# Technical Brief

# Long-term Accuracy of Lipid Profiles Measured with CardioChek® Systems and the Alere Cholestech LDX® System

**Abstract**

CardioChek® systems and the Alere Cholestech LDX® System are rapid, point-of-care testing (POCT) methods that measure total cholesterol, HDL cholesterol, and triglycerides, and report calculated LDL cholesterol. Accuracy of both methods was assessed and compared with clinical diagnostic laboratory methods in four similar studies conducted between May 2008 and May 2015. Fingerstick specimens were obtained from 160 donors and analyzed using multiple lots of reagents and multiple analyzers for each POCT method. Average bias ranged between -23% and +17% for CardioChek® systems and between -8% and +10% for the Alere Cholestech LDX® System. The Alere Cholestech LDX® System provided lipid profile results that were consistently more accurate and two times less variable than those obtained with CardioChek® systems.

## Introduction

The CardioChek® P•A and Plus systems (Polymer Technology Systems, Inc.) and Alere Cholestech LDX® (Alere, Inc.) are small, portable, point-of-care testing (POCT) analyzers capable of measuring a lipid profile: total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), and triglycerides (TRG), and calculating low density lipoprotein cholesterol (LDL-C). These systems measure the lipid profile using a small volume of fingerstick or venous whole blood samples applied to disposable reagent devices and employ reflectance photometry to measure analyte concentrations. The objective here is to report the long-term accuracy of the CardioChek® and Alere Cholestech LDX® lipid profile methods.

## Methods

Four studies of similar design were conducted: in May 2008, July 2011, September 2013, and May 2015. Fingerstick samples were obtained from donor subjects recruited for each study using the capillary collection tubes sold by the manufacturers for use with the devices. A serum sample was obtained by venipuncture at the time the fingerstick samples were obtained. All fingerstick samples were analyzed in each study for TC, HDL-C and TRG using at least two reagent lots and at least three analyzers for each POCT method. Testing was completed at Alere by Alere personnel, except for the September 2013 study which was completed at a contract research facility.

New CardioChek® analyzers were acquired (P•A for the first three studies and Plus for May 2015) and different Alere Cholestech LDX® analyzers were used for each study. The CardioChek® Plus analyzer used in the May 2015 study is a new analyzer that incorporates functionality for amperometric glucose testing but the lipid profile test strips and the portion of the analyzer that tests them are the same as the CardioChek® P•A.

Specific testing for each study was as follows: May 2008, 30 subjects, 2 replicates of each of 2 lots tested on 4 analyzers; July 2011, 33 subjects, 3 replicates of each of 2 lots tested on 3 analyzers; Sept 2013, 54 subjects, 2 replicates of each of 2 lots tested on 4 analyzers; May 2015, 43 subjects, 2 replicates of each of 2 lots tested on 4 analyzers.

Serum levels of TC, HDL-C and TRG were analyzed on either a Synchron CX®4 Pro or a UniCel® DxC 600 (Beckman Coulter, Inc.), clinical diagnostic laboratory systems with Cholesterol Reference Method Laboratory Network (CRMLN) certification for TC and HDL-C and Lipid Standardization Program certification for TC, HDL-C, and TRG (since 2009). LDL-C was calculated for all methods using the Friedewald equation (LDL = TC - HDL - TRG/5). All methods were analyzed according to the manufacturer's instructions.

Accuracy of the POCT methods was assessed by comparing with the clinical diagnostic laboratory methods. Bias was calculated for each replicate of the tested samples with each POCT method compared with the laboratory method.

## Results

Comparisons between each POCT method and the laboratory method for each analyte are shown by study in Figures 1 through 4. Average biases and the 95% confidence intervals of the individual sample biases are shown in Table 1 for each analyte in each study. Average bias ranged between -23% and +17% for CardioChek® systems and between -8% and +10% for the Alere Cholestech LDX® System. 95% confidence intervals of the absolute biases were 2.0-fold greater on average for the CardioChek® systems compared with the Alere Cholestech LDX® System across all analytes and all studies.

