CardioChek®

Evaluation Summary

Spectrum Health Systems
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Evaluation Summary

The study conducted at Spectrum Health Systems consisted of a side-by-side comparative analysis of the CardioChek® PA analyzer using PTS Panels® Lipid Panel test strips and Glucose test strips (CardioChek PA test system), compared with the Beckman Coulter AU5400 Clinical Chemistry System and the Roche Integra. The CardioChek PA test system was also compared to one other point-of-care device, the Alere Cholestech LDX® System. Twenty-one (21) subjects participated in this system evaluation. The results of the individual subjects were analyzed using linear regression analysis and bias estimates. These statistical analyses demonstrate the expected statistical equivalence of the CardioChek PA test system and the reference systems. In addition, the individual results from each donor were assessed as to the degree of agreement in the assignment of heart disease risk using Framingham risk classification. In this analysis, the CardioChek PA test system produced clinically equivalent results to the reference lab results. These combined analyses demonstrate that the CardioChek PA test system may be employed with confidence in this clinical setting.

At the test site, the venous blood was collected by a Polymer Technology Systems, Inc. (PTS) phlebotomist. One (1) lithium heparinized anti-coagulated (green top) tube and one (1) serum clot tube (red top) were collected per participant. An initial fingerstick (fs) sample was collected by a Spectrum Health employee, using a 40µl lithium heparinized glass tube, and analyzed on the Alere Cholestech LDX System. A second fingerstick sample was collected by a PTS technician, using a 40µl and a 15µl lithium heparinized glass tube, and analyzed on two CCPA analyzers. Each venous sample was tested on the CCPA analyzers within thirty (30) minutes of collection. The red top clot tube was allowed to clot for thirty (30) minutes, then immediately centrifuged, and the serum aliquoted into two (2) separate aliquot tubes. The first serum aliquot was transported by courier to Quest Laboratories to be analyzed on the Beckman Coulter AU5400 Clinical Chemistry System. The second serum aliquot was transported directly to PTS and analyzed on the Roche Integra.

Results

The following graphs and tables show the detailed analyses of the relationship of the results from the CardioChek PA test system (CCPA), the Alere Cholestech LDX System (LDX), the Roche Integra (Integra), and the Beckman Coulter AU5400 Clinical Chemistry System (AU5400).

These analyses indicate that the CCPA and LDX test systems produce clinically equivalent results when compared to the laboratory reference analyzers. The linear regression data shows a strong correlation between the POCT methods and the reference laboratory methods for all analytes tested. Further, the risk classification tables indicate that the CCPA and LDX test systems are clinically equivalent to testing performed within a reference laboratory for all analytes, and accurately places a patient within the appropriate health risk category when compared to that reference method.

Actual paired % differences with the Integra analyzer ((Comparator Result – Integra Lab Result) ÷ Integra Lab Result) for venous samples for Total Cholesterol averaged 0.4% for the CCPA and 0.3% for the AU5400. The HDL Cholesterol averaged 2.0% for the CCPA and 3.1% for the AU5400. The Triglycerides averaged 8.6% for the CCPA and 8.0% for the AU5400. The Glucose averaged -1.6% for the CCPA and 0.7% for the AU5400. For the fingerstick samples, the Total Cholesterol was -3.0% for the CCPA and -0.7% for the LDX. The HDL Cholesterol was -2.3% for the CCPA and -0.4% for the LDX. The Triglycerides were 17.3% for the CCPA and 11.2% for the LDX. The Glucose was -1.0% for the CCPA and -4.4% for the LDX.

Actual paired % differences with the AU5400 analyzer ((Comparator Result – AU5400 Lab Result) ÷ AU5400 Lab Result) for venous samples for Total Cholesterol averaged 0.0% for the CCPA, HDL Cholesterol averaged -1.0% for the CCPA, Triglycerides averaged 2.0% for the CCPA, and Glucose averaged -2.1% for the CCPA. For the fingerstick samples, the Total Cholesterol was -3.3% for the CCPA and -1.0% for the LDX. The HDL Cholesterol was -5.0% for the CCPA and -3.3% for the LDX. The Triglycerides were 10.0% for the CCPA and 4.8% for the LDX. The Glucose was -1.6% for the CCPA and -4.8% for the LDX.

