

The Accuracy and Reproducibility of a Rapid, Fingertstick Method for Measuring a Complete Lipid Profile Is Comparable to a Reference Laboratory Method

Rev. B

Abstract

Measurement of a complete lipid profile including total, low density, and high density lipoprotein cholesterol, and triglycerides is necessary to ensure that National Education Cholesterol Program (NCEP) treatment goals are met. A simple, rapid method combines enzymatic methodology and solid-phase technology to measure a complete lipid profile in blood obtained from a fingerstick, in venous whole blood, or in serum. To assay lipid levels, a 35 μ L sample is dispensed into a lipid profile test cassette and then tested using the Cholestech LDX[®] Analyzer. Results are available in 5 minutes. In the present study, precision of the LDX lipid profile method was determined with whole blood specimens and commercial control materials. Comparing the LDX lipid profile method with a clinical diagnostic laboratory reference method in 59 individuals assessed accuracy. Precision for LDX lipid profile tests ranged between 2% and 6% depending on the analyte. Fingertstick LDX lipid profile values were highly correlated with venous plasma values measured by the reference method ($r \geq 0.95$), meeting NCEP criteria for agreement between methods. LDX lipid profile is a rapid, reproducible method for measuring a complete lipid profile yielding results that were comparable to those obtained by a reference method in a clinical diagnostic laboratory.

Introduction

The third Adult Treatment Panel (ATP III) of the National Education Cholesterol Program (NCEP) recently issued updated guidelines for managing patients with hyper- and dyslipidemia.¹ ATP III recommends a complete lipid profile as the initial test and strengthens the emphasis on low density lipoprotein cholesterol (LDL-C) as the primary therapeutic target. High density lipoprotein cholesterol (HDL-C) and triglycerides (TG) are secondary targets depending upon additional risk factors. Availability of a complete lipid profile is thus essential for management of hyper- and dyslipidemias.

A complete lipid profile can be measured in 5 minutes using 35 μ L of whole blood obtained by fingerstick applied to the CLIA-waived Cholestech LDX System. This simple testing methodology enables baseline and follow-up assessments during an individual's health care visit.

In the present study, the precision and accuracy of the LDX lipid profile method was determined and compared with a clinical diagnostic laboratory reference method.

Methods

Fifty-nine individuals attending a community health screening participated in this study. Venous plasma (lithium heparin) was collected by standard venipuncture technique. Capillary whole blood specimens were obtained by fingerstick using a 35 μ L lithium heparin-coated capillary tube and tested immediately by both experienced and inexperienced testers. All fingerstick specimens were analyzed using lipid profile test cassettes and the Cholestech LDX Analyzer (Cholestech, Hayward, CA). Venous plasma specimens were analyzed using a

routine clinical chemistry method (Synchron CX[®]4CE, Beckman Coulter, Fullerton, CA) that has calibration traceable to the CDC reference method. LDL cholesterol values were calculated for each method using the Friedewald equation.²

