



A n E v a l u a t i o n

o f t h e

CardioChek® PA

Cholesterol

Test System,

Health Designs



An Evaluation of the CardioChek[®] PA Cholesterol Test System

Introduction

An evaluation of the CardioChek[®] PA cholesterol test system was conducted at Health Designs, Inc., located at 35 Executive Way, Suite 110, Ponte Vedra Beach, FL 32082. The date of the evaluation was February 18th, 2009.

Objectives

A method comparison of Cholesterol, Triglycerides, and HDL Cholesterol testing results using venous blood samples. The methods being compared are the CardioChek[®]PA (CCPA) point-of-care (POC) instrument versus test results from Quest Diagnostics, Inc.

A method comparison of Cholesterol, Triglycerides, and HDL Cholesterol testing results of fingerstick capillary samples and venous blood samples drawn from the same patients. The methods being compared are the test results from a CCPA analyzer with fingerstick capillary samples versus the results from serum blood samples sent to Quest Diagnostics.

Protocol

- Whole blood and serum samples were collected by venipuncture from 37 subjects.
- Heparinized whole blood from each subject was tested on two CCPA point-of-care instruments.
- Serum from each patient was sent to Quest Diagnostics Laboratory.
- All but one subject had additional capillary blood drawn by fingerstick.
- The capillary specimens were run on a third CCPA (CCPA3) point-of-care instrument.
- PTS Panels[™] Lipid Panel test strips from Polymer Technology Systems, Inc. were used on the CCPA point-of-care instrument.
- Three sets of Data were analyzed for average deviation and linear regression: CCPA1 vs Quest (venous blood vs serum); CCPA2 vs Quest (venous blood vs serum); and CCPA3 vs Quest (capillary blood vs serum).
- For each patient result from the CCPA point-of-care instruments the percent (%) deviation was calculated versus the Quest results. The average (mean) deviation of all sample results was then calculated.
- The slope of the regression line, the y-intercept, and the coefficient of determination (R²; R being the correlation coefficient) was determined by a linear regression analysis of all sample results using Quest results as the X axes, and the CCPA point-of-care instruments on the Y axes.
- The slope and y-intercept values were used to determine what the CCPA values would be vs actual Quest values at clinical application levels.
- Clinical application levels used were Cholesterol:160,200,240,280; HDL:40,60,80,100; Triglycerides: 100,150,200,250

Results

The tables on the following pages contain the results obtained for each CardioChek PA point-of-care instrument vs the results from Quest Diagnostics. Percent deviation was obtained for each subject and the average deviation was calculated and compared to expected results. In every case, the average deviation was less than the expected result.

Linear regression analysis was performed on the data for each CardioChek PA point-of-care instrument vs the results from Quest Diagnostics. The graphs and clinical application points are shown on the pages following each table. Predictive values were obtained for each analyte by using the y-intercept and slope obtained in the linear regression.

Discussion

In some cases the test result for the CardioChek PA cholesterol test system was reported by the point-of-care instrument as less than or greater than the limit of detection for this instrument. See patient number 19, for example, in Table number 1, which was reported as <50. For calculation purposes, this result is reported as 50 in the data table, and in the regression analysis. The actual result from the reference lab is also reported for comparison purposes.

For a bias study, a minimum of 20 patients should be used so that the data is statistically relevant. The assay ranges for the patients selected should encompass the dynamic range of the CardioChek Lipid Panel assays and be distributed to the extent possible as indicated in the sample distribution table below. Note that it is often difficult to fulfill this requirement with just 20 donors. The more donors that can be used the greater the confidence in the analysis of the comparison; thus 20 is a minimum and 30 to 40 donors is preferred. This study contains 37 donors with good distribution, and therefore should be considered statistically relevant.

