CardioChek ® Plus

Comparison Study Summary

OnSite Health
210 S. Michigan Street, Suite 110
South Bend, IN 46601
574-243-5108 ext. 203

July 27, 2015

1 PROTOCOL

This internal evaluation was conducted on July 17 & 20, 2015 by OnSite Health in South Bend, IN. It consisted of a comparative analysis of the CardioChek® Plus analyzer using CardioChek Plus lipid + eGLU™ Smart Bundle™ test strips. The study compared fingerstick samples on the CardioChek Plus analyzer and the Cholestech LDX (LDX), to serum samples sent to The Medical Foundation in South Bend, IN and run on the Roche Cobas analyzer. Twenty-three (23) participants were tested. Both fasting and non-fasting samples were used.

	Testing Range
Total Cholesterol	157 – 291
HDL Cholesterol	33 – 81
Triglyceride	35 – 414
Glucose	73 – 113

Testing range based on The Medical Foundation Cobas testing.

All results are in mg/dL.

2 RESULTS

Evaluation by Average Difference

The following graphs and tables show the detailed analyses of the relationship of the results from the CardioChek Plus test system, Roche Cobas, and the Cholestech LDX.

The difference between the CardioChek Plus result and the laboratory result is calculated in a pair-wise fashion. The average of the differences is calculated. The **average difference** is expected to be:

Total Cholesterol:	± 10%
HDL Cholesterol:	± 12%
Triglycerides:	± 15%
Glucose <75 mg/dL:	± 15 mg/dL
Glucose ≥75 mg/dL:	± 20%

The average difference calculated from the actual individual paired % bias with the Cobas analyzer.

((Comparator Result – Cobas Lab Result) ÷ Cobas Lab Result) X100 are as follows:

Average of Paired % Biases		
vs. Cobas	**CardioChek Plus Analyzer**	**LDX**
Total Cholesterol	-4.2%	-5.6%
HDL Cholesterol	-3.9%	-4.0%
Triglycerides	-1.1%	-7.5%
Glucose	-1.4%	-6.5%

NOTE: This value is the average difference of a population; differences between individual results are expected to vary both below and above the average difference value.

Analyte Summaries

The summary of the linear regression and predicted bias data is shown on the following pages for each analyte. The regression statistics are displayed for each individual instrument used. These data are then used to calculate the predicted biases for each analyte at specific clinical decision values. Predicted bias data was not provided for glucose due to the lack of values spanning the dynamic range of the assay.

Actual predicted % differences with the reference analyzers are calculated as:
((Comparator Result – Reference Lab Result) ÷ Reference Lab Result) X100

3 TOTAL CHOLESTEROL

Total Cholesterol (mg/dL)		
vs. Cobas	CardioChek Plus Analyzer	LDX
N	23	23
Slope	1.15	1.00
Intercept	-37.7	-11.2
R	0.969	0.986