The calculated average biases (based upon the linear regression analyses) for the venous samples at the clinical decision points versus the Integra analyzer were 0.2% for Total Cholesterol, 2.2% for HDL Cholesterol, and 4.9% for Triglycerides on the AU5400. For the CCPA, the calculated average biases were 1.3% for Total Cholesterol, 3.5% for HDL Cholesterol, and 0.5% for Triglycerides. The calculated biases for the fingerstick samples were -2.4% for Total Cholesterol, 1.2% for HDL Cholesterol, and 7.6% for Triglycerides for the CCPA. The fingerstick calculated biases for the LDX were -1.4% for Total Cholesterol, -1.7% for HDL Cholesterol, and 6.4% for Triglycerides.

The calculated average biases (based upon the linear regression analyses) for the venous samples at the clinical decision points versus the AU5400 analyzer were 1.1% for Total Cholesterol, 3.7% for HDL Cholesterol, and -4.2% for Triglycerides on the CCPA. The calculated biases for the fingerstick samples were -2.5% for Total Cholesterol, 0.7% for HDL Cholesterol, and 2.5% for Triglycerides for the CCPA. The fingerstick calculated biases for the LDX were -1.6% for Total Cholesterol, -1.6% for HDL Cholesterol, and 1.1% for Triglycerides.

Linear regression analyses of Glucose were not possible due to all participant data falling within a single risk category, which did not allow data to be calculated with statistical meaning.

Precision analyses were performed by testing ten (10) replicates of three (3) samples for each analyte using PTS Panels® Lipid Panel test strips and Glucose test strips.

Statistical Analysis Summary

The summary of the linear regression and predicted bias data is shown below. 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. Note that the predicted biases can only be determined if there are sufficient data in the relevant range.

Total Cholesterol					
vs Integra	**AU5400**	**CCPA V1**	**CCPA V2**	**CCPA FS**	**LDX FS**
N	21	21	21	21	21
slope	0.99	1.06	1.09	1.02	0.92
intercept	2.4	-10.5	-13.8	-9.3	12.0
R	0.999	0.972	0.982	0.980	0.986
vs AU5400		**CCPA V1**	**CCPA V2**	**CCPA FS**	**LDX FS**
slope		1.08	1.10	1.04	0.93
intercept		-13.5	-16.5	-12.2	9.9
R		0.975	0.983	0.983	0.987

Clinical Application										
Integra	**AU5400**	**% diff**	**CCPA V1**	**% diff**	**CCPA V2**	**% diff**	**CCPA FS**	**% diff**	**LDX FS**	**% diff**
160	161	0.45%	159	-0.43%	160	0.22%	155	-3.38%	160	-0.05%
200	200	0.15%	202	0.89%	204	1.95%	196	-2.22%	197	-1.55%
240	240	-0.05%	244	1.77%	247	3.10%	237	-1.44%	234	-2.55%
280	Insufficient data to calculate (<2 laboratory values in this range)									
Average bias		**0.18%**		**0.74%**		**1.76%**		**-2.35%**		**-1.38%**

Clinical Application								
AU5400	**CCPA V1**	**% diff**	**CCPA V2**	**% diff**	**CCPA FS**	**% diff**	**LDX FS**	**% diff**
160	158	-0.94%	160	-0.27%	154	-3.88%	159	-0.46%
200	201	0.75%	204	1.78%	195	-2.35%	197	-1.70%
240	245	1.88%	248	3.16%	237	-1.34%	234	-2.52%
280	Insufficient data to calculate (<2 laboratory values in this range)							
Average bias		**0.56%**		**1.56%**		**-2.52%**		**-1.56%**

