CardioChek®

Evaluation Summary

DuPage Medical Group
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Evaluation Summary

The study conducted at DuPage Medical Group consisted of a side-by-side comparative analysis of the CardioChek® PA analyzer using PTS Panels® Lipid Panel test strips (CardioChek PA test system or CCPA) compared with the Siemens Dimension EXL 200 (Dimension) 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 one phlebotomist using one (1) lithium heparin anti-coagulated (green top) tube and one (1) serum separator (red top) tube per participant. A fingerstick sample, using a 40µl lithium heparinized glass tube, was collected by a Polymer Technology Systems, Inc. (PTS) employee for CCPA #3 on 8 participants; however, due to the limited number of samples, these results are not used for comparison in this report. From the green top tube, the PTS technician pipetted 40µl whole blood for testing on CCPA #1 and #2. Each sample was tested on the CardioChek PA test system within one hour of collection. The green top tube was then centrifuged, and the plasma separated and shipped “next day” to PTS for testing using the Integra. The red top tube was centrifuged within two hours, refrigerated, and sent the following morning to the main lab for testing using the Dimension.

Results

The following graphs and tables show the detailed analyses of the relationship of the results from the CardioChek PA test system, the Siemens Dimension EXL 200, 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) for Total Cholesterol averaged -5.8% for CCPA and -3.4% for the Dimension, for HDL Cholesterol averaged 7.9% for CCPA and -5.5% for the Dimension, and for Triglycerides averaged 11.4% for CCPA and -5.8% for the Dimension.

Actual paired % differences with the Dimension analyzer ((CCPA Result – Dimension Lab Result) ÷ Dimension Lab Result) for Total Cholesterol averaged -2.4%, for HDL Cholesterol averaged 14.4%, and for Triglycerides averaged 19.3%.

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 -6.1% for Total Cholesterol, 7.8% for HDL Cholesterol, and 2.9% for Triglycerides on the CCPA, and -3.2% for Total Cholesterol, -5.7% for HDL Cholesterol, and -3.8% for Triglycerides on the Dimension laboratory analyzer.

The calculated average biases (based upon the linear regression analyses) for the CCPA samples at the clinical decision points versus the Dimension analyzer were -3.4% for Total Cholesterol, 13.7% for HDL Cholesterol, and 6.0% for Triglycerides.

For the linear regression analyses of Triglycerides, a single result exceeding 300 mg/dL on all systems was excluded. This value caused substantial skewing of the analyses as it is significantly different from the remainder of the data set.

Precision analyses were performed by testing 10 replicates of three samples using PTS Panels® Lipid Panel 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	**Dimension**	**CCPA1**	**CCPA2**
N	40	40	40
slope	1.02	0.85	0.88
intercept	-9.8	17.2	12.1
R	0.995	0.897	0.932
vs Dimension		**CCPA1**	**CCPA2**
slope		0.83	0.85
intercept		25.6	22.0
R		0.901	0.928

Total Cholesterol Predicted Biases						
Integra	**Dimension**	**% diff**	**CCPA1**	**% diff**	**CCPA2**	**% diff**
160	153	-4.31%	153	-4.19%	152	-4.75%
200	194	-3.08%	187	-6.35%	187	-6.26%
240	235	-2.26%	221	-7.78%	223	-7.27%
280	not calculated as <2 values on laboratory analyzer					
Average bias		**-3.22%**		**-6.11%**		**-6.09%**

Total Cholesterol Predicted Biases				
Dimension	**CCPA1**	**% diff**	**CCPA2**	**% diff**
160	159	-0.58%	159	-0.91%
200	192	-3.78%	193	-3.66%
240	226	-5.91%	227	-5.50%
280	not calculated as <2 values on laboratory analyzer			
Average bias		**-3.42%**		**-3.35%**

HDL Cholesterol			
vs Integra	**Dimension**	**CCPA1**	**CCPA2**
N	40	40	40
slope	1.03	1.04	1.10
intercept	-4.9	1.4	-0.1
R	0.997	0.954	0.944
vs Dimension		**CCPA1**	**CCPA2**
slope		0.99	1.07
intercept		7.0	4.9
R		0.946	0.934

