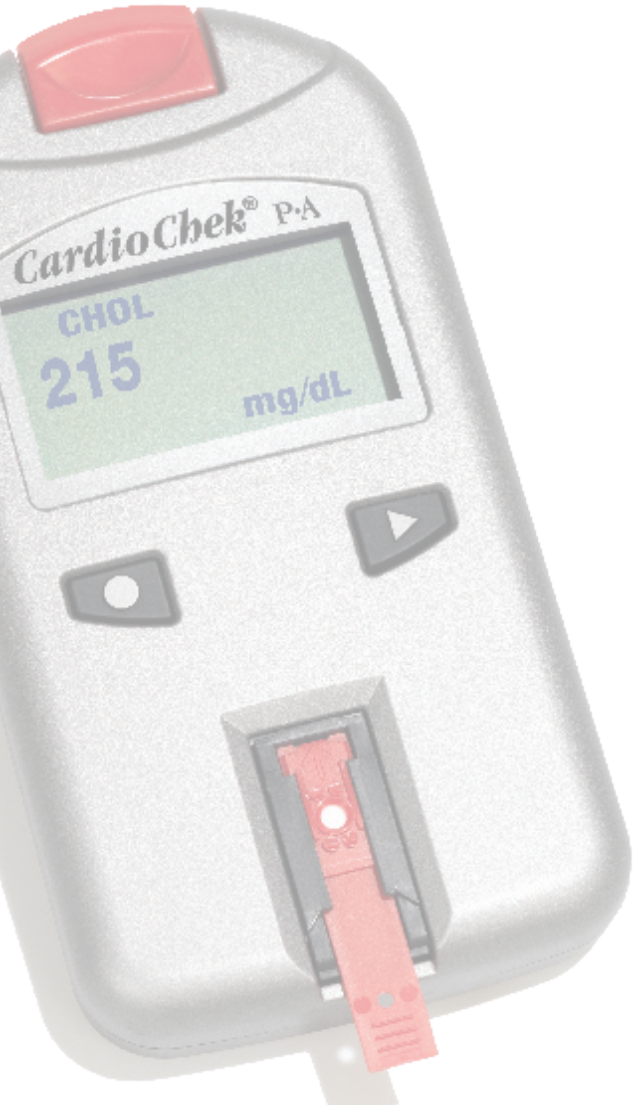
CardioChek®

Evaluation Summary



ProMedica
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Evaluation Summary

The study conducted at ProMedica consisted of a side-by-side comparative analysis of the CardioChek® PA analyzer using PTS Panels® CHOL+HDL+GLU (Total Cholesterol, HDL Cholesterol, Glucose) test strips (CardioChek PA test system or CCPA) compared with the Beckman DxC 800 (DxC 800) and the Roche Integra (Integra). There were 40 participants in this system evaluation. The results of the individual participants 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 participant were assessed as to the degree of agreement in the assignment of heart disease risk using Framingham risk classification. Results of this analysis concluded the CardioChek PA test system produced clinically equivalent results to the reference laboratory. These combined analyses demonstrate that the CardioChek PA test system may be employed with confidence in this clinical setting.

At the test site, the blood was collected by two phlebotomists. Two (2) lithium heparin anti-coagulated (green top) tubes were collected per participant. A fingerstick sample, using a 40µl lithium heparinized glass tube, was collected by a Polymer Technology Systems, Inc. (PTS) employee for CCPA FS on 11 participants; however, due to the limited number of samples, these results are not used for comparison in this report. From one green top tube, the PTS technician pipetted 40µl whole blood for testing on CCPA V1 and CCPA V2. Each sample was tested on the CardioChek PA test system within one hour of collection. The first green top tube was centrifuged, the plasma separated, aliquoted, and shipped “next day” to PTS for testing on the Roche Integra. The second tube was centrifuged within two hours, refrigerated, and held until the evening for testing using the Beckman DxC 800.

Results

The following graphs and tables show the detailed analyses of the relationship of the results from the CardioChek PA test system, the Beckman DxC 800, and the Roche Integra.