HDL Cholesterol					
vs Integra	**AU5400**	**CCPA V1**	**CCPA V2**	**CCPA FS**	**LDX FS**
N	21	21	21	21	21
slope	0.99	1.04	1.14	1.13	0.94
intercept	2.6	-0.9	-7.4	-9.2	3.3
R	0.995	0.940	0.950	0.928	0.923
vs AU5400		**CCPA V1**	**CCPA V2**	**CCPA FS**	**LDX FS**
slope		1.18	1.27	1.23	1.05
intercept		-11.3	-16.9	-17.2	-5.1
R		0.956	0.942	0.905	0.924

Clinical Application										
Integra	**AU5400**	**% diff**	**CCPA V1**	**% diff**	**CCPA V2**	**% diff**	**CCPA FS**	**% diff**	**LDX FS**	**% diff**
40	Insufficient data to calculate (<2 laboratory values in this range)									
60	62	3.06%	61	1.97%	61	2.08%	59	-2.11%	60	-0.53%
80	82	1.98%	82	2.36%	84	5.17%	81	1.70%	78	-1.91%
100	101	1.33%	103	2.60%	107	7.03%	104	3.99%	97	-2.73%
Average bias		**2.12%**		**2.31%**		**4.76%**		**1.19%**		**-1.72%**

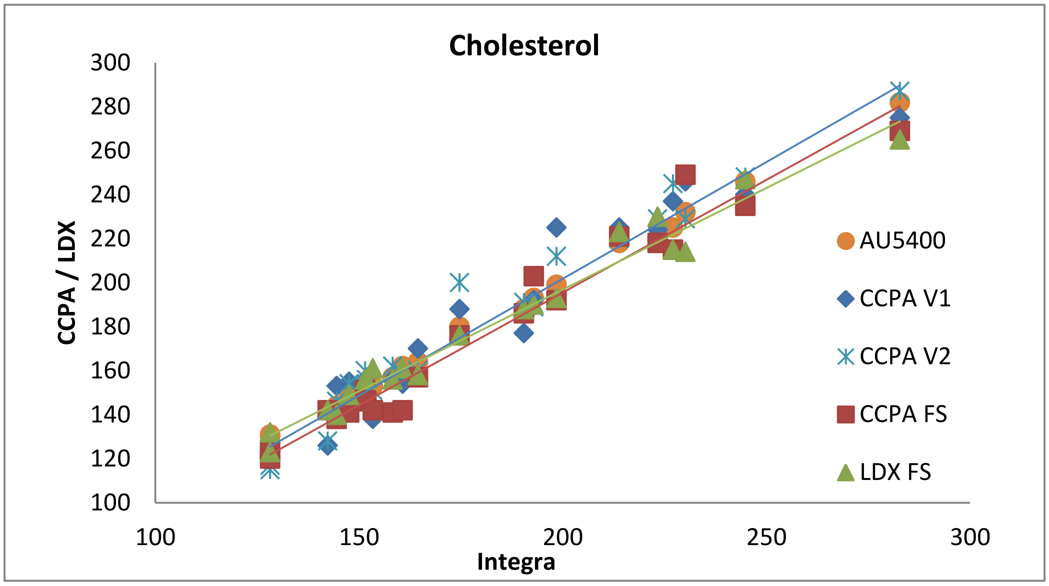
Clinical Application								
AU5400	**CCPA V1**	**% diff**	**CCPA V2**	**% diff**	**CCPA FS**	**% diff**	**LDX FS**	**% diff**
40	Insufficient data to calculate (<2 laboratory values in this range)							
60	59	-1.32%	59	-1.43%	57	-5.50%	58	-3.45%
80	83	3.40%	84	5.61%	81	1.66%	79	-1.34%
100	106	6.23%	110	9.83%	106	5.96%	100	-0.08%
Average bias		**2.77%**		**4.67%**		**0.71%**		**-1.62%**

