

Accuracy of a Rapid, Fingertick Lipid Profile Method Is Comparable to Commercial Laboratory Methods

Abstract

The Centers for Disease Control and Prevention (CDC) has established the Cholesterol Reference Method Laboratory Network (CRMLN) to ensure nation-wide standardization of lipid measurements consistent with National Cholesterol Education Program (NCEP) analytical goals. In the present study, accuracy of the Alere Cholestech LDX[®] lipid profile method and three commercial laboratories were compared to results from a CRMLN laboratory. All methods performed exhibited average bias within the NCEP analytical goal for total cholesterol and low density lipoprotein cholesterol. Substantial variation was observed for high density lipoprotein cholesterol across methods and to a lesser degree for triglycerides. Biases between the Alere Cholestech LDX[®] System and commercial laboratories are as likely to reflect differences between the commercial laboratory and CRMLN as they are to represent Alere Cholestech LDX[®] System deviation from standardized CRMLN lipid values.

Introduction

The third Adult Treatment Panel (ATP III) of the National Cholesterol Education Program (NCEP) recommends a complete lipid profile for coronary heart disease risk assessment and patient management.¹ The lipid profile consists of total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), and triglycerides (TRG). Using the Friedewald equation, the low density lipoprotein cholesterol (LDL-C) can be calculated from these parameters.

The Centers for Disease Control and Prevention (CDC) has established the Cholesterol Reference Method Laboratory Network (CRMLN) to ensure nation-wide standardization of lipid measurements consistent with NCEP analytical goals.² Manufacturers of lipid testing reagents can certify their methods as traceable to CDC reference methods by conducting precision and accuracy studies involving a CRMLN laboratory.

Alere conducted a 20-sample multi-method comparison to characterize performance of the Alere Cholestech LDX[®] System lipid test cassettes relative to commercial laboratories and CRMLN.

Methods

The study protocol generally conformed to CRMLN protocols (www.cdc.gov/labstandards/crmln.html). Twenty donors were identified to obtain samples distributed across the assay ranges. Venous serum and whole blood (in lithium heparin) was collected by standard venipuncture technique. These samples were tested using Alere Cholestech LDX[®] lipid profile test cassettes. Capillary whole blood specimens were also obtained by fingerstick using lithium heparin-coated capillary tubes. All Alere Cholestech LDX[®] System testing was performed immediately following sample collection.