These analyses indicate that the CardioChek PA test system produces clinically equivalent results when compared to the reference labs. The linear regression data shows a strong correlation between the POCT method and the reference laboratory method for all analytes tested. Further, the risk classification tables indicate that the CardioChek PA test system is 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) are as follows:

CCPA (Averaged)

- Total Cholesterol: 0.6%
- HDL Cholesterol: 1.2%
- Glucose: 8.1%

DxC 800

- Total Cholesterol: 0.9%
- HDL Cholesterol: -2.0%
- Glucose: 5.4%

Actual paired % differences with the DxC analyzer ((CCPA Result – DxC Lab Result) ÷ DxC Lab Result) are as follows:

CCPA (Averaged)

- Total Cholesterol: -0.3%
- HDL Cholesterol: 4.0%
- Glucose: 2.8%

As shown in the tables below, the calculated average biases (based upon the linear regression analyses) for the venous samples at the clinical decision points versus the Integra analyzer were 1.3% for Total Cholesterol, 4.9% for HDL

Cholesterol, and 8.2% for Glucose on the CCPA. Versus the DxC laboratory analyzer, the Total Cholesterol was 0.6%, HDL Cholesterol was -2.6%, and Glucose was 5.1%.

The calculated average biases (based upon the linear regression analyses) for the CCPA samples at the clinical decision points versus the DxC analyzer were 0.6% for Total Cholesterol, 8.0% for HDL Cholesterol, and 2.6% for Glucose.

Precision analyses were performed by testing 10 replicates of three samples using PTS Panels® CHOL+HDL+GLU 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. In the tables below, those ranges that have insufficient data to allow a valid calculation are noted.

Total Cholesterol

vs Integra	DxC 800	CCPA V1	CCPA V2
N	40	40	39
slope	1.0	1.1	1.1
intercept	5.3	-11.8	-15.1
R	0.993	0.936	0.932
vs DxC		CCPA V1	CCPA V2
slope		1.1	1.1
intercept		-18.0	-20.5
R		0.944	0.929

Total Cholesterol Predicted Biases

Integra	DxC 800	% bias	CCPA V1	% bias	CCPA V2	% bias
160	162	1.2%	160	0.2%	159	-0.5%
200	201	0.5%	203	1.5%	203	1.5%
240	240	0.1%	246	2.5%	246	2.5%
280	Data Insufficient to Evaluate					
	Average bias	0.6%		1.4%		1.2%

Total Cholesterol Predicted Biases

DxC 800	CCPA V1	% bias	CCPA V2	% bias
160	158	-1.1%	157	-1.9%
200	202	1.1%	201	0.7%
240	246	2.5%	246	2.5%
280	Data Insufficient to Evaluate			
	Average bias	0.8%		0.4%

HDL Cholesterol

vs Integra	DxC 800	CCPA V1	CCPA V2
N	40	38	39
slope	1.0	1.0	1.1
intercept	-0.8	0.4	-0.2
R	0.979	0.930	0.952
vs DxC		CCPA V1	CCPA V2
slope		1.1	1.1
intercept		0.8	-1.2
R		0.903	0.934

HDL Cholesterol Predicted Biases

Integra	DxC 800	% bias	CCPA V1	% bias	CCPA V2	% bias
40	39	-3.1%	42	5.0%	42	5.0%
60	59	-2.5%	62	4.1%	63	5.7%
80	78	-2.1%	83	3.9%	85	5.8%
100	Data Insufficient to Evaluate					
Average bias		**-2.6%**		**4.3%**		**5.5%**

HDL Cholesterol Predicted Biases

DxC800	CCPA V1	% bias	CCPA V2	% bias
40	43	7.50%	43	7.50%
60	64	7.04%	65	9.17%
80	85	6.72%	88	9.68%
100	Data Insufficient to Evaluate			
Average bias		**7.1%**		**8.8%**

Glucose

vs Integra	DxC 800	CCPA V1	CCPA V2
N	40	40	40
slope	1.0	1.1	1.0
intercept	3.0	-6.2	3.7
R	0.945	0.945	0.906
vs DxC		CCPA V1	CCPA V2
slope		1.1	0.9
intercept		-3.0	9.3
R		0.941	0.876