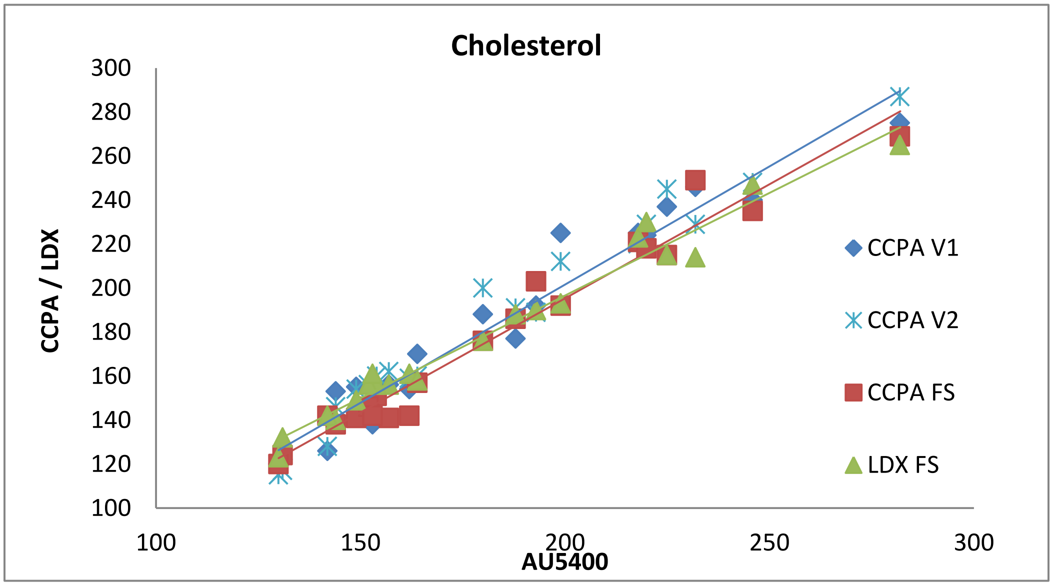
Triglycerides					
vs Integra	**AU5400**	**CCPA V1**	**CCPA V2**	**CCPA FS**	**LDX FS**
N	21	21	21	21	21
slope	1.02	0.87	0.92	0.96	0.99
intercept	3.2	16.7	10.3	13.7	8.9
R	0.997	0.949	0.966	0.931	0.942
vs AU5400		**CCPA V1**	**CCPA V2**	**CCPA FS**	**LDX FS**
slope		0.83	0.88	0.92	0.94
intercept		15.8	8.9	12.9	8.1
R		0.943	0.964	0.926	0.937

Clinical Application										
Integra	**AU5400**	**% diff**	**CCPA V1**	**% diff**	**CCPA V2**	**% diff**	**CCPA FS**	**% diff**	**LDX FS**	**% diff**
100	105	5.41%	104	3.58%	102	1.96%	110	9.93%	108	7.85%
150	157	4.35%	147	-1.99%	148	-1.49%	158	5.36%	157	4.87%
200	Insufficient data to calculate (<2 laboratory values in this range)									
250	Insufficient data to calculate (<2 laboratory values in this range)									
Average bias		**4.88%**		**0.80%**		**0.23%**		**7.64%**		**6.36%**

