + O₂ → Cholesterol-3-one + H₂O₂

2 H₂O₂ + 4-Aminoantipyrine + Phenol → Quinoneimine + 4 H₂O

**Reagent**
Components and Concentrations
- Good's buffer: pH 6.7
- Phenol: 5 mmol/L
- 4-Aminoantipyrine: 0.3 mmol/L
- Cholesterol esterase (CHE): ≥ 200 U/L
- Cholesterol oxidase (CHOD): ≥ 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 respons 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. In very rare cases, samples of patients with gammopathy might give falsified results [8].
3. N-acetylcycteine (NAC), acetaminophen and metamizole medication lead to falsely low results in patient samples.
4. 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.
5. 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 −20°C

Discard contaminated specimens. Freeze only once.

**Calibrators and Controls**
For calibration, DiaSys TruCal U calibrator is recommended. 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 actions in case of deviations in control recovery.

**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 re-run function).

**Limit of detection**
1 mg/dL cholesterol

**On-board stability**
8 weeks

**Calibration stability**
4 weeks

**Interfering substance**

<table>
<thead>
<tr>
<th>Interference</th>
<th>Interference%</th>
<th>Cholesterol [mg/dL]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbate</td>
<td>up to 6 mg/dL</td>
<td>222</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>up to 230 mg/dL</td>
<td>152</td>
</tr>
<tr>
<td>Bilirubin, conjugated</td>
<td>up to 15 mg/dL</td>
<td>147</td>
</tr>
<tr>
<td>Bilirubin, unconjugated</td>
<td>up to 25 mg/dL</td>
<td>236</td>
</tr>
<tr>
<td>Lipemia (triglycerides)</td>
<td>up to 2200 mg/dL</td>
<td>237</td>
</tr>
</tbody>
</table>

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

**Precision**

<table>
<thead>
<tr>
<th>Precision Method (n=106)</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/dL]</td>
<td>139</td>
<td>209</td>
<td>268</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>2.13</td>
<td>1.86</td>
<td>2.70</td>
</tr>
</tbody>
</table>

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

**Reference Range**

<table>
<thead>
<tr>
<th>Range</th>
<th>Desirable</th>
<th>Borderline high risk</th>
<th>High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 - 240 mg/dL</td>
<td>5.2 – 6.2 mmol/L</td>
<td>≥ 240 mg/dL (&gt; 6.2 mmol/L)</td>
<td></td>
</tr>
</tbody>
</table>

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) [5].

**References**
Cholesterol FS
Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Identification
This method is usable for analysis: Yes
Twin reaction: No
Name: CHOL
Shortcut: 024
Reagent barcode reference:
Host reference:

Technic
Type: End point
First reagent [µL]: 180
Blank reagent: Yes
Sensitive to light
Second reagent [µL]: Blank reagent
Sensitive to light
Main wavelength [nm]: 508
Secondary wavelength [nm]: 750
Polychromatic factor: 1.000
1st reading time [min:sec]: (-0.12)
Last reading time [min:sec]: 10:00
Reaction way: Increasing
Linear Kinetics
Linearity: Maximum deviation [%]
Fixed Time Kinetics
Endpoint
Prozone Limit [%]

Reagents
Decimals
Units

Sample
Diluent: DIL A (NaCl)
Hemolysis: Agent [µL]: 0 (no hemolysis)
Cleaner
Sample [µL]: 0
Technical limits
Concentration technical limits-Lower: 1
Concentration technical limits-Upper: 750
SERUM
Normal volume [µL]: 2
Normal dilution (factor): 1
Below normal volume [µL]: 5
Below normal dilution (factor): 1
Above normal volume [µL]: 2
Above normal dilution (factor): 6
URINE
Normal volume [µL]: 2
Normal dilution (factor): 1
Below normal volume [µL]: 5
Below normal dilution (factor): 1
Above normal volume [µL]: 2
Above normal dilution (factor): 6
PLASMA
Normal volume [µL]: 2
Normal dilution (factor): 1
Below normal volume [µL]: 5
Below normal dilution (factor): 1
Above normal volume [µL]: 2
Above normal dilution (factor): 6
CSF
Normal volume [µL]: 2
Normal dilution (factor): 1
Below normal volume [µL]: 5
Below normal dilution (factor): 1
Above normal volume [µL]: 2
Above normal dilution (factor): 6
Whole blood
Normal volume [µL]: 2
Normal dilution (factor): 1
Below normal volume [µL]: 5
Below normal dilution (factor): 1
Above normal volume [µL]: 2
Above normal dilution (factor): 6

Results
Decimals: 0
Units: mg/dL
Correlation factor-Offset: 0.000
Correlation factor-Slope: 1.000

Range
Gender: All
Age:
SERUM: >= <=200
URINE: >= <=200
CSF: Whole blood
Gender
Age:
SERUM: URINE: PLASMA: CSF: Whole blood

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details
Calibrator list
Concentration
Cal. 1/Blank
0
Cal. 2
* Cal. 3 Cal. 4 Cal. 5 Cal. 6

Max delta abs.
Cal. 1 0.003
Cal. 2 0.020
Cal. 3 Cal. 4 Cal. 5 Cal. 6

Calculations
Model
Degree: X

* Enter calibrator value