A Comparative Evaluation of *Mission* Cholesterol and CardioChek PA Point-of-Care Lipid Testing Systems

June 2016

1. Overall summary

- The *Mission* Cholesterol exhibited better measurement reproducibility (imprecision) than the CardioChek PA for HDL-cholesterol and triglyceride. Both the *Mission* Cholesterol and CardioChek PA demonstrated comparable imprecision for total cholesterol.

- Total cholesterol, HDL-cholesterol and triglyceride measured on the *Mission* Cholesterol correlated better with the laboratory reference method than when analysed on the CardioChek PA.

- Both systems are user friendly, but the *Mission* Cholesterol requires a smaller sample volume compared to the CardioChek PA.

In conclusion, in our opinion, the *Mission* Cholesterol is superior in terms of performance, robustness, ease of use and clinical governance.

2. Introduction

Blood lipid measurements are widely accepted for assessing and managing cardiovascular risk. There is a positive relationship between total and LDL cholesterol concentration and the risk of developing coronary events and eventually mortality from coronary heart disease (CHD). In recent years, semi-automated point-of-care testing (POCT) systems have been developed to measure levels of cholesterol and triglyceride. This study was performed to assess the performance of two POCT systems: *Mission* Cholesterol Monitoring System and CardioChek PA Test System.

3. Methods

3.1 Accuracy study

The studies were conducted at 2 clinical sites. A total of 63 volunteers participated in the study. Each participant signed a consent form before starting the study. The professional operator followed the product manuals and package inserts to puncture each participant's finger and collect and apply the blood sample to the Mission Cholesterol Monitoring System and CardioChek PA Test System respectively. After completing the finger stick tests, venous blood was drawn by a phlebotomist into a blood collection tube coated with heparin and sent to the laboratory for testing. The blood was centrifuged at 3000rpm for 10 minutes. Then the plasma collected was tested using a reference method. Two reference methods were used; the Roche Hitachi 7100 was used at site #1 and the Roche Cobas c111 was used at site #2. Both reference instruments were validated against CRMLN certified human lipid samples.

3.2 Precision study

The within run imprecision of both the *Mission* Cholesterol and CardioChek PA monitoring systems were evaluated with fresh venous blood specimens. Nine (9) test devices were tested on each volunteer on each system according to instructions listed in the package inserts. The total coefficient of variation (CV) was then calculated.

3.3 Data analysis

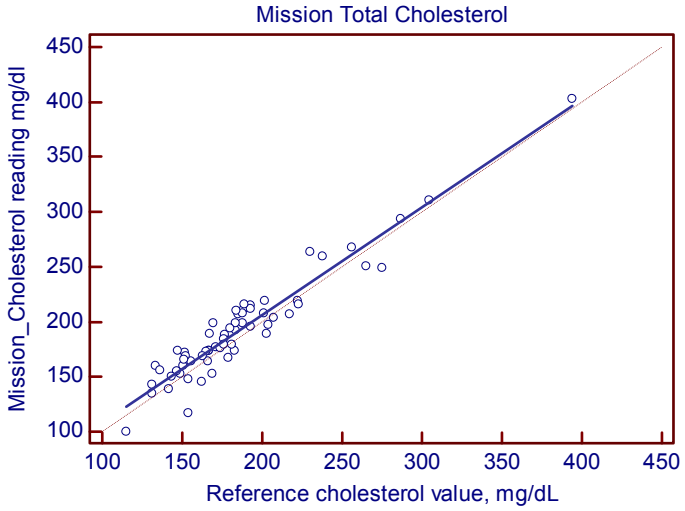
i. Accuracy
   - Linearity regression analysis was performed using Medcalc software
   - Bland-Altman analysis was performed using Medcalc software as well. The Bias, standard deviation (SD) and 95% Limit of Agreement were reported.