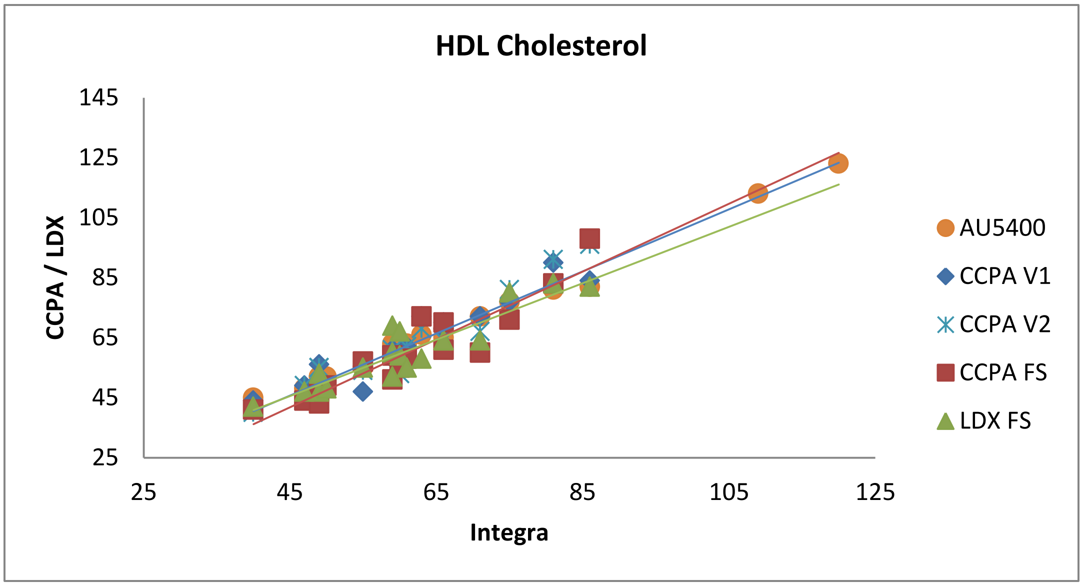
Clinical Application								
AU5400	**CCPA V1**	**% diff**	**CCPA V2**	**% diff**	**CCPA FS**	**% diff**	**LDX FS**	**% diff**
100	99	-1.18%	97	-3.02%	105	4.60%	102	2.44%
150	140	-6.44%	141	-5.99%	150	0.29%	150	-0.27%
200	Insufficient data to calculate (<2 laboratory values in this range)							
250	Insufficient data to calculate (<2 laboratory values in this range)							
Average bias		**-3.81%**		**-4.51%**		**2.45%**		**1.08%**