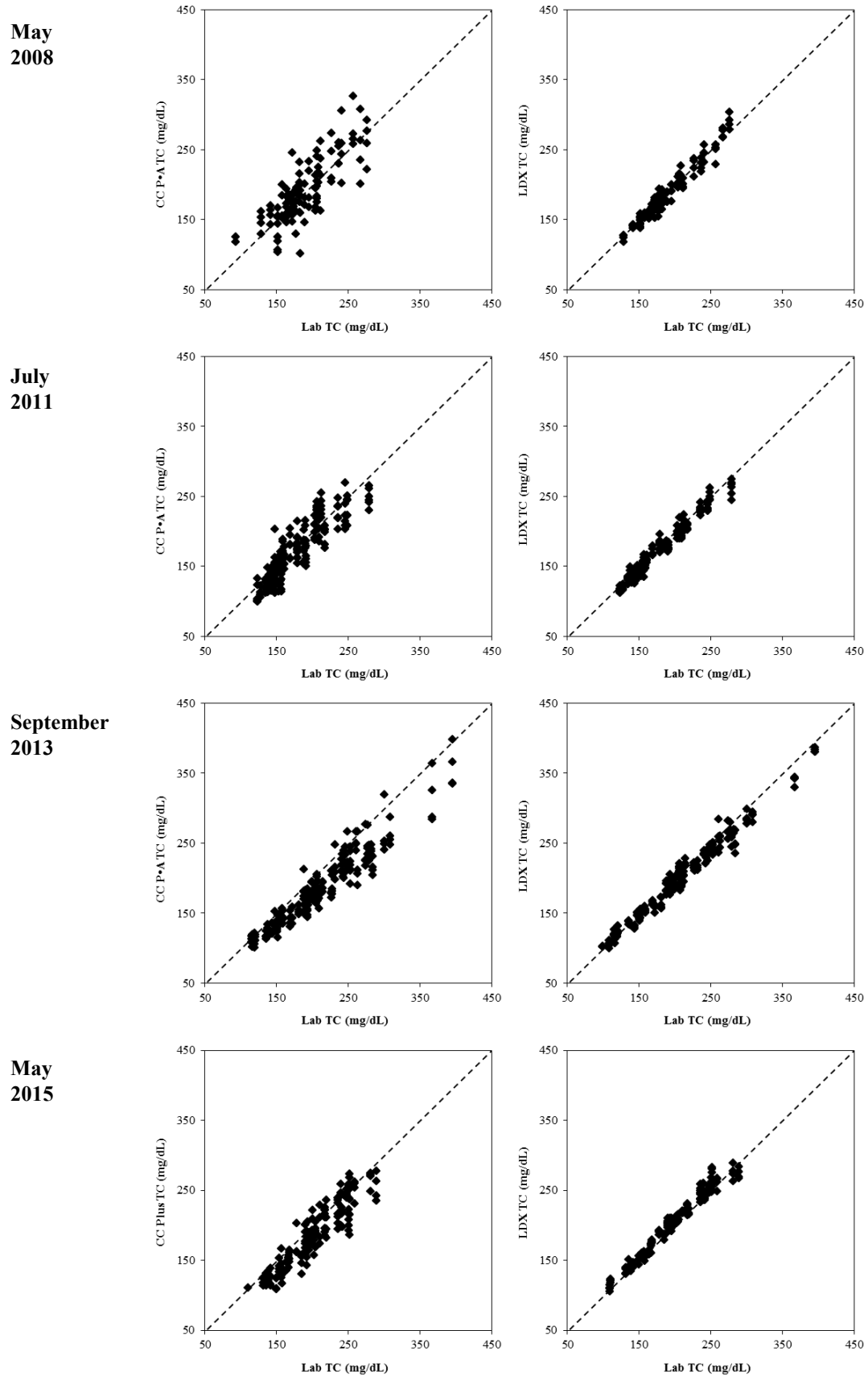


**Figure 1. Total Cholesterol (TC) Comparisons Between POCT and Clinical Diagnostic Laboratory Methods**
CardioChek® (CC) P•A or Plus on the left; Alere Cholestech LDX® (LDX) System on the right; dotted line is $y = x$.

