CardioChek Plus

Comparison Study Summary

Arizona

May 7, 2015

1 PROTOCOL

This study was conducted on May 7, 2015. It consisted of a comparative analysis of the CardioChek® Plus analyzer using CardioChek Plus Lipid+eGlu Smart Bundle™ test strips. This study compared the CardioChek Plus analyzer to the Quest Diagnostics Beckman Coulter AU5400 analyzer (AU5400) and the test site's Siemens Vista analyzer (Vista). Twenty-four (24) subjects participated in the study, of which fifteen (15) participants were fasting. Three samples (4, 5, and 21) were eliminated from the study due to sample integrity questions at the Quest Diagnostics site. All raw values are displayed below for reference.

At the test site a phlebotomist performed a venipuncture blood draw collecting one (1) serum clot tube and one (1) lithium heparin tube. The serum tube was allowed to clot for 30 minutes and centrifuged. Each serum sample was poured off into two (2) aliquot tubes. One aliquot tube was tested at the evaluation site on the Vista analyzer. The second aliquot tube was transported by the Quest courier to Quest Diagnostics for analysis on the AU5400. The lithium heparin tube was used for precision testing. Because of expanding capillary-venous glycemic gradients as blood glucose increases after eating, for the purpose of this evaluation, only fasting patients were utilized for the glucose.

Immediately following the venous draw, a PTS Diagnostics employee executed a fingerstick and dosed the electrochemical glucose strip on the CardioChek Plus analyzer. The drop of blood was wiped from the finger and a 40μL capillary tube was collected and dosed onto the lipid panel test strip.

	Testing Range (mg/dL)
Total Cholesterol	120 - 301
HDL Cholesterol	32 - 124
Triglycerides	54 - 331
Fasting Glucose	72 - 103

Testing range is based on the Quest Diagnostics Beckman AU5400 analyzer.

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, the AU5400 analyzer, and the Vista analyzer.

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

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 **AU5400** analyzer.
((Comparator Result – AU5400 Result) ÷ AU5400 Result) X100) are as follows:

Average of Paired % Biases (mg/dL)		
vsAU5400	**Vista**	**CardioChek Plus Analyzer**
Total Cholesterol	-3.1%	-6.0%
HDL Cholesterol	-3.2%	-3.4%
Triglycerides	-2.7%	-6.8%
Fasting Glucose	0.2%	5.1%

The average difference calculated from the actual individual paired % bias with the **Vista** analyzer.
((Comparator Result – Vista Result) ÷ Vista Result) X100) are as follows:

Average of Paired % Biases (mg/dL)	
vs Vista	**CardioChek Plus Analyzer**
Total Cholesterol	-3.0%
HDL Cholesterol	-0.1%
Triglycerides	-4.4%
Fasting Glucose	4.9%

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 points. 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 AU5400	**Vista**	**CardioChek Plus Analyzer**
N	21	21
Slope	1.02	1.01
Intercept	-9.3	-13.4
R	0.995	0.986
vs Vista		**CardioChek Plus Analyzer**
Slope		0.99
Intercept		-3.1
R		0.985

Total Cholesterol Predicted Biases (mg/dL)				
AU5400	**Vista**	**% Bias**	**CardioChek Plus Analyzer**	**% Bias**
160	154	-3.7%	149	-6.9%
200	195	-2.5%	190	-5.2%
240	236	-1.7%	230	-4.1%
280	277	-1.2%	271	-3.3%
	Average % bias	**-2.3%**		**-4.9%**

Total Cholesterol Predicted Biases (mg/dL)		
vs Vista	**CardioChek Plus Analyzer**	**% Bias**
160	155	-3.1%
200	195	-2.7%
240	234	-2.5%
280	274	-2.3%
	Average % bias	**-2.7%**