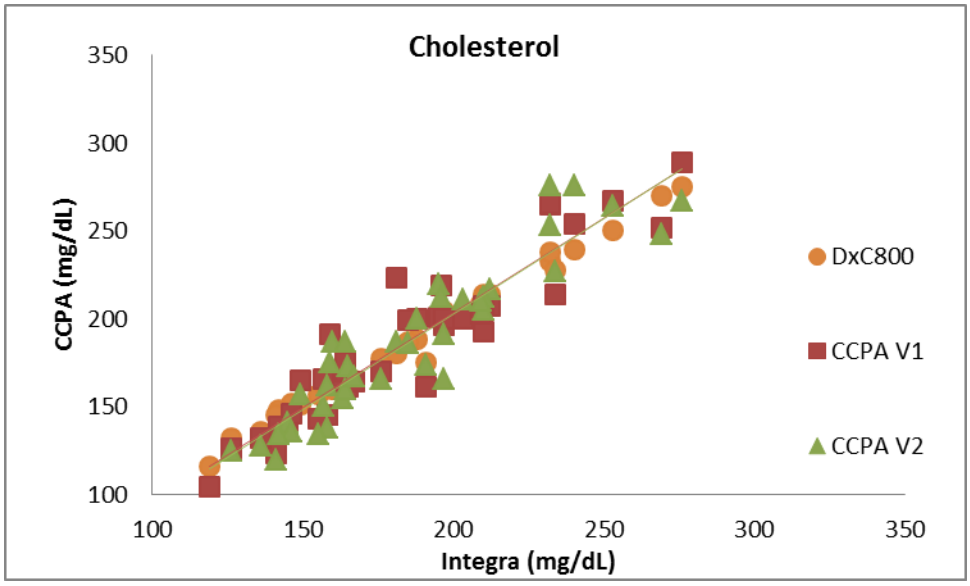
Glucose Predicted Biases

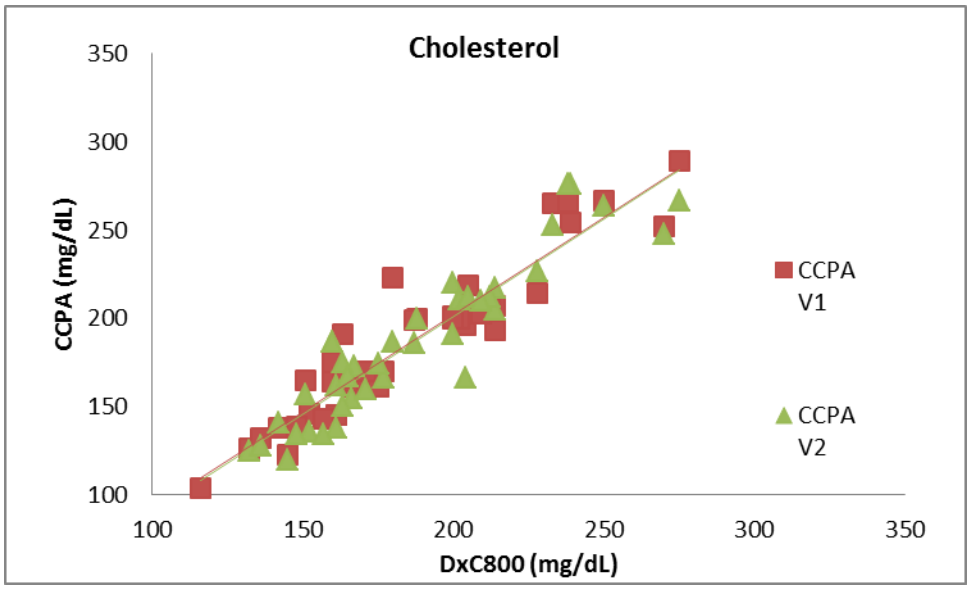
Integra	DxC 800	% bias	CCPA V1	% bias	CCPA V2	% bias
100	105	5.1%	109	8.8%	108	7.6%
150	Data Insufficient to Evaluate					
200						
250						
Average bias		5.1%		8.8%		7.6%