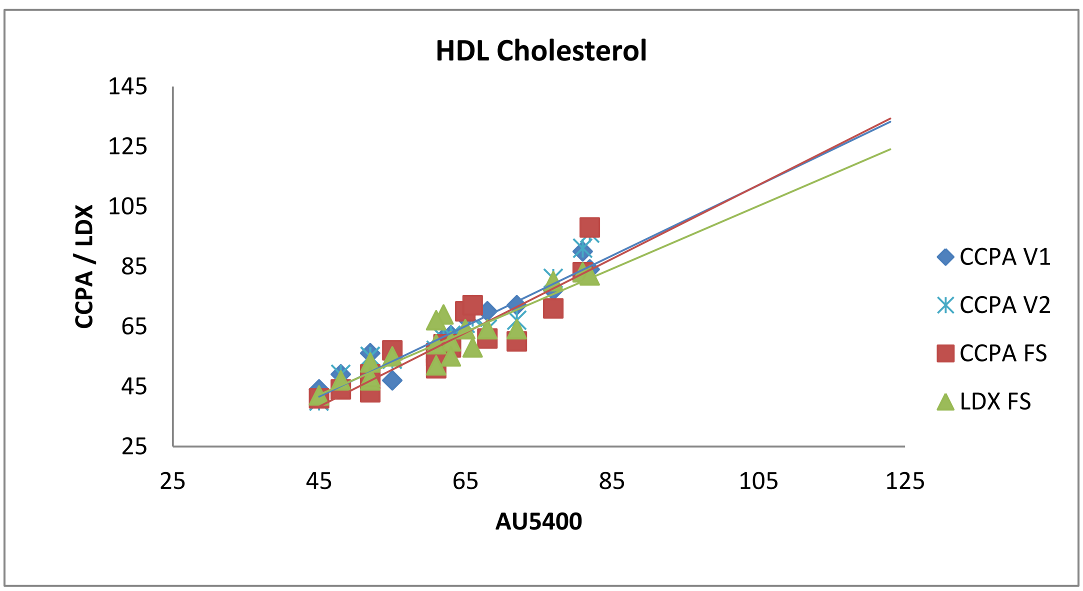
Linear Regression Analyses



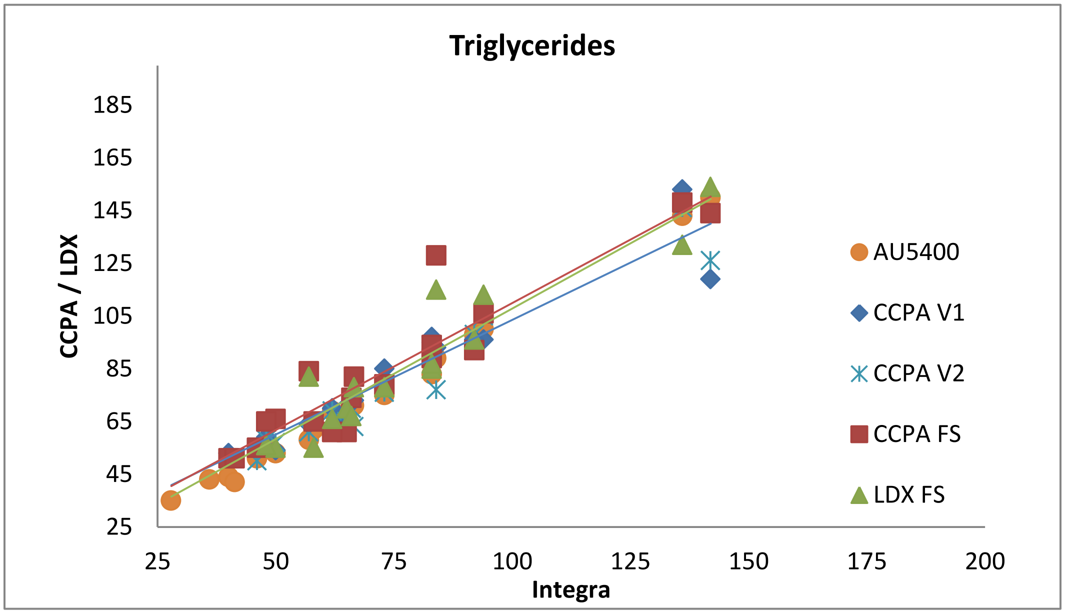


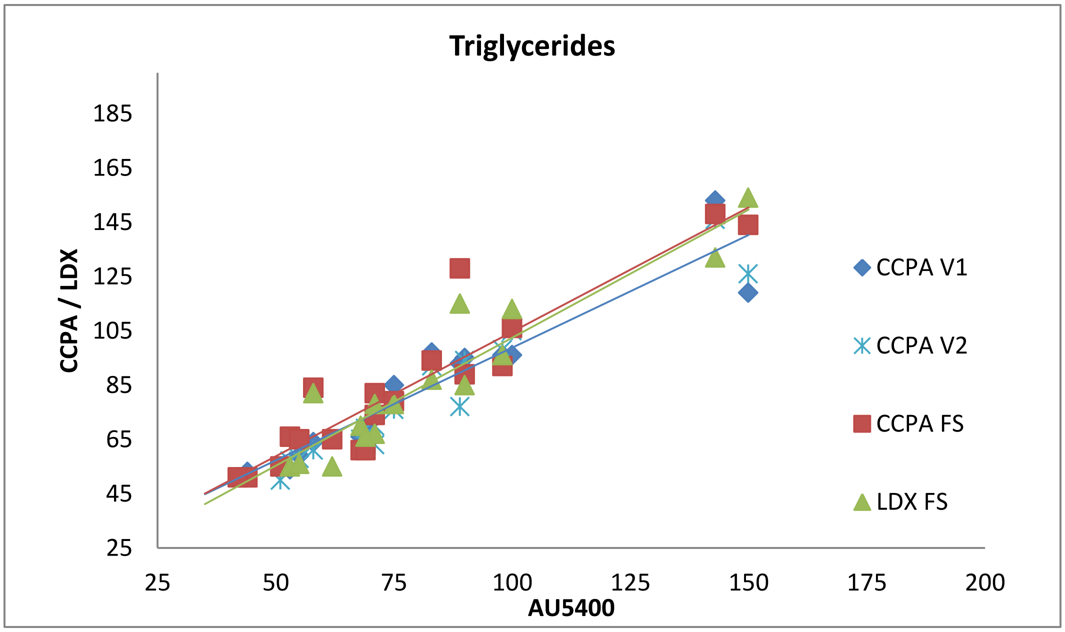
Linear Regression Analyses, continued





Linear Regression, continued





Precision Analyses

Sample 19	TC	HDL	TRIG		Sample 20	TC	HDL	TRIG		Sample 9	TC	HDL	TRIG
1	207	88	54		1	119	52	64		1	252	76	149
2	192	91	61		2	121	51	65		2	253	69	152
3	201	92	65		3	124	52	64		3	235	76	146
4	211	93	65		4	119	52	68		4	241	71	141
5	195	92	74		5	115	48	63		5	252	75	138
6	199	85	69		6	119	51	63		6	244	67	140
7	189	87	68		7	116	52	60		7	247	66	145
8	198	85	67		8	113	55	64		8	241	72	153
9	211	89	62		9	122	53	56		9	251	72	131
10	191	86	64		10	112	53	65		10	246	71	134
n	10	10	10		n	10	10	10		n	10	10	10
Average	199	89	65		Average	118	52	63		Average	246	72	143
SD	8	3	5		SD	4	2	3		SD	6	4	7
CV (%)	4.04	3.43	8.23		CV (%)	3.32	3.45	5.10		CV (%)	2.43	4.90	5.18

Average CV: TC 3.26 HDL 3.93 TRIG 6.17

Sample 1	GLU		Sample 7	GLU		Sample 14	GLU
1	62		1	90		1	71
2	66		2	89		2	73
3	66		3	87		3	70
4	67		4	87		4	69
5	66		5	88		5	68
6	64		6	90		6	62
7	58		7	84		7	68
8	58		8	87		8	67
9	58		9	87		9	64
10	64		10	87		10	69
n	10		**n**	10		**n**	10
Average	63		**Average**	88		**Average**	68
SD	4		**SD**	2		**SD**	3
CV (%)	5.83		**CV (%)**	2.03		**CV (%)**	4.72

Average CV: GLU 4.19

Precision Serial Numbers

Sample	19	20	9	1	7	14
Serial #	3025593	3025536	3025508	3025593	3025536	3025508

Risk Classification

Each result was categorized based on Framingham 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 four test systems was rated as a one (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 PA 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 Cholesterol (mg/dL)**		**Triglycerides (mg/dL)**			**Glucose (mg/dL)**	