Total Cholesterol Predicted Biases (mg/dL)				
vs. Cobas	CardioChek Plus Analyzer	% Bias	LDX	% Bias
160	146	-8.5%	149	-6.9%
200	192	-3.8%	189	-5.5%
240	238	-0.7%	229	-4.5%
280	284	1.6%	269	-3.9%
Average % bias		-2.9%		-5.2%
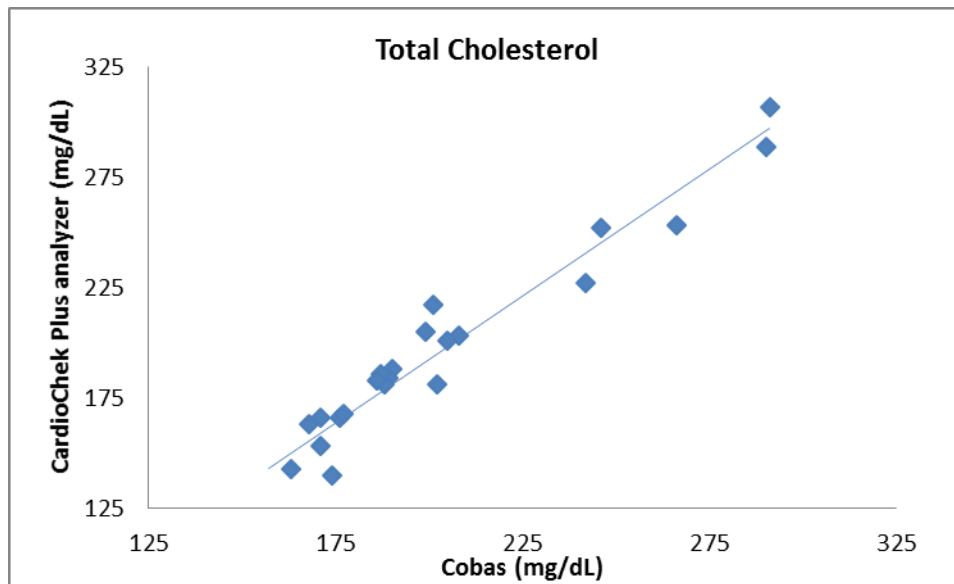
4 HDL CHOLESTEROL

HDL Cholesterol (mg/dL)		
vs. Cobas	**CardioChek Plus Analyzer**	**LDX**
N	23	23
slope	1.19	0.97
intercept	-12.8	-0.7
R	0.946	0.976

HDL Cholesterol Predicted Biases (mg/dL)				
vs. Cobas	**CardioChek Plus Analyzer**	**% Bias**	**LDX Analyzer**	**% Bias**
40	35	-13.0%	38	-4.6%
60	59	-2.3%	58	-4.0%
80	82	3.1%	77	-3.7%
100	106	6.3%	96	-3.5%
	Average % bias	**-1.5%**		**-3.9%**
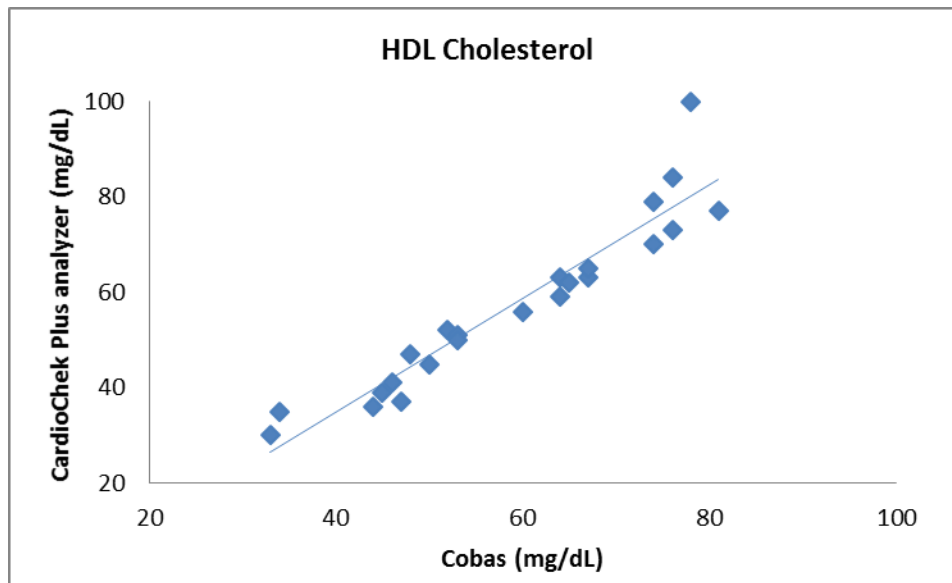
5 TRIGLYCERIDES

Triglycerides (mg/dL)		
vs. Cobas	**CardioChek Plus Analyzer**	**LDX**
N	20	19
slope	0.92	1.03
intercept	6.6	-10.7
R	0.996	0.999