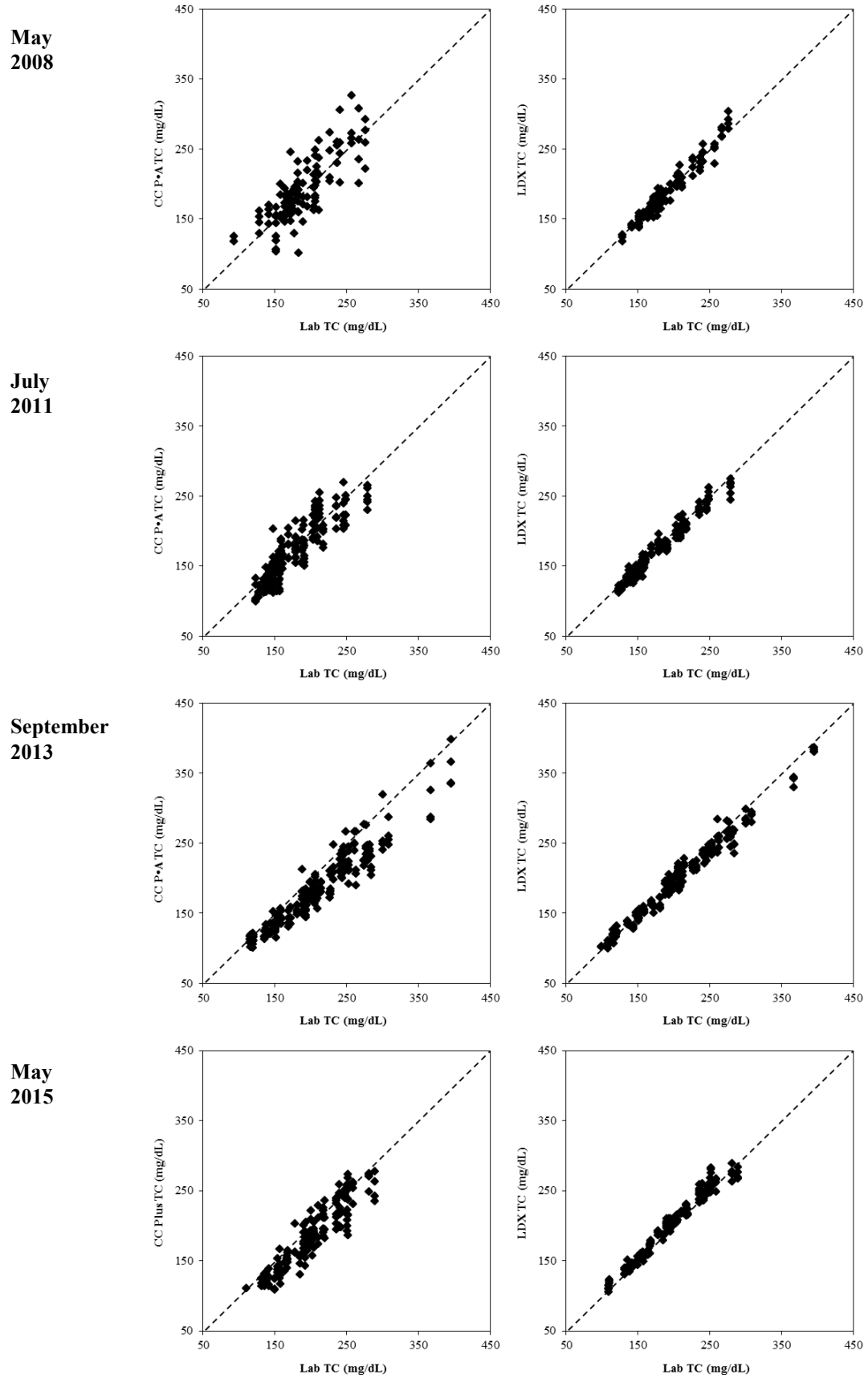


**Figure 2. HDL Cholesterol (HDL-C) Comparisons Between POCT and Clinical Diagnostic Laboratory Methods**
CardioChek® (CC) P•A or Plus on the left; Alere Cholestech LDX® (LDX) System on the right; dotted line is $y = x$.