HDL Cholesterol Predicted Biases						
Integra	**Dimension**	**% diff**	**CCPA1**	**% diff**	**CCPA2**	**% diff**
40	36	-9.02%	43	7.36%	44	9.19%
60	57	-4.97%	64	6.16%	66	9.30%
80	78	-2.94%	84	5.55%	87	9.35%
100	not calculated as < 2 values on laboratory analyzer					
Average bias		**-5.65%**		**6.36%**		**9.28%**

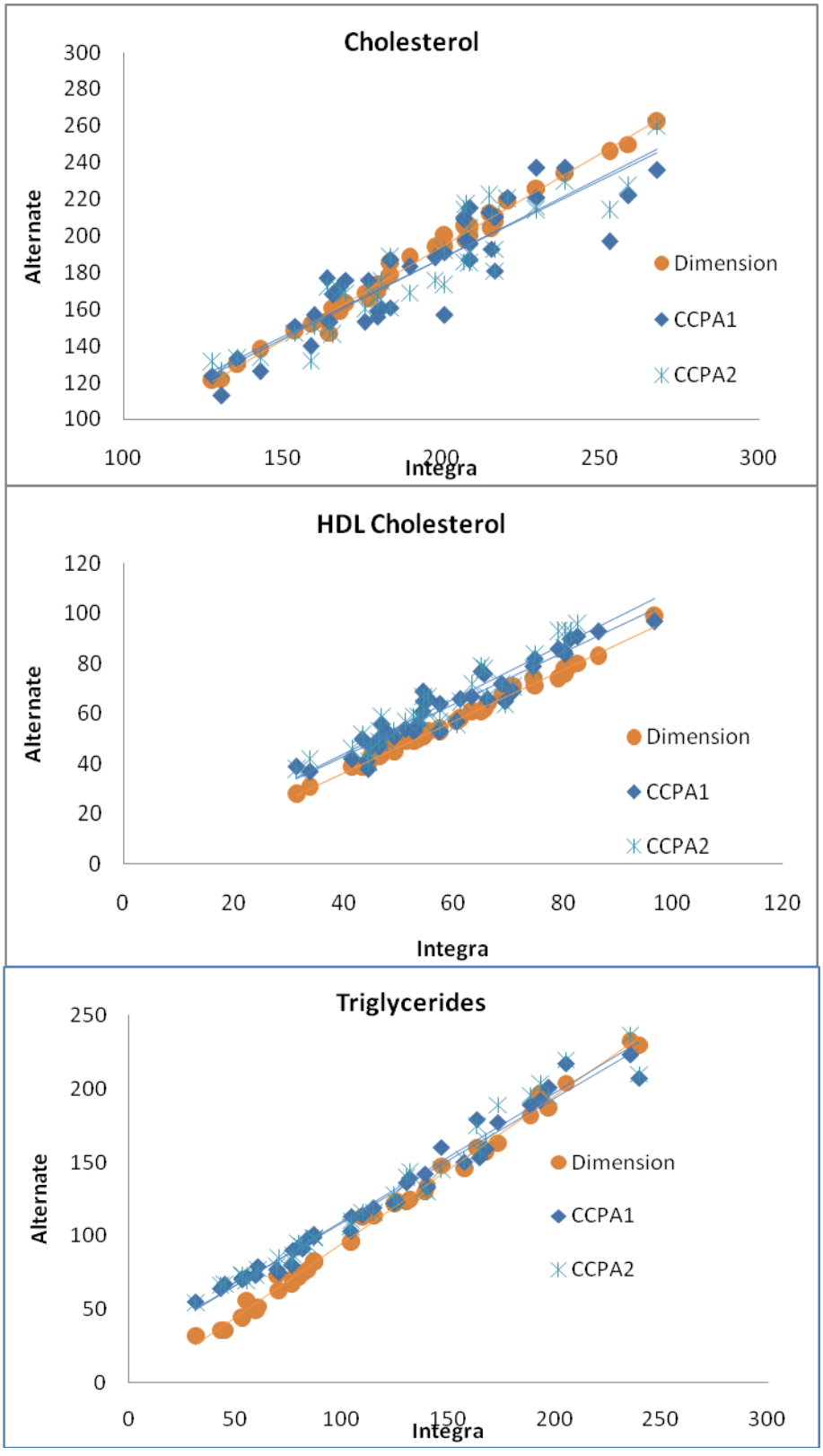
HDL Cholesterol Predicted Biases				
Dimension	**CCPA1**	**% diff**	**CCPA2**	**% diff**
40	47	16.91%	48	18.82%
60	67	11.10%	69	14.73%
80	87	8.19%	90	12.69%
100	not calculated as <2 values on laboratory analyzer			
Average bias		**12.07%**		**15.42%**

