

## The Accuracy and Reproducibility of a Rapid, Point-of-Care Method for Measuring Alanine Aminotransferase and Aspartate Aminotransferase Is Comparable to Clinical Laboratory Methods

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### Abstract

Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels are valuable for assessing damage to the liver that may be due to infection, chronic alcohol or drug ingestion, or as a side effect of therapy with certain drugs. A new method combines enzymatic methodology and solid-phase technology to measure ALT and AST in blood obtained from a fingerstick, in venous whole blood, or in serum. To assay ALT and AST levels, a 35 $\mu$ L sample was dispensed into an ALT•AST test cassette and then processed in the Cholestech LDX<sup>®</sup> Analyzer. Results were available in 5 minutes. Precision of the LDX ALT•AST method was determined with commercial control materials, a frozen serum pool, and a whole blood sample. Accuracy was assessed by comparing the LDX ALT•AST method with clinical diagnostic laboratory methods. Specimens were obtained from healthy individuals and from patients afflicted with liver disease or receiving drug therapies known to increase serum ALT•AST levels. Within-run coefficients of variation (CVs) for LDX ALT•AST whole blood results ranged between 4.2% and 4.8%. Venous whole blood LDX ALT•AST values were highly correlated with IFCC standardized methods:  $r = 0.99$ . Similar data were obtained for comparisons between LDX ALT•AST serum samples and a commercial laboratory. LDX ALT•AST is a rapid, reproducible method for measuring ALT and AST yielding results that are comparable to those obtained by methods used in a clinical diagnostic laboratory.

### Introduction

Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) are enzymes that are present in highest concentrations in cells from the liver, heart, skeletal muscles, and red blood cells. These two enzymes have also been called glutamate pyruvate transaminase (GPT) and glutamate oxaloacetate transaminase (GOT), respectively. ALT and AST levels are a reflection 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.

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 AST (to more than 3 times the upper limit of normal) in about 1% of patients receiving lipid-lowering therapy. It is suggested that patients undergoing lipid-lowering drug therapy should be tested for ALT and AST before (baseline) and shortly after initiation of therapy and then periodically thereafter to determine the ALT and AST levels.

Both the ALT and AST can now be measured in 5 minutes using 35  $\mu$ L of whole blood obtained by fingerstick applied to the CLIA-waived Cholestech LDX System. This testing methodology enables baseline and follow-up assessments during a patient visit with a physician or other allied health professional. Until now, however, assessing the potentially toxic effects of lipid-lowering and other therapies on the liver required that a

blood sample be sent to a moderate complexity testing laboratory.

In the present study, the precision of the LDX ALT•AST method was assessed and accuracy of LDX ALT•AST was determined by comparison with methods performed in clinical diagnostic laboratories.

