PERFORMANCE DATA

- Analytical range
  The test is linear up to a cholesterol concentration of 1200 mg/dl or 30.0 mmol/l. Samples with a higher concentration have to be diluted 1+2 with phys. saline (0.9 %), repeat the determination, multiply result by 3.

- Detection limit
  The detection limit is 4 mg / dL

- Precision
  Within-run reproducibility
  \[ \begin{array}{|c|c|c|c|}
  \hline
  \text{N} & \text{Mean} & \text{SD} & \text{CV} & \text{Unit} \\
  \hline
  \text{Control 1} & 99.6 & 1.75 & 1.76\% & \text{mg/dL} \\
  \text{Control 2} & 196.5 & 2.77 & 1.41\% & \text{mg/dL} \\
  \text{Patient} & 150.7 & 1.68 & 1.11\% & \text{mg/dL} \\
  \hline
  \end{array} \]

  Between-run reproducibility
  \[ \begin{array}{|c|c|c|c|}
  \hline
  \text{N} & \text{Mean} & \text{SD} & \text{CV} & \text{Unit} \\
  \hline
  \text{Control 1} & 100.3 & 1.30 & 1.30\% & \text{mg/dL} \\
  \text{Control 2} & 195.9 & 3.55 & 1.81\% & \text{mg/dL} \\
  \text{Patient} & 147.9 & 1.99 & 1.35\% & \text{mg/dL} \\
  \hline
  \end{array} \]

- Correlation
  A comparative study has been performed between the Greiner method and another commercial reagent on 35 human serum samples. The parameters of linear regression are as follows:
  \[ y = 1.032 x + 1.939 \text{mg/dL} \quad r = 1.000 \]

INTERFERENCES

- Ascorbic Acid: no interference until 5 mg/dL
- Bilirubin: no interference until 25 mg/dL
- Hemoglobin: no interference until 1000 mg/dL
- Triglycerides: no interference until 2000 mg/dL

BIBLIOGRAPHY


SYMBOLS USED

| IVD | For in vitro diagnostic medical use |
| LOT | Batch Code |
| Use by |
| Temperature limitation |
CHOLESTEROL

CHOD-PAP (Monoreagent)

<table>
<thead>
<tr>
<th>Cat.No</th>
<th>Package Sizes</th>
</tr>
</thead>
<tbody>
<tr>
<td>118 000</td>
<td>R1= 2 x 50 ml + Standard</td>
</tr>
<tr>
<td>118 001</td>
<td>R1= 4 x 100 ml + Standard</td>
</tr>
<tr>
<td>118 002</td>
<td>R1= 2 x500 ml + Standard</td>
</tr>
<tr>
<td>118 003</td>
<td>R1= 4 x 50 ml</td>
</tr>
<tr>
<td>118 004</td>
<td>R1= 4 x 100 ml</td>
</tr>
<tr>
<td>118 007</td>
<td>R1= 8 x 70 ml</td>
</tr>
</tbody>
</table>

METHOD
Enzymatic – colorimetric, Trinder . End Point.

PRINCIPLE
Enzymatic colorimetric determination of total cholesterol according to the following reactions:

\[
\text{Chol.-Esterase} \quad \text{Cholesterol ester} + \text{H}_2\text{O} \rightarrow \text{Cholesterol} + \text{Fatty acids}
\]

\[
\text{CHOD} \quad \text{Cholesterol} + \text{O}_2 \rightarrow 4\text{-Cholesten-3-one} + \text{H}_2\text{O}_2
\]

\[
2\text{H}_2\text{O}_2 + \text{Phenol} + 4\text{-Aminoantipyrine} \rightarrow \text{Red quinone} + 4\text{H}_2\text{O}
\]

REAGENT COMPOSITION
Reagent (R1)
- Good’s Buffer (pH 6.7)  50 mmol/l
- Phenol  5 mmol/l
- 4-Aminoantipyrin  0.3 mmol/l
- Cholesterol esterase (CHE)  ≥ 200 U/l
- Cholesterol oxidase (CHO)  ≥ 100 U/l
- Peroxidase (POD)  ≥ 3 kU/l

Standard:
- Cholesterol 200 mg/dL (5.2 mmol/l)

PRECAUTIONS
- For in vitro diagnostic use only.
- The reagent contains < 0.95 g/L sodium azide.
- Avoid contact with skin and/or mucous membranes.
- Use clean or single use glass material to avoid any contaminations.

STABILITY OF REAGENTS
When stored at 2-8° C and protected from light, the unopened reagent is stable until the expiry date stated on the label.

PREPARATION AND STABILITY OF WORKING REAGENT
Reagent and standard are ready for use.

Stability after opening the bottles:
- At least 3 months at 2 – 8 °C (contamination has to be avoided !)

SAMPLES
- Serum, Plasma(EDTA/Heparin)

REFERENCE VALUES
The NCEP (American National Cholesterol Education Program) has established the following classification for serum cholesterol levels according to the risk of developing coronary heart diseases:

<table>
<thead>
<tr>
<th>Level</th>
<th>Range</th>
<th>mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt; 200 mg/dL</td>
<td>(5.18 mmol/L)</td>
</tr>
<tr>
<td>Borderline high</td>
<td>200-239 mg/dL</td>
<td>(5.18 - 6.19 mmol/L)</td>
</tr>
<tr>
<td>High</td>
<td>≥ 240 mg/dL</td>
<td>(6.22 mmol/L)</td>
</tr>
</tbody>
</table>

Note: It is recommended for each laboratory to establish and maintain its own reference values. The data given here are only an indication.

PROCEDURE
This reagent can be used manually (see method below) and on most analyzers. The applications are available on request.

- Wavelength : 500 nm (492-550)
- Temperature : 37°C
- Cuvette : 1 cm light path

Read against reagent blank (R-Blank)

<table>
<thead>
<tr>
<th>R-BLANK</th>
<th>STANDARD</th>
<th>SAMPLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 mL</td>
<td>1 mL</td>
<td>1 mL</td>
</tr>
<tr>
<td>10 µL</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>10 µL</td>
<td>-</td>
<td>10 µL</td>
</tr>
</tbody>
</table>

Mix and read the absorbance (A) after a 5 minute incubation.

The final color is stable for at least 1 hour.

CALCULATION

\[
A \text{ sample} \times C = 200
\]

\[
A \text{ standard} \times C = 2
\]

\[
C = \text{standard concentration.}
\]

CALIBRATION & QUALITY CONTROL
For the calibration of automated analyzers Greiner Multicalibrator is recommended, for quality control use Greiner normal and abnormal control, Unitrol I and Unitrol II, for lipids the special lipid control.