Sample Distribution Table

TEST	MEASURING RANGE	BIN 1 RANGE % SAMPLES	BIN 2 RANGE % SAMPLES	BIN 3 RANGE % SAMPLES	BIN 4 RANGE % SAMPLES	BIN 5 RANGE % SAMPLES
Cholesterol	100-400 mg/dL	100-160 mg/dL 15%	161-199 mg/dL 25%	200-239 mg/dL 25%	240-280 mg/dL 25%	>280 mg/dL 10%
HDL Cholesterol	15-100 mg/dL	15-35 mg/dL 15%	36-45 mg/dL 25%	46-55 mg/dL 25%	56-70 mg/dL 25%	>70 mg/dL 10%
Triglycerides	50-500 mg/dL	50-100 mg/dL 15%	101-150 mg/dL 25%	151-200 mg/dL 25%	201-300 mg/dL 25%	>300 mg/dL 10%

Linear regression analysis was performed using the formula $y=mx+b$, where the laboratory reference method = x, the CCPA value = y, m = the slope of the curve, and b = the y-intercept. This analysis provides information pertaining to the overall relationship of each individual data set and the data collection as a whole. From the linear regression analysis we are able to develop a clinical application model to essentially predict what the CCPA value would be at clinical cutoff points in respect to the reference method. This offers valuable insight to the accuracy and precision of the instrument and its relation to patient care.

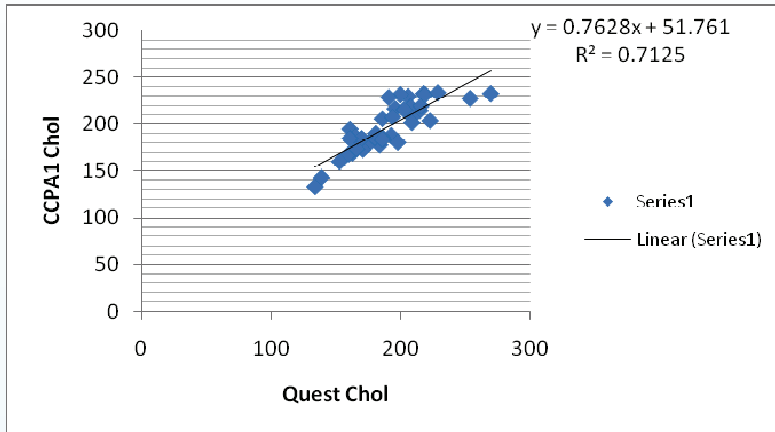
Table 1. CardioChek PA #1 (heparinized plasma) Correlation Versus Quest Serum Sample: Average Deviation

Table 1.

PATIENT ID	CARDIOCHEK PA #1			QUEST			% DEVIATION			ACTUAL RESULT
	CHOL	HDL	TRIG	CHOL	HDL	TRIG	CHOL	HDL	TRIG	
1	188	44	124	193	51	124	-2.6%	-13.7%	0.0%	
2	195	50	102	161	54	100	21.1%	-7.4%	2.0%	
3	230	32	107	206	36	116	11.7%	-11.1%	-7.8%	
4	178	67	77	184	65	86	-3.3%	3.1%	-10.5%	
5	133	27	111	134	33	116	-0.7%	-18.2%	-4.3%	
6	233	25	443	270	35	536	-13.7%	-28.6%	-17.4%	
7	179	35	265	175	41	255	2.3%	-14.6%	3.9%	
8	217	63	81	196	66	91	10.7%	-4.5%	-11.0%	
9	173	60	123	171	58	131	1.2%	3.4%	-6.1%	
10	186	65	94	180	63	103	3.3%	3.2%	-8.7%	
11	233	66	114	218	72	109	6.9%	-8.3%	4.6%	
12	232	100	65	200	83	72	16.0%	20.5%	-9.7%	
13	215	65	118	215	57	140	0.0%	14.0%	-15.7%	
14	219	91	112	208	81	109	5.3%	12.3%	2.8%	
15	187	66	84	165	61	84	13.3%	8.2%	0.0%	
16	169	51	119	163	54	136	3.7%	-5.6%	-12.5%	
17	208	53	372	209	43	380	-0.5%	23.3%	-2.1%	
18	160	81	78	153	71	68	4.6%	14.1%	14.7%	
19	220	94	50	216	75	50	1.9%	25.3%	0.0%	<50, 47
20	186	66	56	186	67	54	0.0%	-1.5%	3.7%	
21	232	70	125	219	59	120	5.9%	18.6%	4.2%	
22	202	47	224	209	38	207	-3.3%	23.7%	8.2%	
23	190	58	116	181	62	114	5.0%	-6.5%	1.8%	
24	168	71	107	160	67	112	5.0%	6.0%	-4.5%	
25	184	83	89	186	79	68	-1.1%	5.1%	30.9%	
26	228	70	110	254	65	118	-10.2%	7.7%	-6.8%	
27	206	91	63	186	84	49	10.8%	8.3%	28.6%	
28	234	98	96	229	92	90	2.2%	6.5%	6.7%	
29	229	87	123	191	66	116	19.9%	31.8%	6.0%	
30	185	43	157	170	35	158	8.8%	22.9%	-0.6%	
31	216	88	143	203	75	152	6.4%	17.3%	-5.9%	
32	208	49	69	194	53	58	7.2%	-7.5%	19.0%	
33	185	75	105	161	68	98	14.9%	10.3%	7.1%	
34	204	48	58	223	65	55	-8.5%	-26.2%	5.5%	
35	181	47	105	198	44	100	-8.6%	6.8%	5.0%	
36	174	71	148	166	63	149	4.8%	12.7%	-0.7%	
37	143	53	133	139	47	156	2.9%	12.8%	-14.7%	
Average Deviation							3.9%	4.4%	0.4%	
Expected Results							±10%	±12%	±15%	

