**INTRODUCTION**

The Mission® Cholesterol Test Devices work with the Mission® Cholesterol Meter to measure the lipid concentration in whole blood, plasma, or serum. For testing plasma, coagulate plasma. The 3-1 Lipid Panel is used to measure the concentrations of Total Cholesterol (CHOL), High Density Lipoprotein (HDL) and Low Density Lipoprotein (LDL). The 3-1 Lipid Panel is used to measure the concentrations of Total Cholesterol (CHOL), HDL, Total Cholesterol/HDL and Triglycerides (TRIG) ratios. The concentrations of CHOL, HDL, and TRIG are reported in mg/dL (mmol/L).

**TESTS DEVELOPED**

<table>
<thead>
<tr>
<th>Tests Developed</th>
<th>Concentration</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHOL</td>
<td>12.9 mmol/L</td>
<td>mg/dL</td>
</tr>
<tr>
<td>HDL</td>
<td>0.39 mmol/L</td>
<td>mg/dL</td>
</tr>
<tr>
<td>TRIG</td>
<td>0.51 mmol/L</td>
<td>mg/dL</td>
</tr>
</tbody>
</table>

**TRIALS**

In another study, heparinized venous whole blood, serum and heparinized plasma were collected from each patient and tested using a Capillary Transfer Tube with the Specimen Application Area to apply the blood. 3 dashed lines will appear on the meter to show the test is in progress. The concentration of Low Density Lipoprotein (LDL) is calculated by the values of CHOL, TRIG and HDL. The system monitors the change in absorbance at 635 nm at a fixed-time interval. The change in absorbance is directly proportional to the lipid concentration in the test device.

**INTERPRETATION OF RESULTS**

- Total Cholesterol
  - 5.2-6.2 mmol/L (200-240 mg/dL)
  - >6.2mmol/L (240mg/dL)
- High Density Lipoprotein
  - 1.0243 -2.7846 0.994 78
- Triglycerides
  - 45-650 mg/dL (0.51-7.34 mmol/L)

**Note:**

- For total cholesterol and high density lipoprotein, 1 mmol/L =38.66 mg/dL; for triglycerides, 1 mmol/L=88.6 mg/dL.
- Hand Ions or creams on the finger should be cleaned before testing or the results of the test will be triglycerides, 1 mmol/L=88.6 mg/dL.

**Linearity**

<table>
<thead>
<tr>
<th>Test Device Lot Linearity Equation R²</th>
<th>Lot 1 Y=0.9996x + 0.2864 0.996</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lot 2 Y=0.9992x + 0.4052 0.997</td>
</tr>
<tr>
<td></td>
<td>Lot 3 Y=x+0.0062 0.998</td>
</tr>
</tbody>
</table>

**Measuring the Lipid Concentrations in Blood**

1. Insert the code chip into the meter and code the meter correctly. Refer to the Meter Section in the User's Manual for details on the test device or pulp and ensure the two numbers are identical to avoid incorrect results.

2. Wait for 2 minutes. The message display on the meter will show the test is in progress. The concentration of LDL is calculated by the values of CHOL, TRIG and HDL. The system monitors the change in absorbance at 635 nm at a fixed-time interval. The change in absorbance is directly proportional to the lipid concentration in the test device.

**Test Devices**

- Code Chip
- Capillary Transfer Tubes
- Package Insert

**Quality Control**

For best results, performance of test devices should be confirmed by testing known specimens/controls whenever a new lot of test devices is performed. Use of certified control materials, either in place or whenever new test devices are sent. DIN 58940:2006 and 2007 recommend the inclusion of a third control for the patient sample. Use of certified control materials should be considered essential. Consult the manufacturer's instructions on specific controls for this patient.

**BIBLIOGRAPHY**

3. Schiffgraben 41

**Store as packaged in the sealed pouch or container, either at room temperature or refrigerated (2-8°C). Do not freeze.**

**Cholesterol Test Devices**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Specimen Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol</td>
<td>Whole Blood, Plasma, Serum</td>
</tr>
<tr>
<td>HDL Lipoprotein</td>
<td>Whole Blood, Plasma, Serum</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>Whole Blood, Plasma, Serum</td>
</tr>
</tbody>
</table>

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