Triglycerides (excluding 1 value, see text)			
vs Integra	**Dimension**	**CCPA1**	**CCPA2**
N	40	40	40
slope	1.00	0.85	0.88
intercept	-5.6	23.6	21.8
R	0.997	0.987	0.987
vs Dimension		**CCPA1**	**CCPA2**
slope		0.85	0.83
intercept		24.1	26.7
R		0.992	0.988

Triglycerides						
Integra	**Dimension**	**% diff**	**CCPA1**	**% diff**	**CCPA2**	**% diff**
100	95	-5.33%	109	8.74%	110	9.59%
150	145	-3.46%	151	0.86%	153	2.31%
200	195	-2.52%	194	-3.08%	197	-1.32%
250	not calculated as <2 values on laboratory analyzer					
Average bias		**-3.77%**		**2.17%**		**3.53%**

Triglycerides				
Integra	**CCPA1**	**% diff**	**CCPA2**	**% diff**
100	113	13.30%	114	14.30%
150	156	3.72%	158	5.25%
200	198	-1.07%	201	0.73%
250	not calculated as <2 values on laboratory analyzer			
Average bias		**5.32%**		**6.76%**

Linear Regression Analyses



Precision Analyses

CCPA SN: 3017419

Sample 3	TC	HDL	Trig		Sample 6	TC	HDL	Trig		Sample 15	TC	HDL	Trig
1	124	45	98		1	171	42	216		1	253	47	253
2	134	46	100		2	165	41	213		2	251	49	254
3	129	43	99		3	166	41	212		3	250	51	233
4	125	40	99		4	185	42	211		4	250	51	226
5	147	46	98		5	165	40	197		5	243	46	238
6	123	42	99		6	171	39	208		6	240	47	238
7	125	43	98		7	170	38	224		7	240	50	243
5	133	43	99		8	186	39	212		8	243	46	237
9	130	46	97		9	175	39	241		9	243	47	249
10	140	48	101		10	170	42	206		10	241	48	238
n	10	10	10		n	10	10	10		n	10	10	10
Average:	131.0	44.2	98.8		Average:	172.4	40.3	214.0		Average:	245.4	48.2	240.9
SD	7.75	2.39	1.14		SD	7.57	1.49	11.74		SD	5.02	1.93	8.90
CV (%)	5.91	5.42	1.15		CV (%)	4.39	3.71	5.48		CV (%)	2.04	4.01	3.69

Avg. CV: **TC:** 4.12
HDL: 4.38
Trig: 3.44

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**.** There was a single two category difference observed in this clinical evaluation for Total Cholesterol. The laboratory values (253 mg/dL Integra and 246 mg/dL Dimension) were slightly (2-5%) above the risk categorization limit of 240. The CCPA1 analyzer reported a 197 mg/dL result; a 1% variation from the one category difference cut-off at 200 mg/dL.

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

Risk Classification Agreement Between Methods and Integra								
	Total Cholesterol			**HDL Cholesterol**		**Triglycerides**		
	Agree	**1 Cat Diff**	**2 Cat Diff**	**Agree**	**1 Cat Diff**	**Agree**	**1 Cat Diff**	**2 Cat Diff**
Dimension	38	2	0	38	2	39	1	0
CCPA1	30	9	1	39	1	38	2	0
CCPA2	31	9	0	39	1	39	1	0

Risk Classification Agreement Between Methods Integra								
	Total Cholesterol			**HDL Cholesterol**		**Triglycerides**		
	Agree	**1 Cat Diff**	**2 Cat Diff**	**Agree**	**1 Cat Diff**	**Agree**	**1 Cat Diff**	**2 Cat Diff**
CCPA1	32	7	1	37	3	38	2	0
CCPA2	31	9	0	37	3	39	1	0

Overview of Evaluation and Analyses

Evaluation Site
DuPage Medical Group, Glen Ellyn, IL

Third Party Comparisons (X-axis)
Roche Integra Specimen: Plasma
Siemens Dimension EXL 200 Specimen: Serum

Reagents Used
PTS Panels® Lipid Panel Test Strips - Lot: P224

POCT Evaluation Instruments (Y-axis)
CardioChek Devices:
2 CardioChek® PA, Version 2.62
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 the following analyses, a point by point comparison was made for each patient evaluating the risk classification category for each result.