Triglycerides Predicted Biases (mg/dL)				
vs. Cobas	**CardioChek Plus Analyzer**	**% Bias**	**LDX**	**% Bias**
100	99	-1.1%	92	-8.2%
150	145	-3.3%	143	-4.6%
200	191	-4.4%	194	-2.8%
250	237	-5.1%	246	-1.8%
	Average % bias	**-3.5%**		**-4.4%**
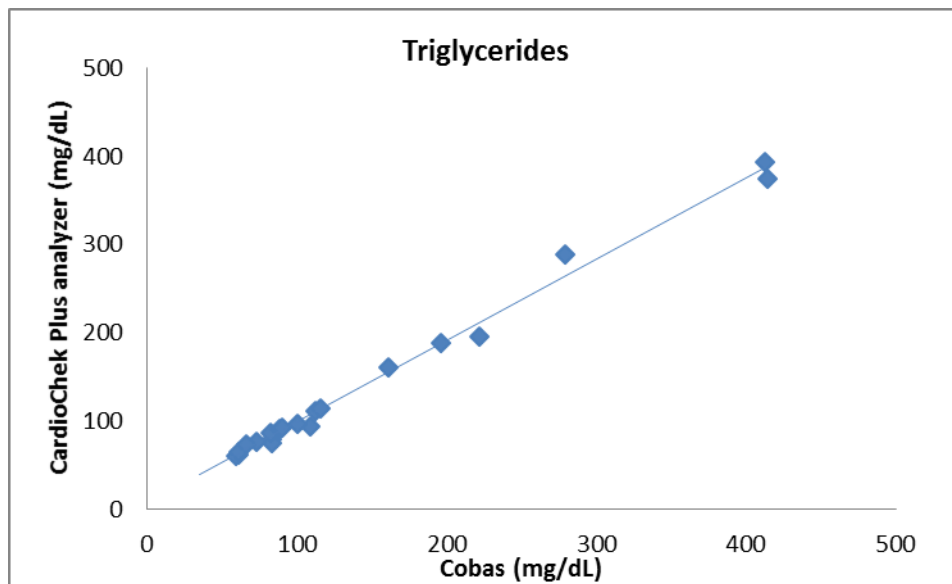
6 GLUCOSE

Glucose (mg/dL)		
vs. Cobas	CardioChek Plus Analyzer	LDX
N	23	23
slope	1.04	0.87
intercept	-5.0	6.3
R	0.811	0.955

Glucose ISO Guidelines
Glucose evaluated according to the current 2003 ISO Standard:
Values up to 75 mg/dL +15mg/dL
Values 75 mg/dL + 20%
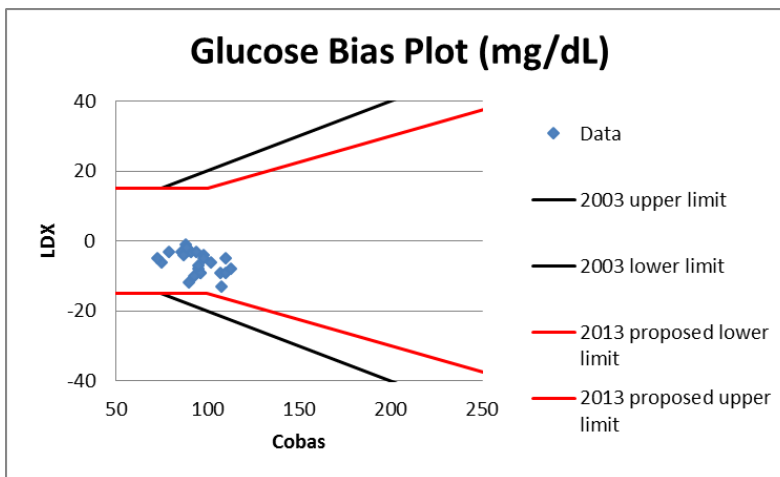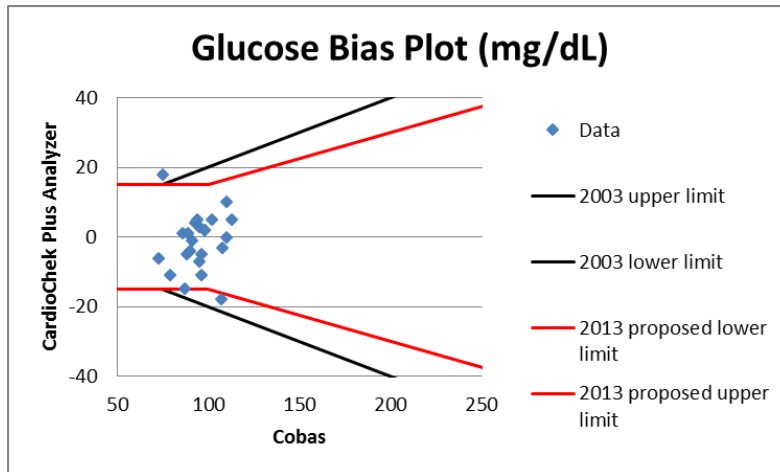
7 RISK CLASSIFICATION

