INTENDED USE

For the quantitative determination of total cholesterol, HDL cholesterol, triglycerides and glucose in whole blood sampled from fingerstick or venipuncture samples.

METHOD

The Alere Cholestech LDX® System combines enzymatic methodology with the use of horseradish peroxidase for the quantitative determination of total cholesterol, HDL cholesterol and triglycerides and glucose.

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Some substances may cause inaccurate results with enzymatic tests. The substance listed below were tested for interference with all analytes. Less than 10% interference was seen at the lowest level:

<table>
<thead>
<tr>
<th>Substance Concentration (mg/dL)</th>
<th>Analyte</th>
<th>Level</th>
<th>Interference</th>
<th>Reference</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>125</td>
<td>Triglycerides</td>
<td>Low</td>
<td>20 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50</td>
<td>Glucose</td>
<td>Low</td>
<td>5 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Creatinine</td>
<td>Low</td>
<td>5 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Uric acid</td>
<td>Low</td>
<td>5 %</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**QUALITY CONTROL**

For optimal system performance, the Alere Cholestech LDX System should be routinely re-evaluated to ensure that the system is giving accurate results. We recommend the following quality control procedures be followed:

**Choice of Materials**

- Laboratories should select and use controls that will work with the Alere Cholestech LDX System. Please refer to the Alere Cholestech LDX Automated Lipid Testing System Product Manual or Insert for available controls.

**Handling**

- Follow instructions in the instructions that come with your controls.
- Check the expiration date before use. Do not use if expired.

**External Quality Control**

- The controls should be used to demonstrate that the system is performing properly. Good Laboratory Practice principles suggest that laboratories keep a minimum number of controls for a specific analyte in the same environment (room temperature, system temperature, magnetic storage conditions, or the realities of test performance).

**LIMITATIONS TO PERFORMANCE**

- Measurements should be made after calibrated dilution. Please refer to instructions that come with products.
- Refer to Lab Service Bulletin before testing patient samples.

**RESULTS**

See "Running a Test" for the procedure.

**EXPECTED VALUES**

**Analyte**

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Value</th>
<th>Value</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cholesterol</td>
<td>120 – 300</td>
<td>mg/dL</td>
<td>mmol/L</td>
<td>mg/dL</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>20 – 400</td>
<td>mg/dL</td>
<td>mmol/L</td>
<td>mg/dL</td>
</tr>
<tr>
<td>HDL cholesterol</td>
<td>26 – 85</td>
<td>mg/dL</td>
<td>mmol/L</td>
<td>mg/dL</td>
</tr>
</tbody>
</table>

**PERFORMANCE CHARACTERISTICS**

**Parameter**

- **Precision**
  - **Precision**
  - **Coefficient of Variation**
  - **Precision**

**ACCURACY (METHOD COMPARISON)**

- The cassette total cholesterol was compared with a validated method traceable to the CDC-modified Abell-Kendall reference method traceable to National Institute of Standards and Technology. The cassette LDL cholesterol was compared with an enzymatic test, utilizing the CDC-developed National Cholesterol Education Program (NCEP) Reference Method for HDL cholesterol.

**RETURN POLICY**

- Please contact Alere® Product Support prior to returning any defective components. Alere® reserves the right to examine any returned parts.

**CONTACT ALERE®**

- Contact the Alere® Product Support Center at your local Alere office or visit our website to locate the nearest Alere® office.

**Glossary of Symbols**

- **CAT**: Category
- **MCL**: Maximum Contamination Level
- **PID**: Performance Indicator
- **PQ**: Performance Quota
- **RR**: Range Read
- **SQA**: System Quality Assurance
- **TQ**: Test Quality

**REFERENCES**