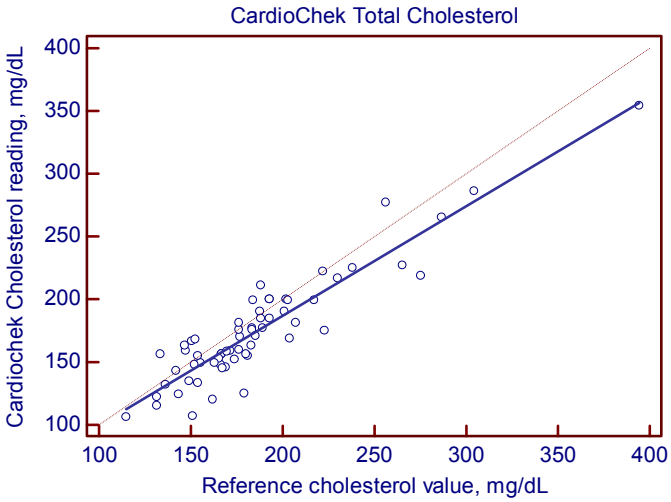
ii. Precision: The within-run imprecision was calculated by performing 9 runs of the same fresh venous whole blood sample on both systems.

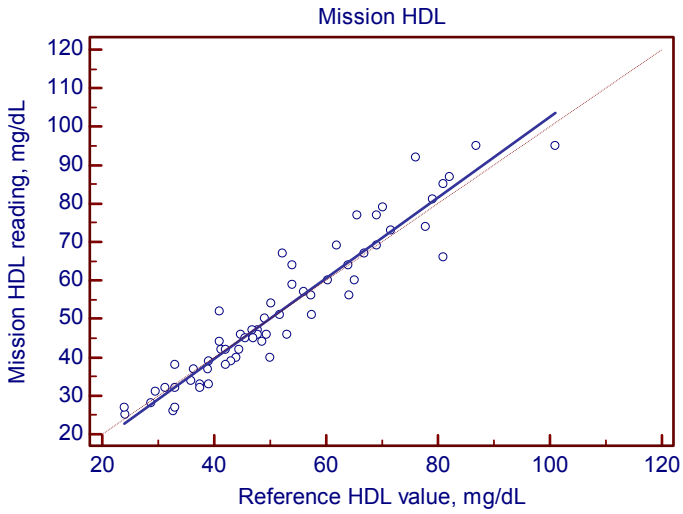
4. Results

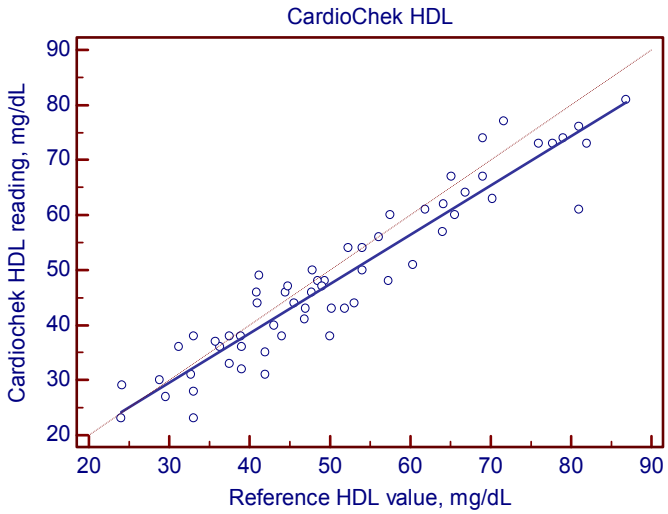
4.1 Accuracy:

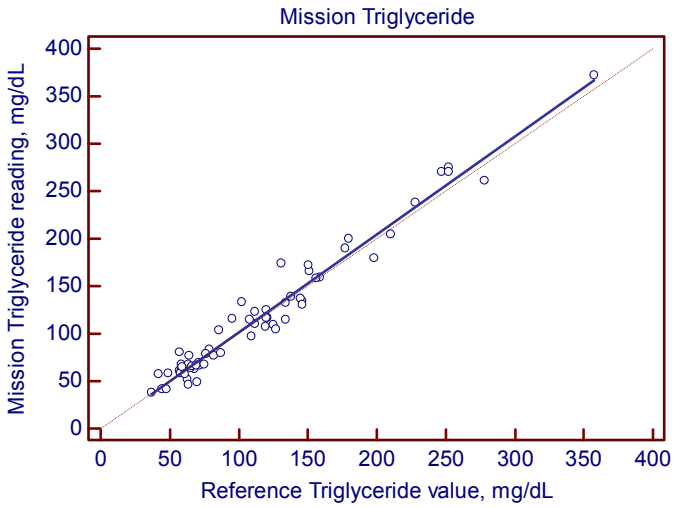
- Linearity analysis











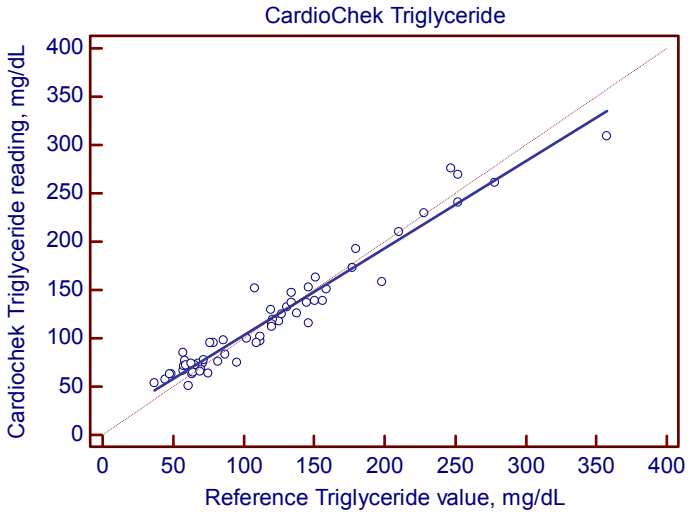
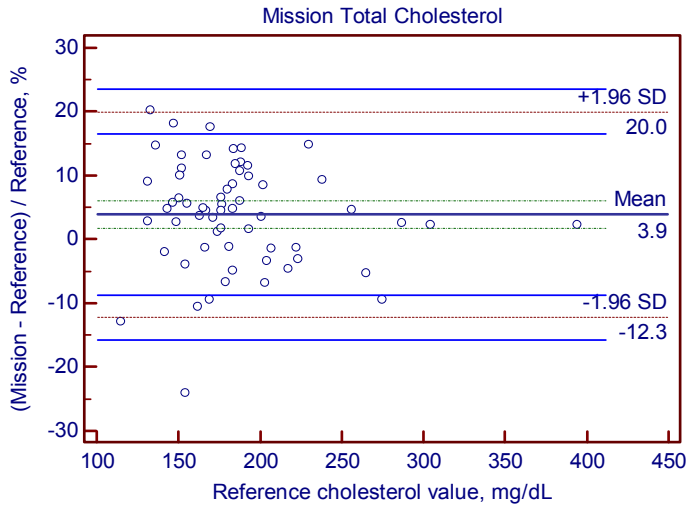
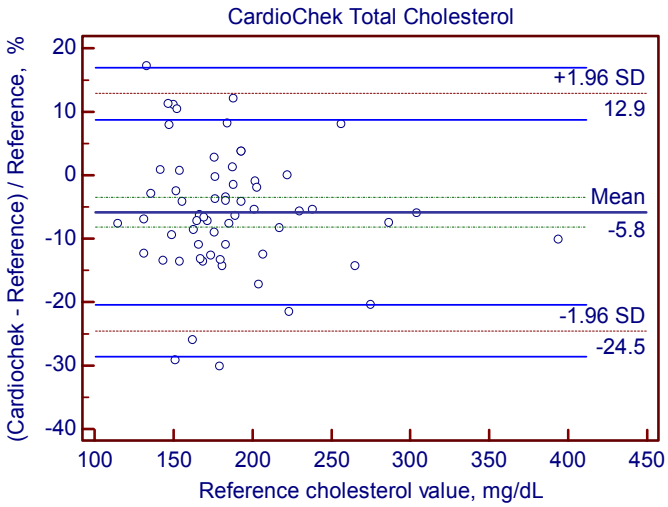