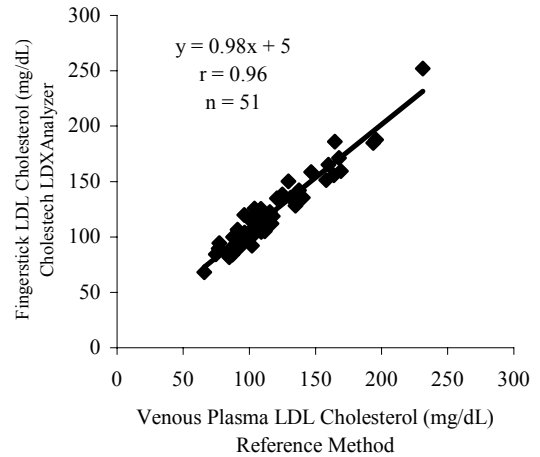
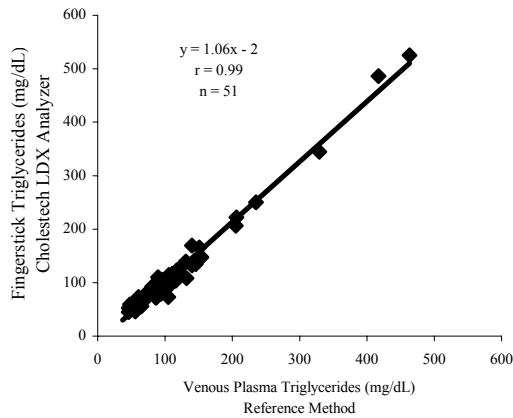
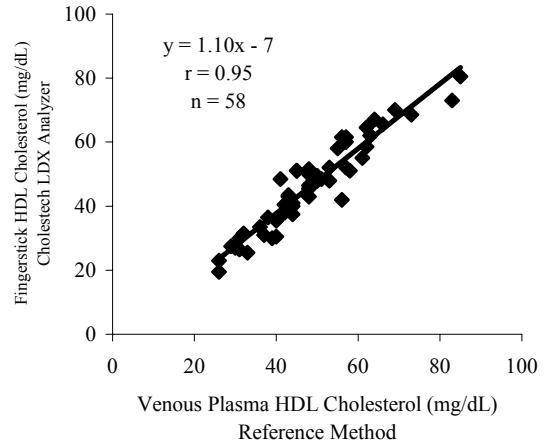
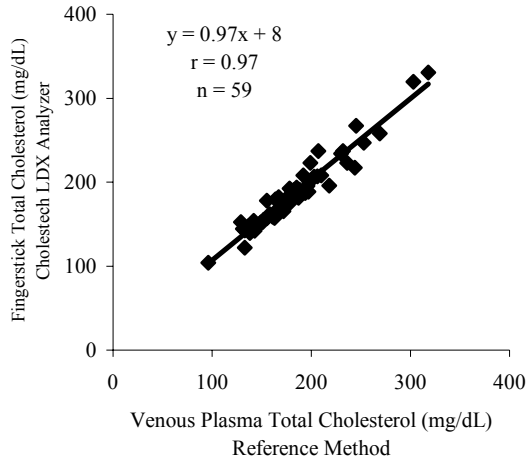
Within-run ($n = 10$) and day-to-day ($n = 20$) coefficients of variation (CVs) for the LDX lipid profile tests were determined in precision studies using two whole blood specimens and bilevel commercial controls.

Test methods were compared using Passing-Bablok regression. Individual test results were evaluated for conformance to the NCEP guidelines for total error that take into account both the accuracy bias and precision of a method.² 95% of all results should be within the total error guidelines when comparing two NCEP-compliant methods using the same specimen. Additional variability can be anticipated when different sample types are compared, e.g. fingerstick to venous plasma comparisons, even when the samples are drawn at the same time.

Results

CVs for the LDX lipid profile tests were 2–3% for total cholesterol (TC), 3–6% for HDL-C, 2–4% for TG, and 4–6% for LDL-C. Fingertstick LDX values were highly correlated with venous plasma reference values (Figures). Data were outside of the LDX TG and/or HDL-C measurement ranges for 8 individuals. No differences were noted between experienced and inexperienced testers. 95%, 97%, 92%, and 98% of LDX values for TC, HDL-C and LDL-C, and TG, respectively, were in complete agreement with the reference method according to NCEP criteria.

Figures. Comparisons between the Cholestech LDX[®] and a clinical diagnostic laboratory reference method.



Conclusions

The Cholestech LDX method enables rapid lipid profile measurement with a fingerstick whole blood sample. Accuracy and precision of the LDX lipid profile was comparable to that obtained by a reference method used routinely in clinical diagnostic laboratories. In the present study, different specimen types were measured with each method. This reflects the most likely evaluation of the LDX method by a health care professional accustomed to sending samples to a clinical diagnostic laboratory for analysis. Even closer agreement would be anticipated if comparisons were made between the two methods using the same specimen.

Health care providers who are not experienced in clinical laboratory techniques can successfully and reliably use the LDX lipid profile method. Availability of this simple method should facilitate the detection and management of individuals with hyper- and dyslipidemia.

References

1. Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults. Executive summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults (Adult Treatment Panel III). JAMA 2001; 285:2486-97.
2. Bachorik PS, Ross JW, for the National Cholesterol Education Program Working Group on Lipoprotein Measurement. National Cholesterol Education Program recommendations for measurement of low-density lipoprotein cholesterol: executive summary. Clin Chem 1995; 41:1414-20.