	<200	200 - 240	>240	<40	≥40	*<150*	*150-200*	*>200*	<126	≥126

Risk Classification Agreement Between Methods Integra

	Total Cholesterol			**HDL Cholesterol**		**Triglycerides**			**Glucose**	
	Agree	**1 Cat Diff**	**2 Cat Diff**	**Agree**	**1 Cat Diff**	**Agree**	**1 Cat Diff**	**2 Cat Diff**	**Agree**	**1 Cat Diff**
AU5400	21	0	0	21	0	20	1	0	21	0
CCPA V1	19	2	0	19	0	15	1	0	21	0
CCPA V2	18	3	0	19	0	17	0	0	21	0
CCPA FS	18	3	0	19	0	19	0	0	21	0
LDX FS	21	0	0	19	0	15	1	0	21	0

Risk Classification Agreement Between Methods Integra

	Total Cholesterol			**HDL Cholesterol**		**Triglycerides**			**Glucose**	
	Agree	**1 Cat Diff**	**2 Cat Diff**	**Agree**	**1 Cat Diff**	**Agree**	**1 Cat Diff**	**2 Cat Diff**	**Agree**	**1 Cat Diff**
CCPA V1	19	2	0	19	0	14	2	0	21	0
CCPA V2	18	3	0	19	0	16	1	0	21	0
CCPA FS	18	3	0	19	0	18	1	0	21	0
LDX FS	21	0	0	19	0	16	0	0	21	0

Raw Data Tables

Total Cholesterol

Sample #	Integra	AU5400	CCPA V1	CCPA V2	CCPA FS	LDX FS
1	175	180	188	200	176	176
2	158	157	156	162	141	156
3	283	282	275	287	269	265
4	145	144	153	146	138	140
5	161	162	154	159	142	161
6	148	149	155	154	141	149
7	199	199	225	212	192	193
8	214	218	225	220	221	223
9	230	232	246	229	249	214
10	223	220	224	229	218	230
11	128	131	122	117	124	132
12	152	154	154	160	151	156
13	152	152	147	156	146	156
14	142	142	126	128	142	142
15	245	246	240	248	235	247
16	227	225	237	245	215	215
17	165	164	170	160	157	158
18	191	188	177	191	186	188
19	193	193	192	189	203	190
20	128	130	120	115	120	123
21	153	153	138	151	142	161