Predicted biases are based strictly on the linear regression line of the data collected.
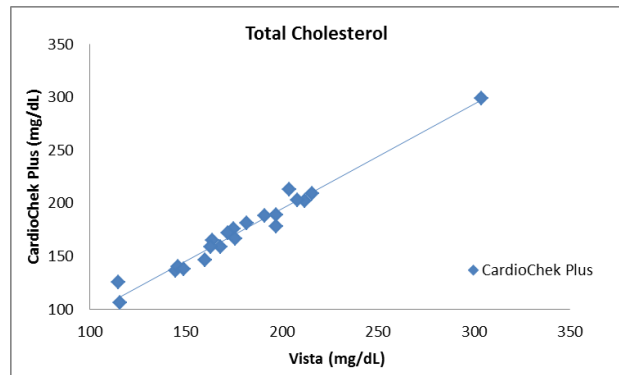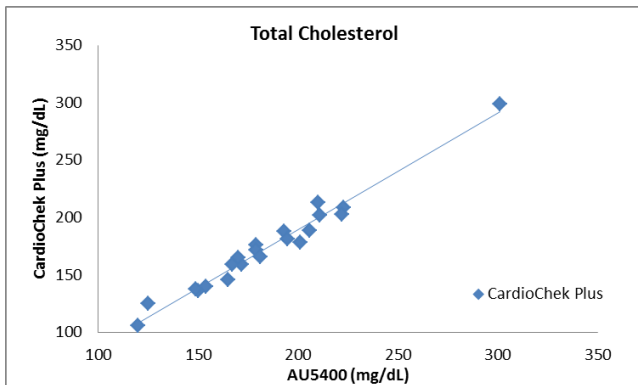
4   HDL CHOLESTEROL

HDL Cholesterol (mg/dL)		
vs AU5400	**Vista**	**CardioChek Plus Analyzer**
N	21	21
Slope	0.94	0.96
Intercept	1.5	0.5
R	0.993	0.961
vs Vista		**CardioChek Plus Analyzer**
Slope		0.99
Intercept		0.4
R		0.956

HDL Cholesterol Predicted Biases (mg/dL)				
AU5400	**Vista**	**% Bias**	**CardioChek Plus Analyzer**	**% Bias**
40	39	-2.3%	39	-2.9%
60	58	-3.6%	58	-3.4%
80	77	-4.2%	77	-3.6%
100	95	-4.6%	96	-3.7%
	Average % bias	**-3.7%**		**-3.4 %**

HDL Cholesterol Predicted Biases (mg/dL)		
vs Vista	**CardioChek Plus Analyzer**	**% Bias**
40	40	0.4%
60	60	0.0%
80	80	-0.1%
100	100	-0.2%
	Average % bias	**0.0%**

Predicted biases are based strictly on the linear regression line of the data collected.
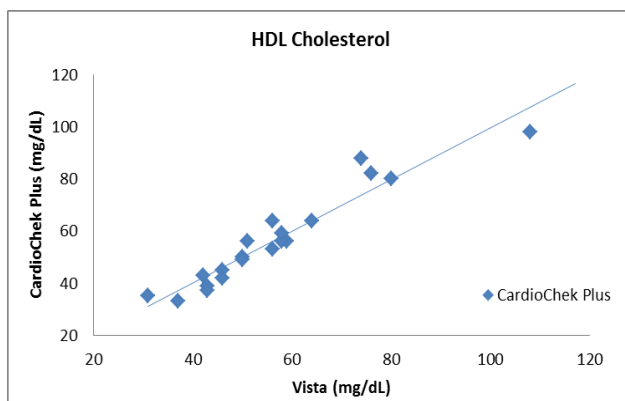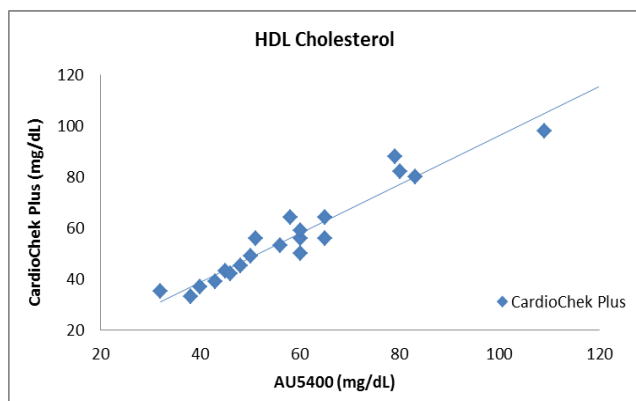
5 TRIGLYCERIDES

