Technical Brief

Clinical Performance of the CardioChek P.A™ and the Cholestech LDX® System Compared to a Clinical Diagnostic Laboratory Reference Method for the Determination of Lipid Profiles

Abstract

The CardioChek P.A and the Cholestech LDX System are rapid, point-of-care testing methods that measure total cholesterol, HDL cholesterol, and triglycerides. In the present study, accuracy and precision of both methods were assessed and compared with a clinical diagnostic laboratory reference method. Venous whole blood specimens were obtained from 19 healthy donors. Coefficients of variation ranged between 7% and 9% for the CardioChek P.A and between 2% and 5% for the Cholestech LDX Analyzer. Lipid profile results obtained with the Cholestech LDX Analyzer were in complete clinical agreement with the reference method. Clinical misclassification occurred in two-thirds of individuals tested with the CardioChek P.A. The Cholestech LDX System provides lipid profile results that are more reproducible and accurate than those obtained with the CardioChek P.A.

Introduction

A fasting lipid profile consisting of total cholesterol, low density lipoprotein cholesterol (LDL-C), high density lipoprotein cholesterol (HDL-C), and triglycerides (TRG) should be measured every five years in all adults aged 20 years or older.[1] Rapid, point-of-care testing (POCT) methods are available for obtaining lipid profile results from whole blood samples.

The CardioChek P.A (Polymer Technology Systems, Inc.) is a hand held, battery operated analyzer that measures TC, HDL-C, and TRG. A whole blood sample is applied to a disposable reagent test strip. The CardioChek P.A uses reflectance photometry to measure the analyte concentration. The analyzer automatically calculates LDL-C values.

The Cholestech LDX (Cholestech Corp.) is a small, lightweight analyzer designed for POCT lipid profile analysis. A whole blood sample is dispensed into a single, disposable cassette. The Cholestech LDX uses reflectance photometry to measure the analyte concentration. The analyzer automatically calculates LDL-C values.

The objective of the present study was to compare the precision and accuracy of the Cholestech LDX System and the CardioChek P.A to clinical diagnostic laboratory reference methods (Synchron CX®4CE, Beckman Coulter, Inc.). The calibration of the Synchron CX4CE methods for TC, HDL-C, and TRG is traceable to the Centers for Disease Control and Prevention (CDC) reference methods for these analytes.

Methods

Nineteen donors were recruited for the study. Venous whole blood samples were collected into lithium heparin collection tubes. All samples were analyzed for TC, HDL-C and TRG using a single Cholestech LDX and CardioChek P.A analyzer and one lot of test reagents. Serum levels of TC, HDL-C and TRG were also analyzed on the Synchron CX4CE using. LDL-C was determined for all methods using the Friedewald equation.

Precision was assessed by calculating root mean square coefficients of variation (CVs) for all samples assayed in duplicate. Methods were compared using least squares linear regression. Results were evaluated for conformance to the National Cholesterol Education Program (NCEP) guidelines for total error that take into account both the accuracy bias and precision of a method (Table 1).[2,3] It is expected that 95% of all results will be within the total error guidelines when comparing methods that both meet NCEP total error guidelines.

Bias calculations for the difference between the reference and POCT methods enabled determination of conformance to NCEP total error guidelines for individual samples. Results were also evaluated for clinical agreement at medical decision cut-points defined by NCEP.[1] The cut-points were 200 and 240 mg/dL for TC, 40 mg/dL for HDL-C, 150 and 200 mg/dL for TRG, and 100, 130, 160, and 190 mg/dL for LDL-C.

Table 1. NCEP Guidelines for Total Error

Analyte	Total Error
TC	≤ 8.9%
HDL-C	≤ 13%
TRG	≤ 15%
LDL-C	≤ 12%

Table 2. Accuracy of Point-of-care Methods for a Lipid Profile Compared to a Reference Method and Precision

Analyte	Comparison of Reference vs.	R^2	Mean Bias (%)	Values Exceeding NCEP Total Error (%)	Clinical Misclassification* (%)	CV (%)
TC	CardioChek P.A	0.80	-12.2	68	32	8.0
	Cholestech LDX	0.98	-2.7	0	0	2.1
HDL-C	CardioChek P.A	0.86	-9.5	39	17	7.3
	Cholestech LDX	0.96	0.2	0	0	4.1
TRG	CardioChek P.A	0.79	-16.2	67	0	6.8
	Cholestech LDX	0.96	-4.8	5	0	3.3
LDL-C	CardioChek P.A	0.68	-8.1	56	39	8.8
	Cholestech LDX	0.96	-3.0	0	0	4.7

*At NCEP medical decision cut-points

Results

The range of values tested for each analyte was: TC, 147–267 mg/dL, HDL-C, 29–75 mg/dL, TRG, 69–431 mg/dL. Correlation coefficients and bias assessments for comparisons between the reference methods and the Cholestech LDX were in excellent agreement, but were in weaker agreement for the CardioChek P.A (Table 2). CardioChek P.A results exceeded NCEP total error guidelines for one or more tests in all but one of the samples overall. One sample gave a Cholestech LDX TRG value that exceeded NCEP guidelines. The Cholestech LDX met NCEP guidelines for all other tests. None of the Cholestech LDX individual values resulted in clinical misclassification. Individual tests resulted in clinical misclassification in up to 39% of CardioChek P.A values (Table 2). Overall, CardioChek P.A misclassified values in 13 out of 19 individuals.

Precision CVs of the four tests ranged between 6.8% and 8.8% for the CardioChek P.A and between 2.1% and 4.7% for the Cholestech LDX System (Table 2).

Discussion

In the present study, two rapid, POCT methods for measuring lipid profiles were compared. Both methods were reproducible when repeated measurements were made in individual subjects. However, Cholestech LDX CVs were 2 to 4 times lower than those of the CardioChek P.A.

Only one Cholestech LDX test value (for TRG) exceeded the NCEP total error guidelines when comparisons were made with the reference method, meeting the 95% requirement. Total error exceptions occurred in up to two-thirds of samples tested with the CardioChek P.A for each test. Only one sample had all four test results within NCEP guidelines. A further analysis of accuracy indicated that lipid profile values obtained with the Cholestech LDX System were in complete clinical agreement with the reference methods based on NCEP medical decision cut-points. Up to 39% of values obtained with the CardioChek P.A for each test disagreed with the reference method at the cut-points. These results would be considered as clinical misclassification in two-thirds of the individuals tested if the reference methods were used as the gold standard.

In summary, the Cholestech LDX System provides lipid profile results that are more reproducible and accurate than those obtained with the CardioChek P.A.

References

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