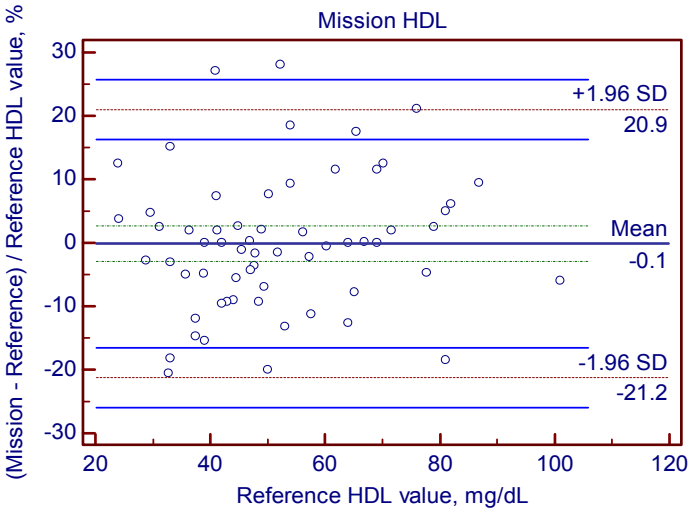
Table 1: Coefficient parameters of linear regression:

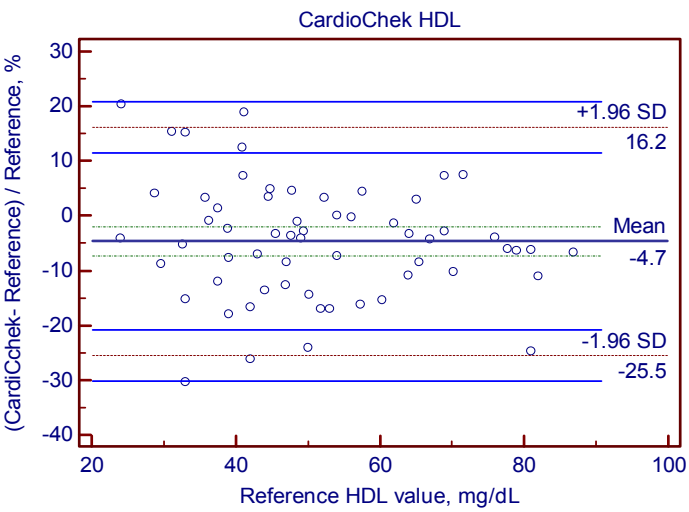
System	Mission Cholesterol			CardioChek PA		
Analyte	**Total Cholesterol**	**HDL**	**Triglyceride**	**Total Cholesterol**	**HDL**	**Triglyceride**
Intercept	10.80	-2.35	-1.36	12.30	2.67	12.93
Slope	0.98	1.05	1.03	0.87	0.90	0.90
95% Confidence interval of Slope	0.90-1.06	0.96-1.14	0.98-1.08	0.78-0.97	0.82-0.98	0.84-0.96
Coefficient of Determination (R^2)	0.91	0.91	0.96	0.85	0.89	0.95
No. of Data Points	63	62	61	62	63	60
Sample Range, mg/dL	114-394	24-101	44-357	114-394	24-101	44-357
Predicted Bias	At 200mg/dL, 3.4%	At 40mg/dL, -0.9%	At 150mg/dL, 2.1%	At 200mg/dL, -6.8%	At 40mg/dL, -3.3%	At 150mg/dL, -1.4%
	At 240mg/dL, 3.0%	At 60mg/dL, 1.1%	At 250mg/dL, 2.5%	At 240mg/dL, -7.8%	At 60mg/dL, -5.6%	At 250mg/dL, -4.8%