Glucose Predicted Biases

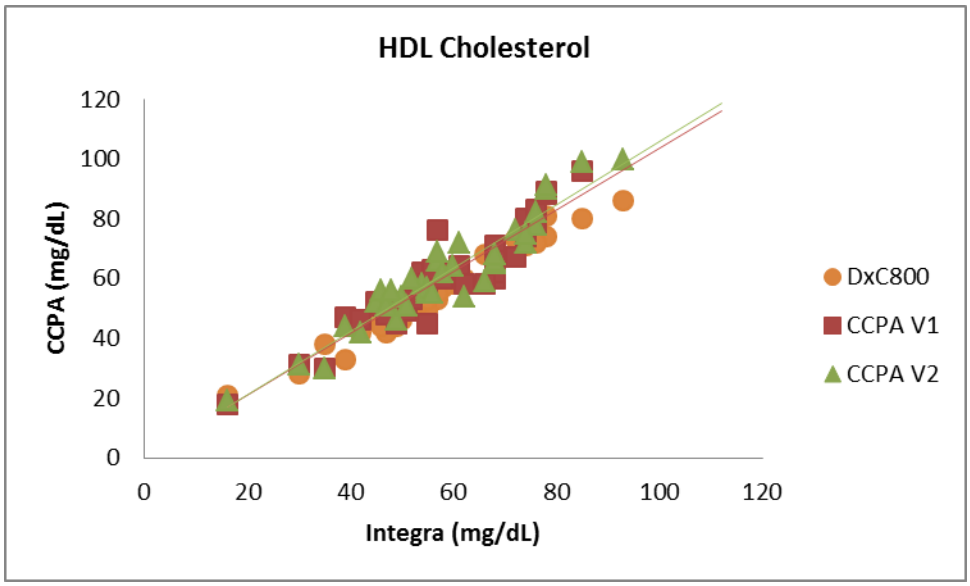
DxC 800	CCPA V1	% bias	CCPA V2	% bias
100	103	2.9%	102	2.2%
150	Data Insufficient to Evaluate			
200				
250				
Average bias		2.9%		2.2%