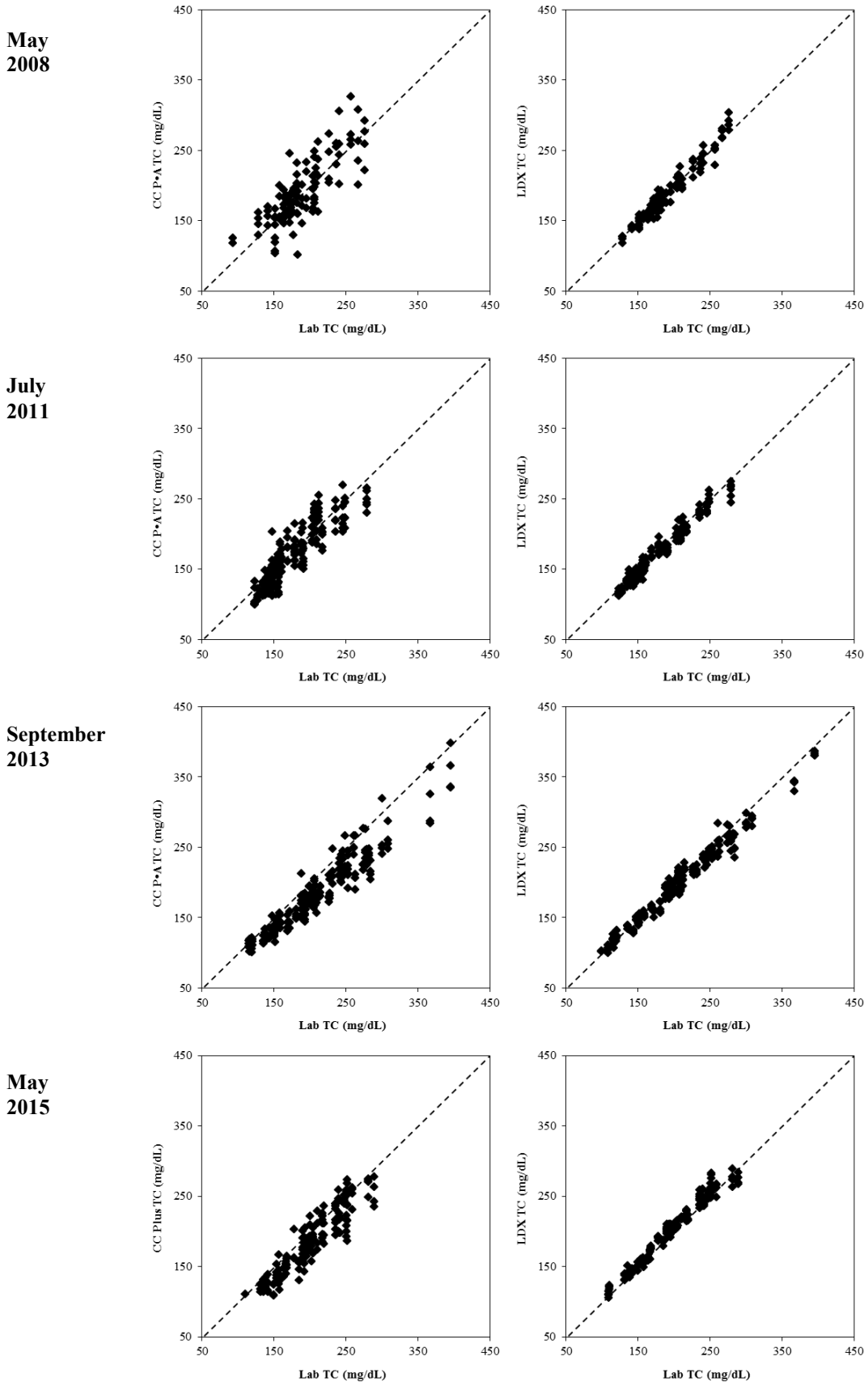


**Figure 3. Triglycerides (TRG) Comparisons Between POCT and Clinical Diagnostic Laboratory Methods**
CardioChek® (CC) P•A or Plus on the left; Alere Cholestech LDX® System (LDX) on the right; dotted line is $y = x$.