Each result was categorized based on traditional risk categories for each of the analytes (top table below). From these analyses, a clinical agreement table was compiled (bottom table below) applying strict limits to quantify "Agreement." This means that a sample yielding total cholesterol results of 199 and 200 mg/dL on the three test systems was rated as a 1 category difference despite the clinical insignificance of the discrepancy. These results are shown as the number of values where there is clinical agreement (Agree), a one category difference (1 Cat Diff) or a two category difference (2 Cat Diff) between the CardioChek Plus analyzer and the reference laboratory result. In no instance was a "2 category difference" observed in this clinical evaluation for total cholesterol, HDL cholesterol, triglycerides, or glucose.

Risk Classification (mg/dL)									
Categories Compared	**Total Cholesterol**			**HDL Cholesterol**		**Triglycerides**			**Glucose**
	<200	200 - 240	>240	<40	≥40	<150	150 - 200	≥200	<126 ≥126

Risk Classification Agreement Between Methods and Cobas (mg/dL)									
	Total Cholesterol			**HDL Cholesterol**		**Triglycerides**			**Glucose**	
All Samples	Agree	1 Cat Diff	2 Cat Diff	Agree	1 Cat Diff	Agree	1 Cat Diff	2 Cat Diff	Agree	1 Cat Diff
CardioChek Plus Analyzer	20	3	0	20	3	22	1	0	23	0
LDX	18	5	0	23	0	22	0	0	23	0

8 RAW DATA: CHOLESTEROL (mg/dL)

Sample #	Roche Cobas	CardioChek Plus Analyzer	LDX
1	290	289	265
2	176	166	166
3	208	203	199
4	174	140	164
5	291	307	290
6	168	163	151
7	266	253	258
8	201	217	199
9	163	143	156
10	205	201	201
11	171	166	164
12	190	188	183
13	171	153	155
14	189	184	171
15	177	168	163
16	188	181	184
17	242	227	234
18	202	181	182
19	157	123	138
20	187	186	185
21	246	252	229
22	199	205	185
23	186	183	173

9 RAW DATA: HDL CHOLESTEROL (mg/dL)

Sample #	Roche Cobas	CardioChek Plus Analyzer	LDX
1	46	41	40
2	67	63	65
3	81	77	78
4	47	37	44
5	52	52	55
6	45	39	41
7	44	36	40
8	74	79	70
9	64	59	63
10	67	65	62
11	74	70	71
12	53	51	53
13	64	63	57
14	65	62	58
15	76	73	75
16	34	35	37
17	76	84	73
18	50	45	44
19	60	56	56
20	53	50	52
21	33	30	31
22	78	100	81
23	48	47	51

10 RAW DATA: TRIGLYCERIDES (mg/dL)

Sample #	Roche Cobas	CardioChek Plus Analyzer	LDX
1	222	196	212
2	109	94	98
3	47	<50	<45
4	83	79	75
5	279	288	277
6	196	189	180
7	413	394	409
8	83	75	76
9	35	<50	<45
10	61	62	46
11	59	61	33*
12	82	86	79
13	61	65	54
14	100	97	95
15	88	91	85
16	414	374	422
17	90	93	87
18	112	111	104
19	55	<50	<45
20	73	76	65
21	161	160	156
22	66	73	57
23	116	114	99

* Triglycerides value not used in calculations due to clerical error.