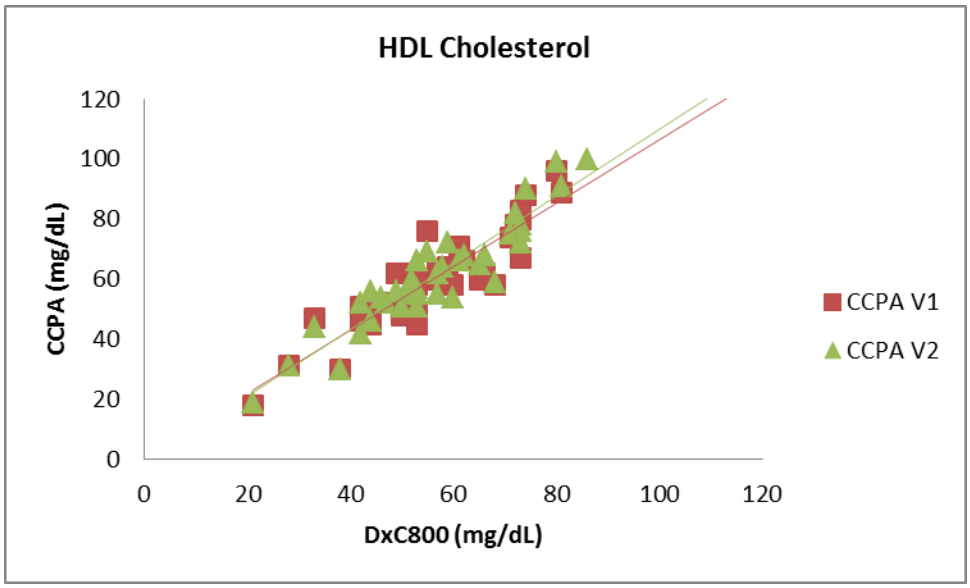
Linear Regression Analyses



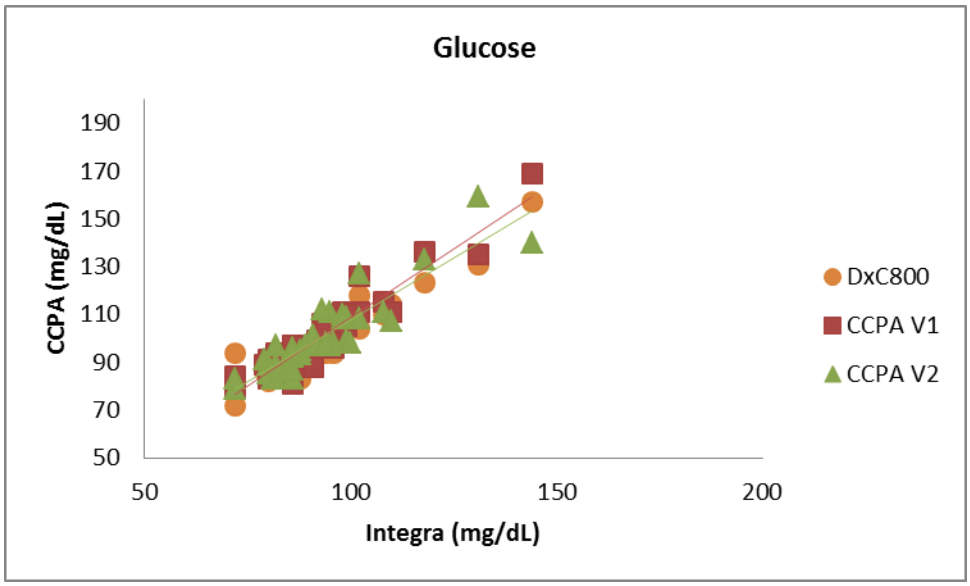


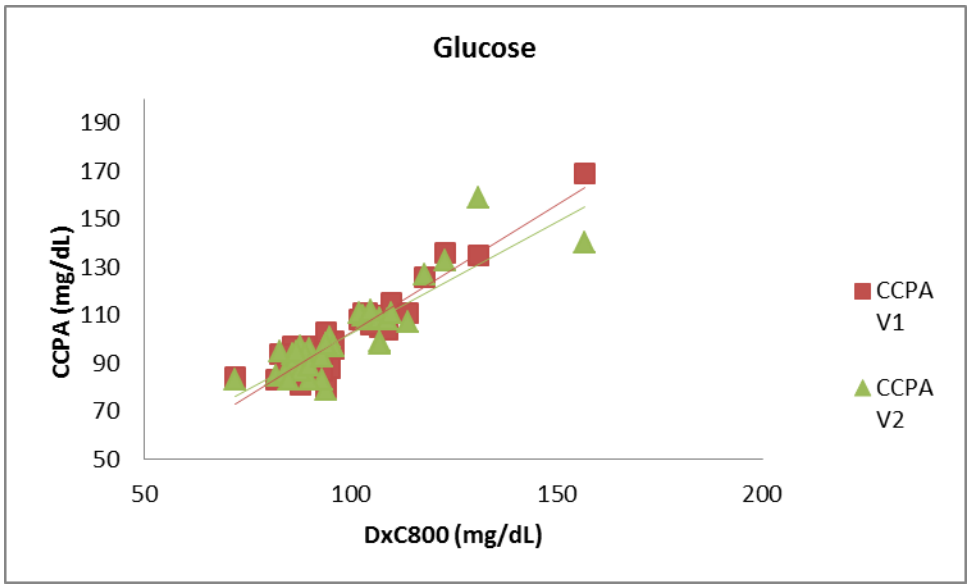
Linear Regression Analyses, Continued





Linear Regression Analyses, Continued





Precision Analyses

	High			Mid			Low		
	CHOL	HDL	GLU	CHOL	HDL	GLU	CHOL	HDL	GLU
1	207	76	100	263	48	132	109	22	97
2	199	64	116	273	48	127	111	22	100
3	179	64	102	237	43	132	110	19	101
4	203	80	99	270	45	134	113	20	106
5	187	72	111	262	42	132	109	20	104
6	209	67	106	238	47	132	103	20	105
7	203	68	103	236	49	144	118	17	108
5	212	73	98	263	45	123	104	18	108
9	209	81	90	262	46	121	119	19	96
10	198	64	112	256	45	122	110	20	95
n	10	10	10	10	10	10	10	10	10
Average:	200.6	70.9	103.7	256.0	45.8	129.9	110.6	19.7	102.0
SD	10.5	6.5	7.7	13.9	2.3	6.9	5.2	1.6	4.9
CV (%)	5.2	9.2	7.5	5.4	4.9	5.3	4.7	8.0	4.8

	CHOL	HDL	GLU
Average %CV	5.1%	7.4%	5.9%

Serial Number: 30203380

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 two test systems was rated as a one 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 comparator and the reference laboratory result.

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

Risk Classification Agreement Between Methods and Integra							
	Total Cholesterol			HDL Cholesterol		Glucose	
	Agree	1 Cat Diff	2 Cat Diff	Agree	1 Cat Diff	Agree	1 Cat Diff
DxC 800	35	5	0	40	0	40	0
CCPA V1	32	8	0	39	1	38	2
CCPA V2	35	5	0	39	1	38	2

Risk Classification Agreement Between Methods DxC							
	Total Cholesterol			HDL Cholesterol		Glucose	
	Agree	1 Cat Diff	2 Cat Diff	Agree	1 Cat Diff	Agree	1 Cat Diff
CCPA V1	33	7	0	39	1	38	2
CCPA V2	34	6	0	39	1	38	2