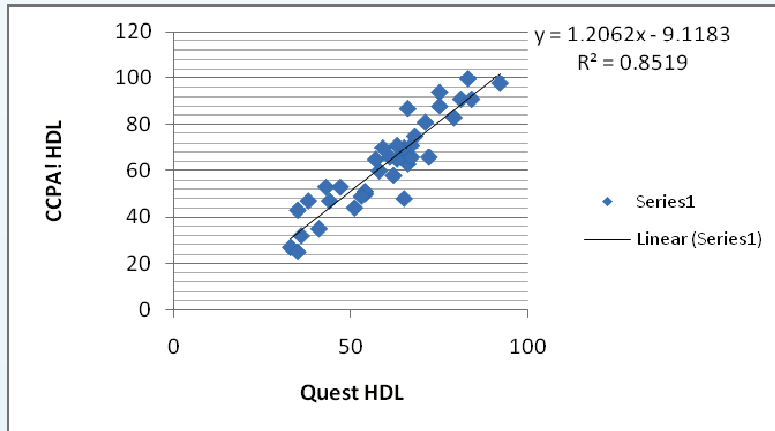
Data Summary: CardioChek PA #1

Cholesterol Summary: CardioChek PA #1



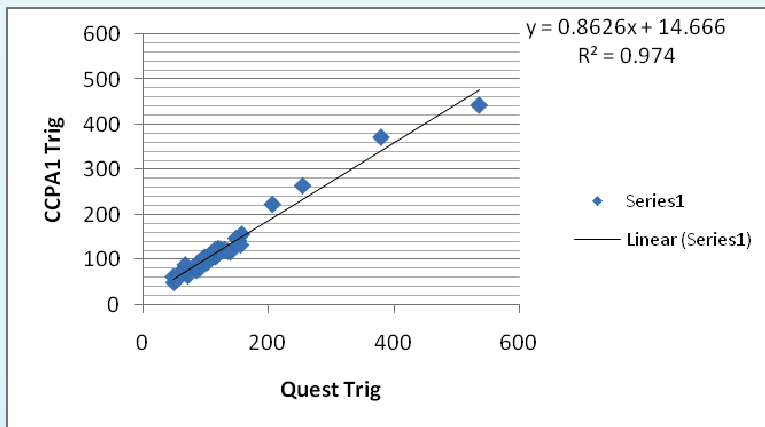
CLINICAL APPLICATION		
QUEST	CCPA	% DIFF
160	173	8.37%
200	204	1.90%
240	234	-2.42%
280	265	-5.50%
Average Deviation		0.59%

HDL Cholesterol Summary: CardioChek PA #1



CLINICAL APPLICATION		
QUEST	CCPA	% DIFF
40	39	-2.00%
60	63	5.67%
80	88	9.50%
100	112	11.80%
Average Deviation		6.24%

Triglycerides Summary: CardioChek PA #1



CLINICAL APPLICATION		
QUEST	CCPA	% DIFF
100	101	0.60%
150	144	-4.27%
200	187	-6.70%
250	230	-8.16%
Average Deviation		-4.63%

