Technical Brief

The Accuracy and Reproducibility of a Rapid, Fingerstick Method for Measuring a Complete Lipid Profile Is Comparable to Clinical Diagnostic Laboratory Methods

Abstract

Measurement of a complete lipid profile including total, low density, and high density lipoprotein cholesterol, and triglycerides is necessary to ensure that National Cholesterol Education 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 µL sample* is dispensed into a lipid profile test cassette and then tested using the Alere Cholestech LDX® System. Results are available in 5 minutes. In the present study, precision of the Alere Cholestech LDX® Lipid Profile method was determined with whole blood specimens and commercial control materials. Comparing the Alere Cholestech LDX® Lipid Profile method with clinical diagnostic laboratory methods in 59 individuals assessed accuracy. Precision for Alere Cholestech LDX® Lipid Profile tests ranged between 2% and 6% depending on the analyte. Fingerstick Alere Cholestech LDX® lipid profile values were highly correlated with venous plasma values measured by the comparative methods ($r \geq 0.95$), meeting NCEP criteria for agreement between methods. Alere Cholestech LDX® Lipid Profile is a rapid, reproducible method for measuring a complete lipid profile yielding results that were comparable to those obtained by commercial methods in a clinical diagnostic laboratory.

Introduction

The third Adult Treatment Panel (ATP III) of the National Cholesterol Education 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 (TRG) 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 µL* of whole blood obtained by fingerstick applied to the CLIA-waived Alere 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 Alere Cholestech LDX® Lipid Profile method was determined and compared with commercial clinical diagnostic laboratory methods.

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 µL* 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 Alere Cholestech LDX® System (San Diego, CA). Venous plasma specimens were analyzed using commercial clinical diagnostic laboratory methods (Synchron CX®4CE, Beckman Coulter, Fullerton, CA) that have calibration traceable to the CDC reference method. LDL-C values were calculated for each method using the Friedewald equation.[2]

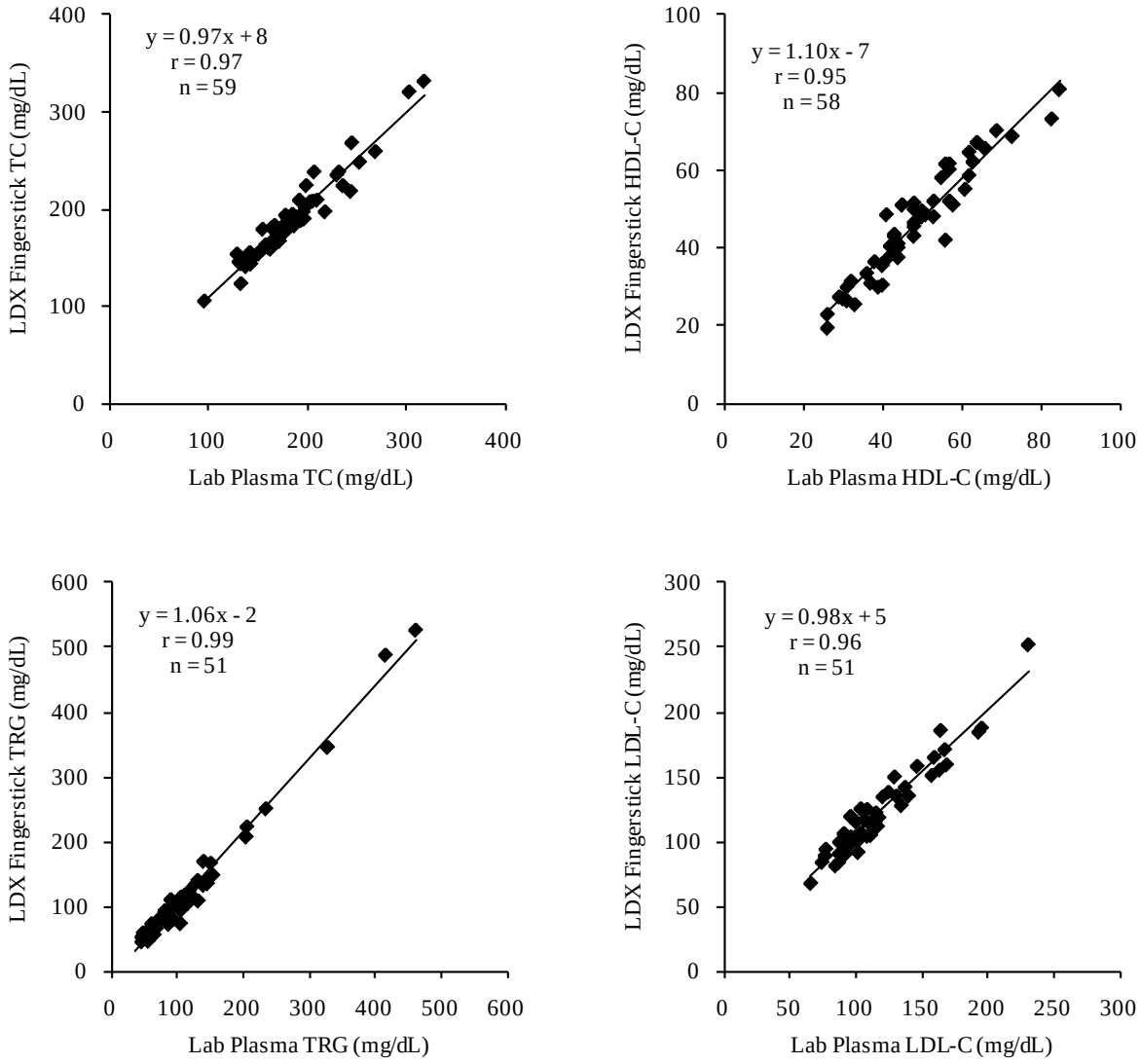
Within-run (n = 10) and day-to-day (n = 20) coefficients of variation (CVs) for the Alere Cholestech LDX® Lipid Profile tests were determined in precision studies using two whole blood specimens and bilevel commercial controls.

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 Alere Cholestech LDX® Lipid Profile tests were 2–3% for total cholesterol (TC), 3–6% for HDL-C, 2–4% for TRG, and 4–6% for LDL-C. Fingerstick Alere Cholestech LDX® lipid values were highly correlated with venous plasma comparative values (Figures). Data were outside of the Alere Cholestech LDX® TRG and/or HDL-C measurement ranges for 8 individuals. No differences were noted between experienced and inexperienced testers. 95%, 97%, 92%, and 98% of Alere Cholestech LDX® System values for

TC, HDL-C and LDL-C, and TRG, respectively, were in complete agreement with the clinical diagnostic laboratory methods according to NCEP criteria.



Figures. Lipid Profile Method Comparisons
LDX, Alere Cholestech LDX® System; Lab, commercial clinical diagnostic laboratory methods

Conclusions

The Alere Cholestech LDX® method enables rapid lipid profile measurement with a fingerstick whole blood sample. Accuracy and precision of the Alere Cholestech LDX® Lipid Profile was comparable to that obtained by methods 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 Alere Cholestech LDX® Lipid Profile method by a health care professional accustomed to sending samples to a contract 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 Alere Cholestech 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.

*Sample volume increased to 40 µL in 2011; clinical performance is equivalent.