Raw Data Tables

CHOLESTEROL

Sample #	Dimension	Integra	CCPA1 venous	CCPA2 venous	CCPA2 fingerstick
1	204	216	193	210	
2	174	181	160	175	200
3	152	159	140	132	
4	194	198	188	176	
5	185	184	161	161	
6	153	164	177	172	
7	169	176	153	160	
8	262	268	236	260	262
9	206	207	209	214	
10	205	209	187	185	
11	208	217	210	193	
12	226	230	221	216	
13	194	201	157	173	
14	211	217	181	181	
15	234	239	237	230	
16	205	207	210	186	
17	200	201	191	192	
18	159	168	172	170	161
19	198	208	198	217	
20	147	165	153	150	
21	148	154	151	147	
22	250	259	222	227	302
23	174	180	159	167	
24	188	190	183	169	
25	122	131	113	127	
26	219	221	221	220	
27	226	230	237	214	
28	138	143	126	134	
29	246	253	197	214	
30	204	209	215	204	
31	212	215	213	222	233
32	153	160	157	151	
33	121	128	124	131	
34	179	184	187	189	
35	166	177	176	172	174
36	163	170	176	169	
37	130	136	133	133	
38	170	180	156	164	164
39	161	166	168	146	146
40	200	209	196	190	

Raw Data Tables

HDL CHOLESTEROL

Sample #	Dimension	Integra	CCPA1 venous	CCPA2 venous	CCPA2 fingerstick
1	39	42	42	46	
2	49	51	54	57	57
3	43	45	47	46	
4	71	71	69	71	
5	74	75	79	78	
6	31	34	37	42	
7	44	46	50	53	
8	74	79	86	93	75
9	51	55	69	67	
10	67	70	65	64	
11	83	87	93	>100	>100
12	61	63	67	72	
13	53	58	64	62	
14	40	45	38	41	
15	39	43	50	52	
16	79	81	90	93	
17	99	97	97	>100	>100
18	44	47	56	59	49
19	62	66	76	78	
20	28	31	39	38	
21	58	61	66	65	
22	71	75	82	84	89
23	54	58	53	57	
24	64	66	66	67	
25	40	44	41	45	
26	78	80	85	86	
27	61	65	77	79	
28	43	47	47	49	
29	57	61	57	56	
30	54	58	53	55	
31	46	48	53	49	48
32	52	54	61	57	
33	50	54	56	59	
34	51	55	65	62	
35	53	56	66	67	56
36	76	80	84	93	
37	45	49	51	53	
38	67	69	72	72	65
39	49	53	53	59	56
40	80	83	91	96	

Raw Data Tables

TRIGLYCERIDES

Sample #	Dimension	Integra	CCPA1 venous	CCPA2 venous	CCPA2 fingerstick
1	163	173	177	189	
2	97	104	113	110	81
3	96	104	103	106	
4	36	43	64	66	
5	72	79	92	95	
6	204	205	217	220	
7	148	146	160	145	
8	122	124	122	128	134
9	73	69	77	79	
10	45	53	71	73	
11	130	139	142	132	
12	83	87	101	98	
13	134	140	133	130	
14	159	164	153	158	
15	233	235	223	237	
16	52	60	79	77	
17	49	59	73	73	
18	123	130	136	140	189
19	157	167	159	165	
20	365	381	345	323	
21	114	115	119	116	
22	125	132	139	144	118
23	75	81	91	93	
24	113	109	114	116	
25	124	126	123	123	
26	44	53	70	73	
27	182	188	189	196	
28	82	87	99	99	
29	63	70	75	85	
30	71	77	90	87	
31	197	193	192	204	185
32	56	55	72	69	
33	32	31	55	54	
34	160	163	179	175	
35	187	197	201	195	216
36	36	45	67	67	
37	230	239	207	210	
38	67	76	80	83	119
39	77	84	98	94	74
40	146	157	150	152	