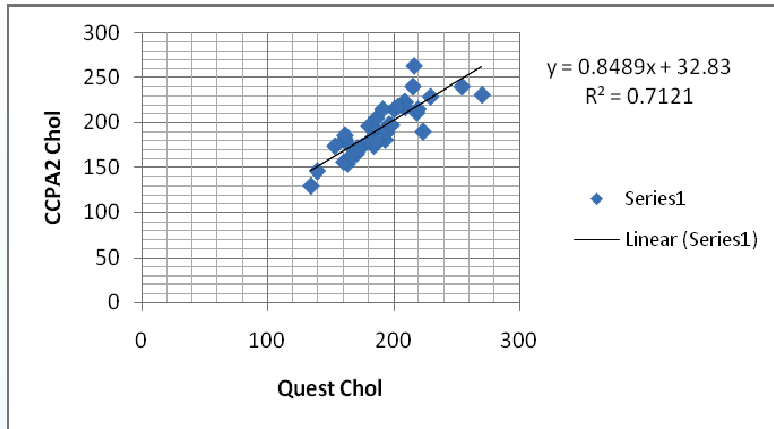
Table 2. CardioChek PA #2 (heparinized plasma) Correlation Versus Quest Serum Sample: Average Deviation

Table 2.

PATIENT ID	CARDIOCHEK PA #2			QUEST			% DEVIATION			ACTUAL RESULT
	CHOL	HDL	TRIG	CHOL	HDL	TRIG	CHOL	HDL	TRIG	
1	181	41	107	193	51	124	-6.2%	-19.6%	-13.7%	
2	182	49	98	161	54	100	13.0%	-9.3%	-2.0%	
3	220	31	100	206	36	116	6.8%	-13.9%	-13.8%	
4	174	65	66	184	65	86	-5.4%	0.0%	-23.3%	
5	130	21	101	134	33	116	-3.0%	-36.4%	-12.9%	
6	231	29	420	270	35	536	-14.4%	-17.1%	-21.6%	
7	174	32	248	175	41	255	-0.6%	-22.0%	-2.7%	
8	198	61	66	196	66	91	1.0%	-7.6%	-27.5%	
9	172	60	124	171	58	131	0.6%	3.4%	-5.3%	
10	196	65	97	180	63	103	8.9%	3.2%	-5.8%	
11	211	64	99	218	72	109	-3.2%	-11.1%	-9.2%	
12	215	94	68	200	83	72	7.5%	13.3%	-5.6%	
13	240	56	136	215	57	140	11.6%	-1.8%	-2.9%	
14	223	84	108	208	81	109	7.2%	3.7%	-0.9%	
15	174	55	75	165	61	84	5.5%	-9.8%	-10.7%	
16	154	49	115	163	54	136	-5.5%	-9.3%	-15.4%	
17	223	48	356	209	43	380	6.7%	11.6%	-6.3%	
18	174	69	81	153	71	68	13.7%	-2.8%	19.1%	
19	263	82	51	216	75	47	21.8%	9.3%	8.5%	
20	192	55	65	186	67	54	3.2%	-17.9%	20.4%	
21	215	64	118	219	59	120	-1.8%	8.5%	-1.7%	
22	217	52	212	209	38	207	3.8%	36.8%	2.4%	
23	181	54	98	181	62	114	0.0%	-12.9%	-14.0%	
24	156	62	113	160	67	112	-2.5%	-7.5%	0.9%	
25	179	82	107	186	79	68	-3.8%	3.8%	57.4%	
26	240	69	107	254	65	118	-5.5%	6.2%	-9.3%	
27	205	88	53	186	84	49	10.2%	4.8%	8.2%	
28	229	94	91	229	92	90	0.0%	2.2%	1.1%	
29	215	80	109	191	66	116	12.6%	21.2%	-6.0%	
30	165	42	167	170	35	158	-2.9%	20.0%	5.7%	
31	218	80	146	203	75	152	7.4%	6.7%	-3.9%	
32	189	44	59	194	53	58	-2.6%	-17.0%	1.7%	
33	186	68	94	161	68	98	15.5%	0.0%	-4.1%	
34	190	45	55	223	65	55	-14.8%	-30.8%	0.0%	
35	197	54	95	198	44	100	-0.5%	22.7%	-5.0%	
36	163	68	135	166	63	149	-1.8%	7.9%	-9.4%	
37	146	53	132	139	47	156	5.0%	12.8%	-15.4%	
Average Deviation							2.4%	-1.3%	-3.3%	
Expected Results							±10%	±12%	±15%	