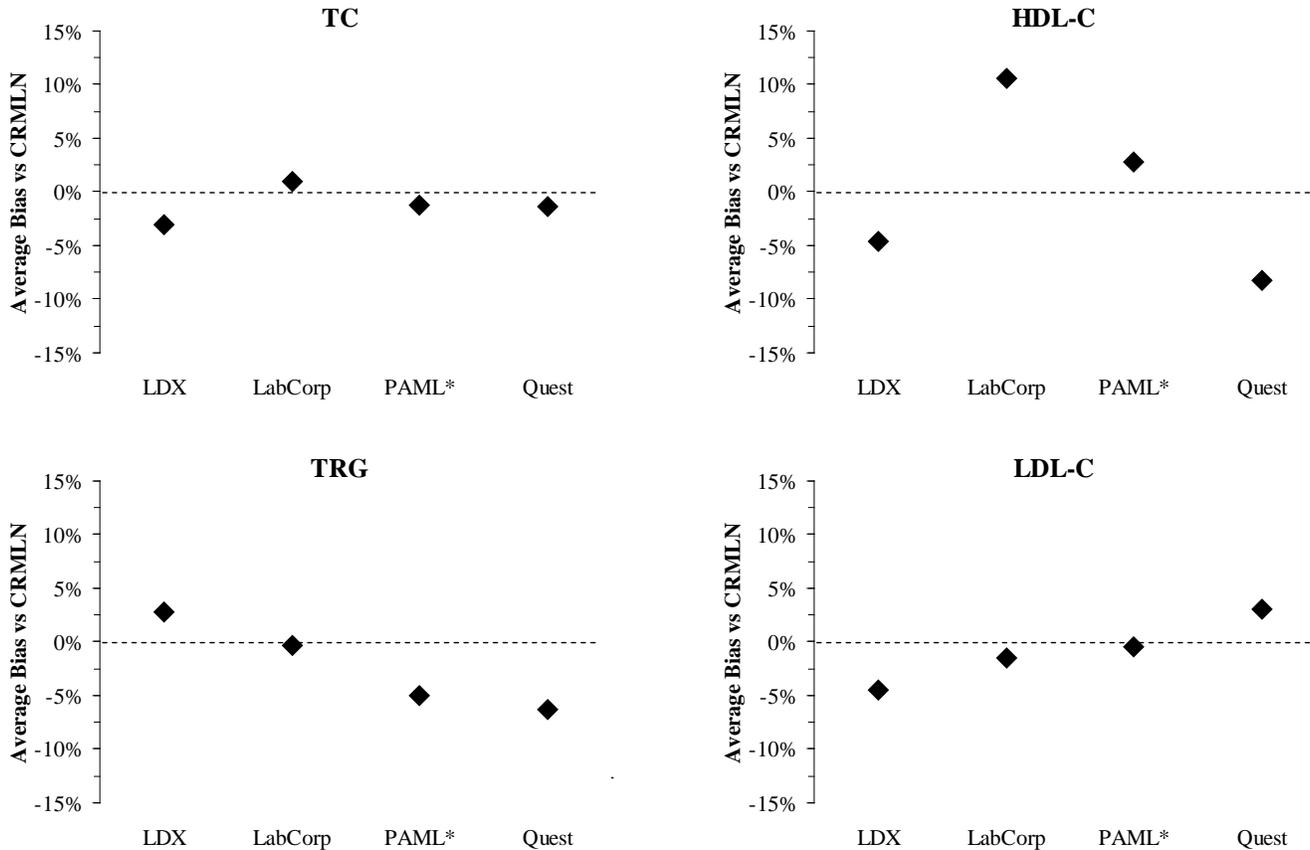
Serum specimens were shipped overnight to Northwest Lipid Metabolism and Diabetes Research Laboratories (University of Washington, Seattle, WA), one of three US CRMLN laboratories. They were analyzed using CDC reference methods for TC and HDL-C and for TRG using Roche/Hitachi methods. Serum samples were also sent to a regional reference laboratory, Pathology Associates Medical Laboratories (PAML), and two national reference laboratories, Laboratory Corporation of America (LabCorp) and Quest Diagnostics (Quest). Samples were tested using Bayer reagents on a Bayer ADVIA[®] 2400 analyzer (PAML), Roche reagents on a Roche MODULAR analyzer (LabCorp), and Olympus reagents on an Olympus AU600[™] analyzer (Quest). Reagents from all of these TC and HDL-C manufacturers are listed as certified by the CRMLN on the CDC website. TRG results were not blanked. LDL cholesterol values were calculated for each method using the Friedewald equation.

Bias compared to the CRMLN laboratory result was calculated for all specimens tested using the Alere Cholestech LDX[®] System and the commercial laboratory methods. Average bias results are reported.

Results

The figures present average bias (%) for each tested method compared to the CRMLN laboratory results. Average TC bias was within the $\pm 3\%$ CRMLN goal for all methods. Only two of the four methods met the CRMLN average bias goal of $\pm 4\%$ HDL-C, with the two national reference laboratories failing at the two extremes. Only one method exceeded the $\pm 5\%$ average bias goal for TRG and all methods met the $\pm 4\%$ average bias goal for LDL-C.

Figures. Average bias for each method compared to CRMLN laboratory results.



CRMLN, Cholesterol Reference Method Laboratory Network laboratory; LDX, Alere Cholestech LDX[®] System; LabCorp, Laboratory Corporation of America, Roche reagents/analyzer; PAML*, Pathology Associates Medical Laboratories (n = 14), Bayer reagents/analyzer; Quest, Quest Diagnostics, Olympus reagents/analyzer

Conclusions

Average Alere Cholestech LDX[®] System bias compared to CRMLN was comparable to commercial laboratory results in this study. These data represent performance that might be expected in routine method comparison studies.

In the extreme case, average HDL-C bias was 21% between LabCorp and Quest. Bias for individual samples could be even greater. Biases between the Alere Cholestech LDX[®] System and commercial laboratories are as likely to reflect differences between the commercial laboratories and CRMLN as they are to represent Alere Cholestech LDX[®] System deviation from standardized CRMLN lipid values.

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. Working Group on Lipoprotein Measurement. National Cholesterol Education Program: recommendations on lipoprotein measurement. NIH Publication No. 95-3044, 1-186. 1995. National Institutes of Health, National Heart, Lung, and Blood Institute.