Triglycerides (mg/dL)		
vs AU5400	**Vista**	**CardioChek Plus Analyzer**
N	21	21
Slope	1.02	0.97
Intercept	-4.0	-3.7
R	0.998	0.983
vs Vista		**CardioChek Plus Analyzer**
Slope		0.95
Intercept		0.2
R		0.983

Triglycerides Predicted Biases (mg/dL)				
AU5400	**Vista**	**% Bias**	**CardioChek Plus Analyzer**	**% Bias**
100	98	-2.1%	93	-6.6%
150	149	-0.7%	142	-5.4%
200	200	-0.1%	191	-4.7%
250	251	-0.3%	239	-4.4%
	Average % bias	**-0.6%**		**-5.3%**

Triglycerides Predicted Biases (mg/dL)		
vs Vista	**CardioChek Plus Analyzer**	**% Bias**
100	95	-4.7%
150	143	-4.8%
200	190	-4.8%
250	238	-4.8%
	Average % bias	**-4.8%**

Predicted biases are based strictly on the linear regression line of the data collected
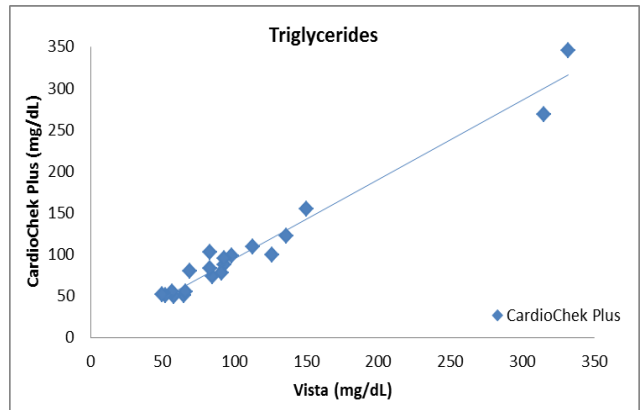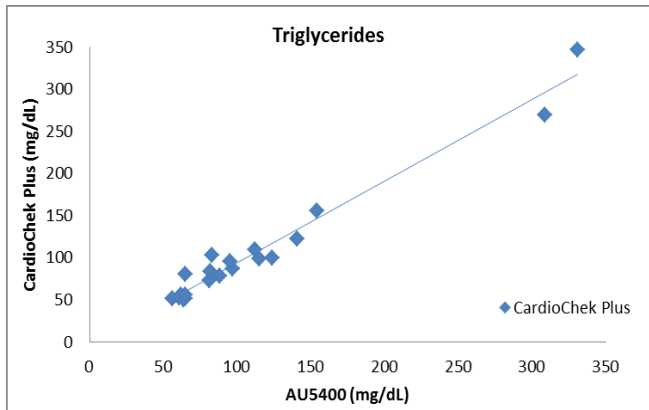
6 FASTING GLUCOSE

Fasting Glucose (mg/dL)		
vs AU5400	**Vista**	**CardioChek Plus Analyzer**
N	12	12
Slope	1.08	0.80
Intercept	-7.3	20.7
R	0.984	0.866
vs Vista		**CardioChek Plus Analyzer**
Slope		0.73
Intercept		27.3
R		0.864

Glucose ISO Guidelines

Glucose evaluated according to the current 2003 ISO 15197 Standard:

Values up to 75 mg/dL $\pm$15mg/dL

Values 75 mg/dL $\pm$ 20%
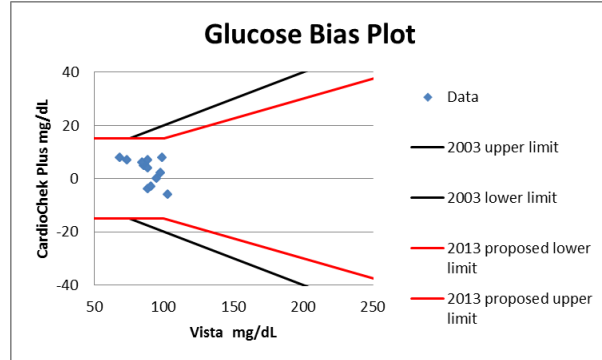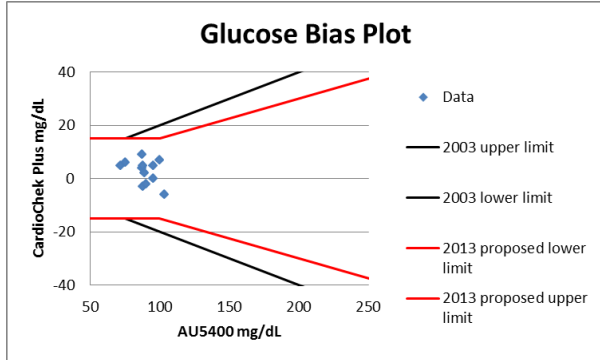
7 RISK CLASSIFICATION