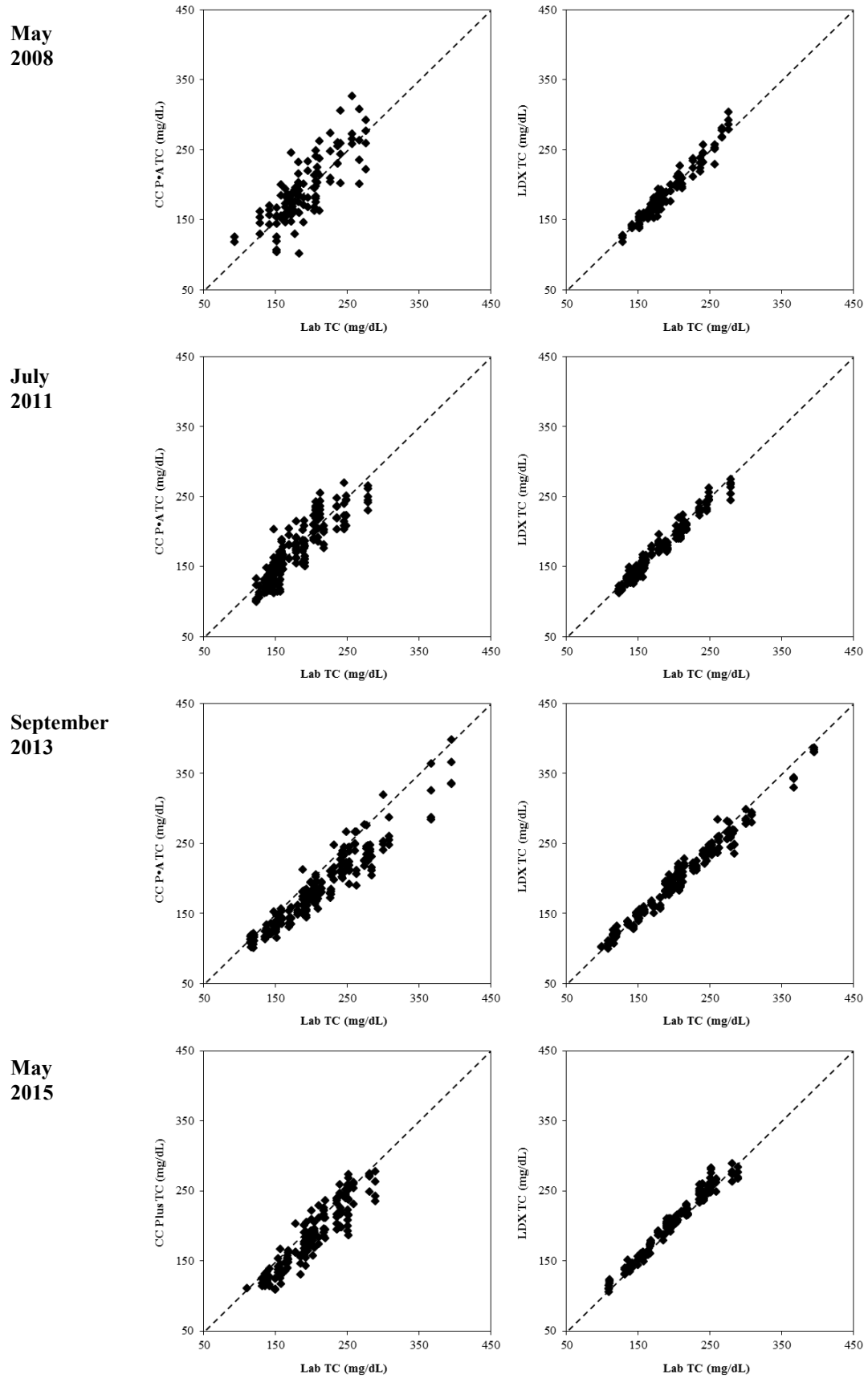


**Figure 4. LDL Cholesterol (LDL-C) Comparisons Between POCT and Clinical Diagnostic Laboratory Methods**
CardioChek® (CC) P•A or Plus on the left; Alere Cholestech LDX® System (LDX) on the right; dotted line is $y = x$.

**Table 1. Accuracy of POCT Lipid Profile Methods: Average Bias (95%CI)**

| | | CardioChek® P•A or Plus* | | | | Alere Cholestech LDX® System | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | TC | HDL-C | TRG | LDL-C | TC | HDL-C | TRG | LDL-C |
| May 2008 | Avg. bias (95%CI) | 1.5% (-27.0%–+27.0%) | -13.3% (-40.8%–+15.6%) | -20.5% (-37.1%–-0.1%) | 17.0% (-34.6%–+89.9%) | -1.3% (-10.3%–+7.2%) | -7.7% (-38.2%–+20.3%) | -5.0% (-16.6%–+6.5%) | 3.3% (-14.6%–+21.8%) |
| July 2011 | Avg. bias (95%CI) | -5.2% (-24.5%–+17.8%) | 15.8% (-7.6%–+48.7%) | -5.4% (-32.4%–+23.3%) | -15.1% (-83.3%–+31.8%) | -3.2% (-10.3%–+5.4%) | -1.1% (-22.3%–+15.7%) | -0.9% (-18.4%–+16.5%) | -5.6% (-20.9%–+14.7%) |
| September 2013 | Avg. bias (95%CI) | -11.7% (-24.2%–+2.4%) | -9.4% (-27.9%–+11.5%) | -22.5% (-38.5%–-5.5%) | -7.5% (-26.4%–+24.7%) | -3.2% (-12.3%–+6.7%) | -7.2% (-22.2%–+5.4%) | -5.5% (-15.4%–+3.0%) | +0.1% (-18.6%–+31.3%) |
| May 2015* | Avg. bias (95%CI) | -8.9% (-26.2%–+7.4%) | -11.4% (-34.2%–+8.8%) | 2.1% (-17.7%–+28.5%) | -13.6% (-39.8%–+11.8%) | 2.0% (-4.6%–+9.8%) | 3.1% (-14.8%–+17.5%) | 9.6% (-4.5%–+19.5%) | -1.6% (-14.1%–+10.7%) |

## Discussion

In the present report, two rapid, POCT methods for measuring lipid profiles were compared in four studies of similar design conducted over a seven-year period. Average biases were lower for the Alere Cholestech LDX® System than for CardioChek® systems for all four analytes in all of the studies except for TRG in May 2015. Individual results were seen to be significantly more variable for CardioChek® systems than for the Alere Cholestech LDX® System for each analyte in each study. These observations were confirmed by the 95% confidence intervals of the individual biases for each POCT method. Two published reports of studies conducted during the same time period as these studies made similar observations regarding the relative performance of these POCT systems.[1,2]

In summary, the Alere Cholestech LDX® System provided lipid profile results that were consistently more accurate and two times less variable than those obtained with CardioChek® systems over a period of seven years.

## References

1. Dale RA, Jensen LH, Krantz MJ. Comparison of two point-of-care lipid analyzers for use in global cardiovascular risk assessments. Ann Pharmacother 2008;42:633-9.

2. Whitehead SJ, Ford C, Gama R. A combined laboratory and field evaluation of the Cholestech LDX and CardioChek PA point-of-care testing lipid and glucose analysers. Ann Clin Biochem 2013; 51:54-67.