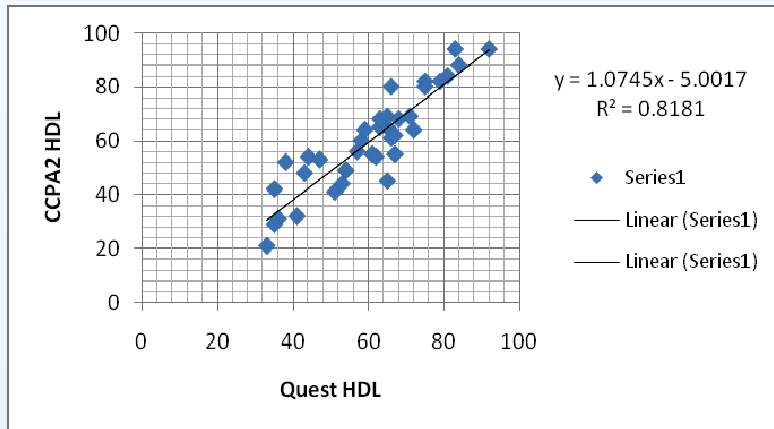
Data Summary: CardioChek PA #2

Cholesterol Summary: CardioChek PA #2



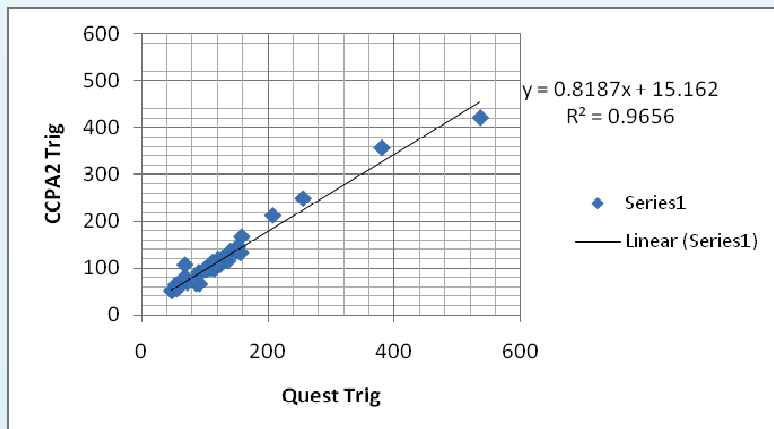
CLINICAL APPLICATION		
QUEST	CCPA	% DIFF
160	169	5.52%
200	203	1.41%
240	237	-1.32%
280	271	-3.28%
Average Deviation		0.58%

HDL Cholesterol Summary: CardioChek PA #2



CLINICAL APPLICATION		
QUEST	CCPA	% DIFF
40	38	-5.00%
60	60	-0.83%
80	81	1.25%
100	103	2.50%
Average Deviation		-0.52%

Triglycerides Summary: CardioChek PA #2



CLINICAL APPLICATION		
QUEST	CCPA	% DIFF
100	97	-3.00%
150	138	-8.00%
200	179	-10.50%
250	220	-12.00%
Average Deviation		-8.23%

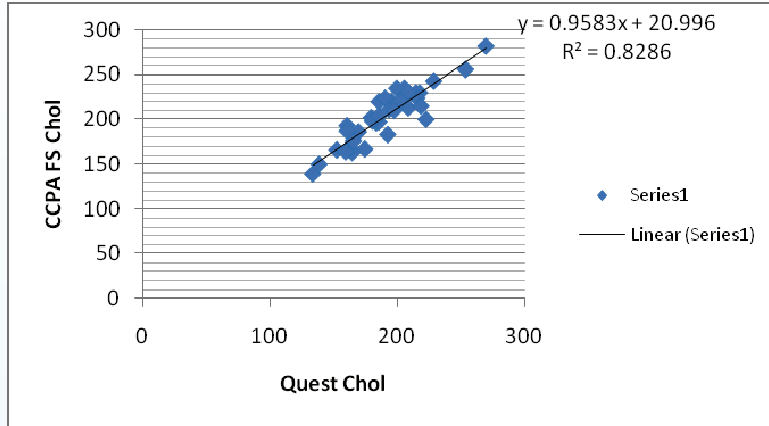
Table 3. CardioChek PA #3 (fingerstick) Correlation Versus Quest Serum Sample: Average Deviation

Table 3.