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 (top 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 four 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									
Categories Compared	**Total Cholesterol (mg/dL)**			**HDL Chol (mg/dL)**		**Triglycerides (mg/dL)**			**Glucose (mg/dL)**	
	<20 0	200 - 240	>240	<40	≥40	<150	150 – 200	>200	<126	>126

Risk Classification Agreement Between Methods and AU5400										
	Total Cholesterol			**HDL Cholesterol**		**Triglycerides**			**Fasting 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
Vista	19	2	0	21	0	21	0	0	12	0
CardioChek Plus Analyzer	19	2	0	19	2	21	0	0	12	0

Risk Classification Agreement Between Methods and Vista										
	Total Cholesterol			**HDL Cholesterol**		**Triglycerides**			**Fasting Glucose**	
All Samples	Agree	1 Cat	2 Cat	Agree	1 Cat	Agree	1 Cat Diff	2 Cat Diff	Agree	1 Cat Diff
CardioChek Plus Analyzer	21	0	0	19	2	21	0	0	12	0

8 PRECISION

CardioChek Plus analyzer SN 5121814 (mg/dL)				
Sample ID	12	12	12	12
Analyte	CHOL	HDL	TRIG	eGLU
1	127	56	105	85
2	130	58	108	83
3	122	55	102	75
4	134	54	107	78
5	125	55	109	68
6	122	56	98	78
7	126	58	104	80
8	132	55	101	75
9	128	56	99	78
10	125	55	100	70
Number	10	10	10	10
Average	127.1	55.8	103.3	77
SD	4.0	1.3	3.9	5.3
%CV	3.1	2.4	3.8	6.8

CardioChek Plus analyzer SN 5121814(mg/dL)				
Sample ID	8	8	8	8
Analyte	CHOL	HDL	TRIG	eGLU
1	177	65	111	56
2	186	63	109	67
3	180	64	105	61
4	189	62	107	58
5	182	66	109	55
6	184	69	119	68
7	177	67	106	66
8	180	65	101	60
9	170	64	108	60
10	176	62	115	56
Number	10	10	10	10
Average	180.1	64.7	109	60.7
SD	5.5	2.2	5.1	4.8
%CV	3.0	3.4	4.7	7.9

9 PRECISION, CONTINUED

CardioChek Plus analyzer SN 5121814(mg/dL)				
Sample ID	15	15	15	15
Analyte	CHOL	HDL	TRIG	eGLU
1	299	88	289	100
2	305	87	301	95
3	308	84	311	106
4	301	82	309	110
5	295	80	288	101
6	288	86	298	108
7	315	87	302	104
8	298	89	287	98
9	305	85	275	92
10	301	87	302	108
Number	10	10	10	10
Average	301.5	85.5	296.2	102.2
SD	7.4	2.8	11.2	6.0
%CV	2.5	3.3	3.8	5.9

10 RAW DATA – TOTAL CHOLESTEROL (mg/dL)

Sample #	AU5400	Vista	CardioChek Plus analyzer
1	223	216	209
2	193	191	188
3	150	145	136
4	206	147	139
5	230	185	188
6	195	182	181
7	172	168	159
8	179	175	176
9	179	172	172
10	170	164	165
11	154	146	140
12	125	115	125
13	211	212	202
14	201	197	178
15	301	304	299
16	181	176	166
17	210	204	213
18	206	197	189
19	167	163	159
20	222	208	203
21	161	165	159
22	120	116	106
23	165	160	146
24	149	149	138

Three samples (4, 5, and 21) were eliminated from the study due to sample integrity questions at the reference laboratory site.