Raw Data Tables

HDL Cholesterol

Sample #	Integra	AU5400	CCPA V1	CCPA V2	CCPA FS	LDX FS
1	75	77	77	81	71	80
2	59	61	58	55	51	52
3	59	63	60	59	59	60
4	40	45	44	40	41	42
5	66	68	70	64	61	64
6	60	61	57	53	56	59
7	66	65	68	66	70	64
8	59	62	61	61	59	69
9	63	66	72	68	72	58
10	120	123	>100	>100	>100	>100
11	61	63	62	62	58	55
12	49	52	56	55	47	53
13	47	48	49	49	44	47
14	49	52	49	55	43	47
15	109	113	>100	>100	>100	>100
16	81	81	90	91	83	83
17	71	72	72	67	60	64
18	55	55	47	54	57	55
19	86	82	84	96	98	82
20	50	52	49	49	49	48
21	60	61	54	57	55	67

Raw Data Tables

Triglycerides

Sample #	Integra	AU5400	CCPA V1	CCPA V2	CCPA FS	LDX FS
1	65	68	66	65	61	70
2	57	58	64	61	84	82
3	84	89	93	77	128	115
4	142	150	119	126	144	154
5	50	53	54	57	66	55
6	40	44	53	<50	51	<45
7	66	71	73	70	74	67
8	94	100	96	105	106	113
9	136	143	153	146	148	132
10	48	55	59	58	65	56
11	36	43	<50	<50	<50	<45
12	83	90	95	94	89	85
13	73	75	85	76	79	78
14	83	83	97	92	94	87
15	62	69	70	69	61	66
16	92	98	96	98	92	96
17	41	42	<50	<50	51	<45
18	46	51	<50	50	55	<45
19	67	71	73	63	82	78
20	58	62	<50	65	65	55
21	28	35	<50	<50	<50	<45

Raw Data Tables

Glucose

Sample #	Integra	AU5400	CCPA V1	CCPA V2	CCPA FS	LDX FS
1	81	83	81	78	80	84
2	90	86	92	85	79	82
3	90	88	85	87	82	85
4	99	101	99	103	107	95
5	85	84	85	85	83	79
6	80	81	83	78	94	90
7	97	94	100	99	101	100
8	82	85	84	84	82	80
9	98	97	98	103	106	91
10	74	75	74	68	74	72
11	86	88	90	89	93	78
12	82	90	84	77	82	75
13	91	90	94	95	95	87
14	78	75	73	76	80	87
15	84	82	78	76	70	73
16	87	87	89	80	84	82
17	83	88	75	74	69	67
18	88	88	80	86	81	82
19	85	84	80	88	88	89
20	84	87	85	89	80	73
21	78	80	70	74	76	71

Overview of Evaluation and Analyses

Evaluation Site
Spectrum Health Systems, Indianapolis, IN

Third Party Comparisons (X-axis)
Beckman Coulter AU5400 (Quest): Serum
Roche Integra (PTS): Serum

Reagents Used
PTS Panels® Lipid Panel Test Strips - Lot: P311
PTS Panels® Glucose Test Strips - Lot: U209

POCT Evaluation Instruments (Y-axis)
CardioChek Analyzers:
3 CardioChek® PA analyzers, Version 2.62
Alere Cholestech LDX analyzer, No. 40 & 13

Data Analyses Performed
All analyses are completed by creating a 2-way table for each analyte, then generating the correlation statistics for the comparison of the results to the Beckman Coulter AU5400 and Roche Integra. These data can then be evaluated graphically and for clinical interpretation.

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 these analyses, a point-by-point comparison was made for each patient evaluating the risk classification category for each result.