### Methods

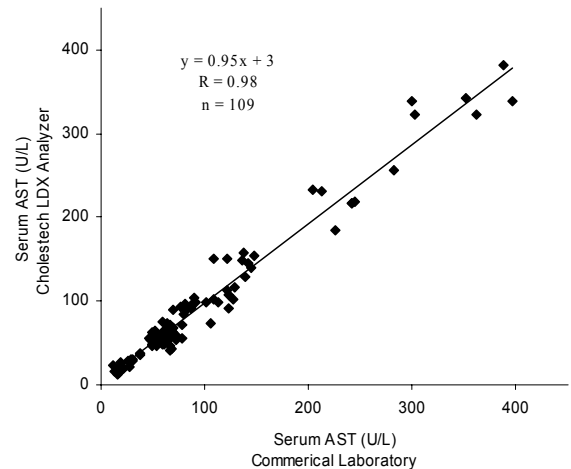
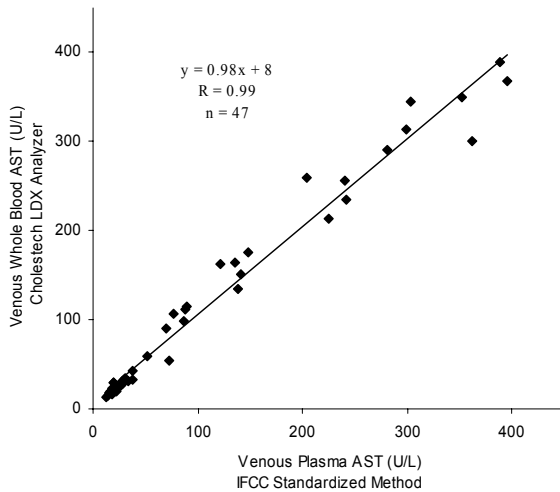
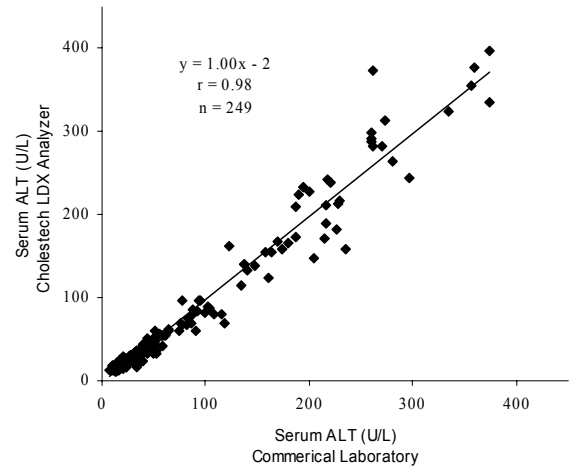
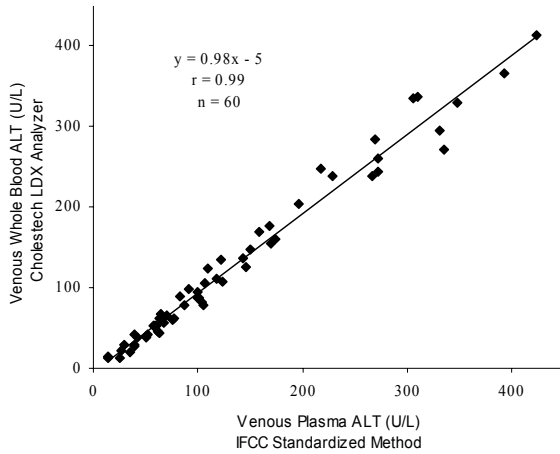
Blood donors with AST and/or ALT values across the measuring range were recruited. Venous (lithium heparin) whole blood and serum tubes were drawn by standard venipuncture technique. Both whole blood and serum samples were run on each of two Cholestech LDX Analyzers (Cholestech, Hayward, CA) using ALT•AST test cassettes. Whole blood was run within 30 minutes of collection. The serum tube was allowed to clot for 30 minutes, centrifuged and the serum removed to an aliquot tube. The serum were stored refrigerated (2-8°C) until assayed on the Beckman Synchron CX<sup>®</sup>5 (Beckman Coulter, Fullerton, CA). Whole blood samples were compared to IFCC standardized ALT and AST methods.

LDX ALT•AST precision was assessed according to NCCLS protocol EP5-A, Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guidelines (Vol. 19, No. 2). ALT and AST methods were compared using least squares linear regression.

**Table. Precision of Cholestech LDX ALT•AST**

	ALT			AST			Mean (U/L)	ALT WB	AST WB
	Control Level 1	Control Level 2	Frozen Serum Pool	Control Level 1	Control Level 2	Frozen Serum Pool			
Mean (U/L)	31	58	169	31	106	277		55	58
Within-run CV (%)	3.2	3.1	3.4	6.1	3.5	3.8	Within-run SD (U/L)	2.3	2.8
Total CV (%)	5.4	4.6	6.5	8.8	4.4	5.3	Within-run CV (%)	4.2	4.8

**Figures. Comparisons between the Cholestech LDX ALT•AST method and clinical diagnostic laboratory method.**



**Results**

Comparison between LDX ALT•AST (venous whole blood) and an IFCC standardized method (plasma) yielded a strong correlation (Figures). Serum values were similarly correlated with a commercial laboratory method (Figures).

Total precision using the control material and serum pool ranged between 4.4-8.8% CV. Whole blood within-run precision of the LDX ALT•AST test cassettes was less than 5% CV (Table).

**Conclusions**

A new method enables rapid ALT and AST measurement within 5 minutes from a whole blood sample. Accuracy and reproducibility of Cholestech LDX ALT•AST are comparable to that obtained by methods used routinely in clinical diagnostic laboratories.