Raw Data Tables

CHOLESTEROL

Sample #	DxC 800	Integra	CCPA V1	CCPA V2	CCPA fingerstick
1	161	158	145	162	
2	166	163	164	155	
3	151	149	165	157	
4	204	197	196	166	
5	200	195	201	220	
6	233	232	265	253	
7	167	165	161	173	
8	161	158	145	138	
9	142	145	138	141	
10	177	176	170	166	
11	132	126	126	125	
12	180	181	223	187	
13	175	191	161	174	
14	160	160	164	187	**179**
15	202	203	200	211	
16	250	253	267	264	**263**
17	275	276	289	267	**294**
18	152	146	146	136	
19	116	119	104	<100	
20	214	212	207	217	**251**
21	171	164	170	160	**188**
22	148	142	139	134	
23	270	269	252	248	
24	214	210	193	205	**227**
25	157	155	143	134	
26	145	141	123	120	
27	136	136	132	128	
28	205	196	219	212	**236**
29	239	240	254	276	
30	212	210	207	212	
31	238	232	266	276	
32	228	234	214	227	
33	200	197	200	191	**231**
34	188	188	200	200	**206**
35	160	164	175	187	
36	187	185	199	186	
37	163	159	191	175	
38	165	167	164	167	
39	209	209	203	210	**211**
40	163	157	166	150	**179**

Raw Data Tables

HDL CHOLESTEROL

Sample #	DxC 800	Integra	CCPA V1	CCPA V2	CCPA fingerstick
1	65	68	60	65	
2	66	68	62	68	
3	58	60	62	64	
4	42	47	51	52	
5	59	61	64	72	
6	33	39	47	44	
7	73	74	80	72	
8	61	68	71	66	
9	53	57	60	66	
10	47	45	52	52	
11	73	76	83	78	
12	80	85	96	99	
13	73	72	67	76	
14	49	55	62	56	**65**
15	52	54	62	58	
16	86	93	>100	100	**>100**
17	46	50	52	54	**47**
18	62	68	66	68	
19	21	16	18	19	
20	74	78	88	90	**82**
21	44	46	51	56	**48**
22	28	30	31	31	
23	53	55	58	55	
24	72	76	78	82	**83**
25	60	62	58	54	
26	44	49	45	46	
27	38	35	30	30	
28	122	112	>100	>100	**>100**
29	50	47	48	51	
30	57	58	60	62	
31	81	78	89	91	
32	53	51	49	51	
33	53	55	45	57	**54**
34	51	48	52	56	**54**
35	57	56	63	55	
36	52	52	53	60	
37	55	57	76	69	
38	42	42	46	42	
39	71	74	74	75	**71**
40	68	66	58	59	**58**

Raw Data Tables

GLUCOSE

Sample #	DxC 800	Integra	CCPA V1	CCPA V2	CCPA fingerstick
1	94	72	80	79	
2	86	79	89	91	
3	90	86	96	96	
4	104	102	111	108	
5	103	98	111	110	
6	118	102	126	127	
7	86	86	97	94	
8	107	99	105	99	
9	107	100	108	98	
10	107	99	110	109	
11	95	91	88	101	
12	93	86	87	83	
13	90	81	84	83	
14	123	118	136	133	**121**
15	102	95	108	111	
16	87	80	91	89	**85**
17	109	98	104	108	**96**
18	88	86	93	92	
19	105	93	106	112	
20	72	72	84	83	**112**
21	88	82	94	97	**116**
22	157	144	169	140	
23	96	89	96	97	
24	110	108	115	111	**138**
25	82	80	83	85	
26	87	86	91	92	
27	84	84	88	86	
28	131	131	135	159	**144**
29	89	86	97	94	
30	96	95	98	97	
31	83	88	94	95	
32	94	96	96	98	
33	88	86	81	87	**85**
34	96	92	99	97	**103**
35	85	82	83	83	
36	90	82	91	89	
37	93	88	94	93	
38	114	110	111	107	
39	87	86	90	95	**97**
40	94	94	103	98	**114**

Overview of Evaluation and Analyses

Evaluation Site
ProMedica Inc., Toledo, OH

Third Party Comparisons (X-axis)
Roche Integra Specimen: Plasma
Beckman DxC 800: Plasma

Reagents Used
PTS Panels® CHOL+HDL+GLU Test Strips - Lot: I301

POCT Evaluation Instruments (Y-axis)
CardioChek Devices:
3 CardioChek® PA analyzers, Version 2.62
Serial #s 3020525, 3020477, 3020380
Specimen: Heparinized venous whole blood

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. 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.