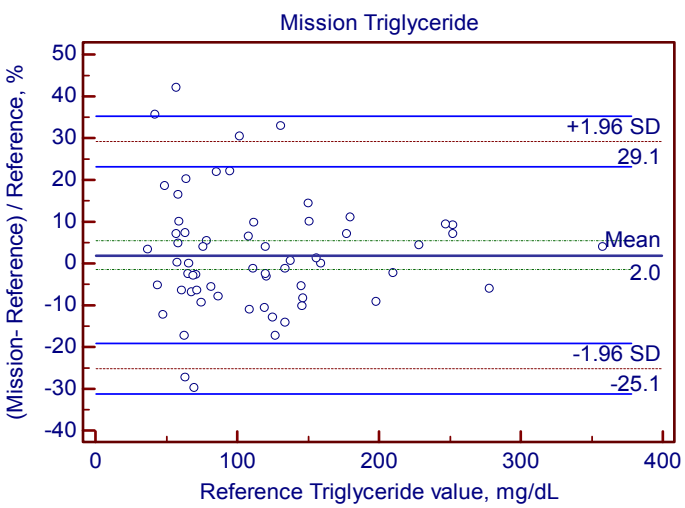
- Bland-Altman analysis











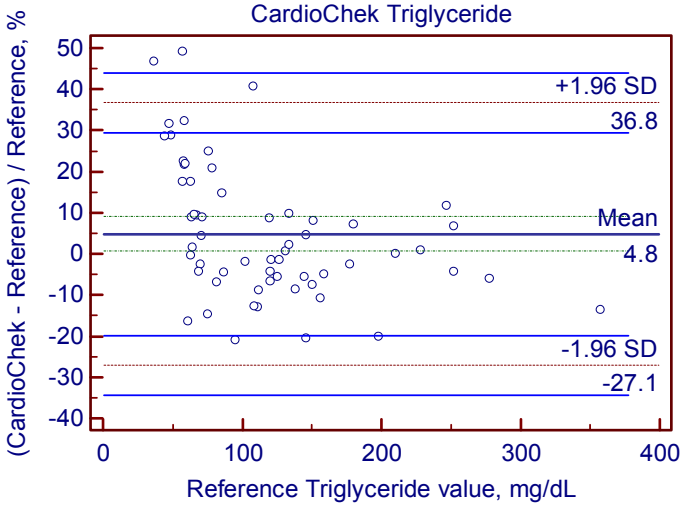


Table 2: Bias and 95% Limit of Agreement

				95% Limit of Agreement	
Analyte	**Meter**	**Mean of Difference**	**SD**	**Low**	**High**
Total Cholesterol	**Mission Cholesterol**	3.9%	8.1%	-12.3%	20%
	CardioChek PA	-5.8%	9.4%	-24.5%	12.9%
HDL	**Mission Cholesterol**	-0.1%	10.6%	-21.2%	-20.9%
	CardioChek PA	-4.7%	8.1%	-25.5%	16.2%
Triglyceride	**Mission Cholesterol**	2%	13.6%	-25.1%	29.1%
	CardioChek PA	4.8%	16.0%	-27.1%	36.8%

4.2 Precision:

Table 3: Within-run imprecisions

Instrument	**Total Cholesterol**	**HDL**	**Triglyceride**
CardioChek PA	5.1%	6.0%	6.5%
Mission Cholesterol	3.8%	4.7%	2.4%
F test Mission vs CardioChek	P>0.05	P<0.05	P<0.05
Reference value, mg/dL	189	42	131

5. Conclusion

5.1 Accuracy

Test results from the *Mission* Cholesterol Monitoring System and the CardioChek PA Test System showed similar agreement compared with reference methods, but the average Bias of the *Mission* measurement vs. reference method was less than the Bias of the CardioChek PA measurement vs. reference method. The analysis of 95% confidence interval slope of the linear regression indicated that the slope of the *Mission* Cholesterol Monitoring System covered 1.0, but the CardioChek PA Test System did not cover 1.0 which demonstrated a proportional measurement difference between the CardioChek PA and the reference method.

5.2 Precision

Whole blood samples with analyte concentrations close to the therapeutic relevance level were tested with both systems. There was no significant difference for the imprecision of total cholesterol. In fact, the CV of the *Mission* Cholesterol system was lower than the CardioChek PA system.

For HDL and triglyceride, the F test indicated that there was a significant difference between the two systems and the precision of the *Mission* Cholesterol system was better than that of the CardioChek PA system.