There are a number of lipid-lowering drugs available to treat hyperlipidemia. A side effect of such therapy can be a persistent increase in serum ALT and/or AST (to more than 3 times the upper limit of normal) in about 1% of patients receiving lipid-lowering therapy. In such patients, the liver may be injured, and liver damage may be due to chronic alcohol or drug ingestion, or infection.

ALT and AST are indicators of alterations in liver function and therefore are a valuable measurement of damage to the liver. Liver damage may be due to chronic alcohol or drug ingestion, or infection.

The Cholestech LDX System combines enzymatic methodology and solid-phase technology to measure ALT and AST in a rapid, accurate technology. An ALT/AST Cassette is transferred to the testing area of the system, where a reaction chamber contains a biochemical assay to measure the activity of ALT and AST. The biochemical analysis is performed in the reaction chamber by the application of a reagent, which is to be transferred to the ALT and AST reaction pads.

SUMMARY AND EXPLANATION

The Cholestech LDX System employs enzymatic methodology and solid-phase technology to measure ALT and AST. Simplified enzyme chemistry and the use of a fingerstick sample facilitates testing. An ALT/AST Cassette is transferred to the testing area of the system, where a reaction chamber contains a biochemical assay to measure the activity of ALT and AST. The biochemical analysis is performed in the reaction chamber by the application of a reagent, which is transferred to the ALT and AST reaction pads.

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### Reference Method Comparison

A study was conducted according to NCCLS protocol EP5-A, Evaluation of Precision of Clinical Chemistry Devices. Agreement was evaluated for AST measured using the Cholestech LDX cassette was compared with a validated reference method based on the IFCC reference method.

####RESULTS

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Control Material</th>
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<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
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<td>Serum</td>
<td>12 – 396</td>
</tr>
<tr>
<td>Fingerstick</td>
<td>Fingerstick</td>
<td>Fingerstick</td>
<td>13 – 65</td>
</tr>
<tr>
<td>Blood</td>
<td>Blood</td>
<td>Blood</td>
<td>10 – 349</td>
</tr>
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### ACCURACY (METOD COMPARISON)

####AST

ALT measured using the Cholestech LDX cassette was compared with a validated reference method based on the IFCC reference method.

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### REFERENCES