Blue highlighted data was not used in the calculations due to being outside the measuring range of the analyte.

11 RAW DATA: GLUCOSE (mg/dL)

Sample #	Roche Cobas	CardioChek Plus Analyzer	LDX
1	96	85	87
2	107	89	98
3	110	110	101
4	88	83	87
5	95	98	87
6	108	105	95
7	113	118	105
8	86	87	83
9	91	90	88
10	87	72	83
11	110	120	105
12	79	68	76
13	96	91	87
14	102	107	96
15	75	93	69
16	98	100	94
17	93	97	83
18	73	67	68
19	90	86	78
20	89	90	87
21	98	100	93
22	95	88	88
23	94	99	91

12 OVERVIEW OF EVALUATION

Evaluation Site
OnSite Health
210 S. Michigan Street, Suite 110
South Bend, IN 46601

Technical Service Specialist (TSS)
Emily Suscha

Account Contact
Ron Bryan
Phone: 574-243-5108, ext. 203
rbryan@onsitehealthllc.com

Third Party Comparison: (X-axis)
The Medical Foundation Roche Cobas

Reagents Used
Lipid + eGLU Smart Bundle Kit: Lot Q504
Multi-Chemistry Controls: Lot MC21
HDL Cholesterol Controls: Lot HC20

Accuracy Instruments: (Y-axis)
CardioChek Plus analyzer: SN 5122797

13 REGRESSION STATISTICS SUMMARY

Statistical Definitions

Slope: The slope of a line in the plane containing the *x* and *y* axes is generally represented by the letter *m*, and is defined as the change in the *y* coordinate divided by the corresponding change in the *x* coordinate, between two distinct points on the line. (A perfect slope is "1")

Intercept: Where a straight line crosses the Y axis of a graph. (A perfect intercept is "0")

R Value: A statistic that gives a measure of how closely two variables are related, also known as the correlation coefficient. It represents the extent to which variations in one variable are related to variations in another or "goodness of fit."

Comparison Key Aspects

Any method comparison must be approached with a clear understanding of variables that affect the test results. The known variation of chemistry analytical systems must always be considered when evaluating observed bias. Such variation is not only evident between point-of-care testing and laboratory systems but also between laboratory systems. Even in the most closely aligned systems, two methods may "correlate" but rarely "match." Identity is not a prerequisite for acceptance, but rather an understanding of the bias at clinical decision limits for the analyte in question and the clinical consequences of these biases. The critical evaluation criterion is the placement of a given patient into appropriate risk categories by each system. In this analysis, a point-by-point comparison was made for each patient evaluating the risk classification category for each result.

Data Summary

In this evaluation, the CardioChek Plus analyzer produced clinically equivalent values for total cholesterol, HDL cholesterol, triglycerides, and glucose compared to those reported for the same patients' samples analyzed in a reference laboratory. The linear regression results between the methods indicate a good correlation between the CardioChek Plus analyzer point-of-care method and the reference laboratory method for total cholesterol, HDL cholesterol, triglycerides, and glucose. The risk classification tables demonstrate that the CardioChek Plus analyzer accurately identifies patient risk category with a high level of correlation with reference methods. In summation, the data as a whole demonstrate clinical equivalency between all methods used.

Lee B. Springer Ph.D. MLS(ASCP)
Director of Clinical Laboratory Medicine

9/8/2015

PTS Diagnostics Approval Signature   Date

pts Diagnostics