11 RAW DATA – HDL CHOLESTEROL (mg/dL)

Sample #	AU5400	Vista	CardioChek Plus analyzer
1	109	108	98
2	80	76	82
3	60	59	56
4	68	61	64
5	42	76	88
6	65	58	56
7	60	58	59
8	65	64	64
9	83	80	80
10	60	50	50
11	43	43	39
12	51	51	56
13	38	37	33
14	45	42	43
15	79	74	88
16	48	46	45
17	58	56	64
18	32	31	35
19	56	56	53
20	124	117	>100
21	48	19	25
22	46	46	42
23	40	43	37
24	50	50	49

- The above highlighted data was not used in the calculations due to the reference value being outside the measuring range of the CardioChek Plus test system.
- Three samples (4, 5, and 21) were eliminated from the study due to sample integrity questions at the reference laboratory site.

12 RAW DATA – TRIGLYCERIDES (mg/dL)

Sample #	AU5400	Vista	CardioChek Plus analyzer
1	54	49	<50
2	97	93	87
3	65	65	51
4	102	59	59
5	148	127	127
6	64	58	50
7	62	57	55
8	112	113	109
9	56	52	51
10	141	136	122
11	154	150	155
12	83	83	103
13	61	50	52
14	124	126	99
15	331	332	346
16	88	91	78
17	81	85	73
18	309	315	269
19	82	83	83
20	65	66	55
21	149	155	159
22	65	69	80
23	115	98	98
24	95	93	95

- The above highlighted data was not used in the calculations due to the reference value being outside the measuring range of the CardioChek Plus test system.
- Three samples (4, 5, and 21) were eliminated from the study due to sample integrity questions at the reference laboratory site.

13 RAW DATA – GLUCOSE (mg/dL)

Sample #	AU5400	Vista	CardioChek Plus analyzer
1	75	74	81
2	89	86	91
3	95	95	95
4	96	98	92
5	94	87	88
6	87	85	91
7	88	89	93
8	59	59	68
9	72	69	77
10	103	103	97
11	95	91	112
12	78	80	93
13	87	89	96
14	85	87	94
15	110	109	119
16	87	85	83
17	88	89	85
18	103	107	102
19	90	91	88
20	93	94	85
21	86	87	91
22	72	76	80
23	100	99	107
24	95	98	100

- Samples 8, 11, 12, 14 through 16, 18, 20 and 22 are non-fasting.
- Three samples (4, 5, and 21) were eliminated from the study due to sample integrity questions at the reference laboratory site.

14 OVERVIEW OF EVALUATION

Technical Service Specialist (TSS)
Maria Shafai, MT (ASCP)

Third Party Comparison: (X-axis)
Beckman Coulter AU5400 (Quest Diagnostics)
Siemens Vista (testing site)

Reagents Used
CardioChek Plus Smart Bundle® Test Strips Lot Q501
Multi-Chemistry Controls: Lot MC20
HDL Cholesterol Controls: Lot HC20

Accuracy Instruments: (Y-axis)
CardioChek Plus analyzer: SN 5120608

Precision Instruments:
CardioChek Plus analyzer: SN 5121814

15 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")
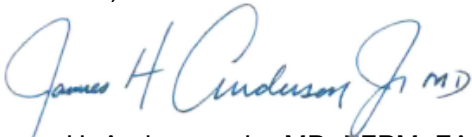
R Value: A statistic that gives a measure of how closely two variables are related, also known as the correlation coefficient. It represents the extent to which variations in one variable are related to variations in another or "goodness of fit."

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 POCT 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 point-of-care method and the reference laboratory method(s) for total cholesterol, HDL cholesterol, triglycerides, and glucose. The risk classification tables demonstrate that the CardioChek Plus System accurately identifies patient risk category with a high level of correlation with reference methods. The multiple repetition analyses confirm good precision of the CardioChek Plus System for all four analytes. In summation, the data as a whole demonstrate clinical equivalency between all methods used.

James H. Anderson, Jr., MD, FFPM, FACE
Medical Director   18 JUNE 2015

PTS Diagnostics Approval Signature   Date

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