PATIENT ID	CARDIOCHEK PA #3			QUEST			% DEVIATION			ACTUAL RESULT
	CHOL	HDL	TRIG	CHOL	HDL	TRIG	CHOL	HDL	TRIG	
1	183	38	86	193	51	124	-5.2%	-25.5%	-30.6%	
2	193	45	90	161	54	100	19.9%	-16.7%	-10.0%	
3	235	48	122	206	36	116	14.1%	33.3%	5.2%	
4	196	61	67	184	65	86	6.5%	-6.2%	-22.1%	
5	139	24	110	134	33	116	3.7%	-27.3%	-5.2%	
6	282	45	425	270	35	536	4.4%	28.6%	-20.7%	
7	167	41	222	175	41	255	-4.6%	0.0%	-12.9%	
8	220	70	65	196	66	91	12.2%	6.1%	-28.6%	
9	202	70	113	180	63	103	12.2%	11.1%	9.7%	
10	230	72	97	218	72	109	5.5%	0.0%	-11.0%	
11	235	98	64	200	83	72	17.5%	18.1%	-11.1%	
12	230	61	117	215	57	140	7.0%	7.0%	-16.4%	
13	229	96	99	208	81	109	10.1%	18.5%	-9.2%	
14	163	64	78	165	61	84	-1.2%	4.9%	-7.1%	
15	169	50	122	163	54	136	3.7%	-7.4%	-10.3%	
16	213	49	352	209	43	380	1.9%	14.0%	-7.4%	
17	166	65	99	153	71	68	8.5%	-8.5%	45.6%	
18	224	93	50	216	75	50	3.7%	24.0%	0.0%	
19	197	56	124	186	67	54	5.9%	-16.4%	129.6%	<50, 47
20	215	71	126	219	59	120	-1.8%	20.3%	5.0%	
21	231	46	196	209	38	207	10.5%	21.1%	-5.3%	
22	198	55	96	181	62	114	9.4%	-11.3%	-15.8%	
23	164	63	110	160	67	112	2.5%	-6.0%	-1.8%	
24	220	75	67	186	79	68	18.3%	-5.1%	-1.5%	
25	256	56	114	254	65	118	0.8%	-13.8%	-3.4%	
26	204	84	126	186	84	49	9.7%	0.0%	157.1%	
27	243	94	94	229	92	90	6.1%	2.2%	4.4%	
28	224	70	122	191	66	116	17.3%	6.1%	5.2%	
29	186	36	146	170	35	158	9.4%	2.9%	-7.6%	
30	221	86	202	203	75	152	8.9%	14.7%	32.9%	
31	211	43	53	194	53	58	8.8%	-18.9%	-8.6%	
32	187	73	86	161	68	98	16.1%	7.4%	-12.2%	
33	200	43	50	223	65	55	-10.3%	-33.8%	-9.1%	
34	210	35	77	198	44	100	6.1%	-20.5%	-23.0%	<45
35	176	68	142	166	63	149	6.0%	7.9%	-4.7%	
36	150	51	103	139	47	156	7.9%	8.5%	-34.0%	
Average Deviation							7.0%	1.1%	1.8%	
Expected Results							±10%	±12%	±15%	

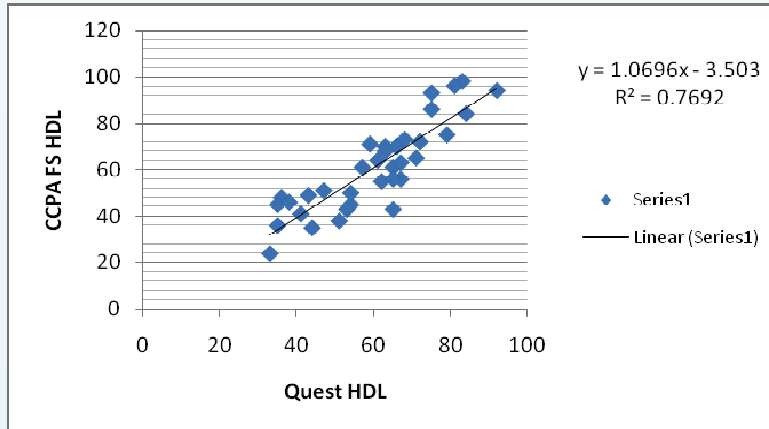
Data Summary: CardioChek PA #3

Cholesterol Summary: CardioChek PA #3



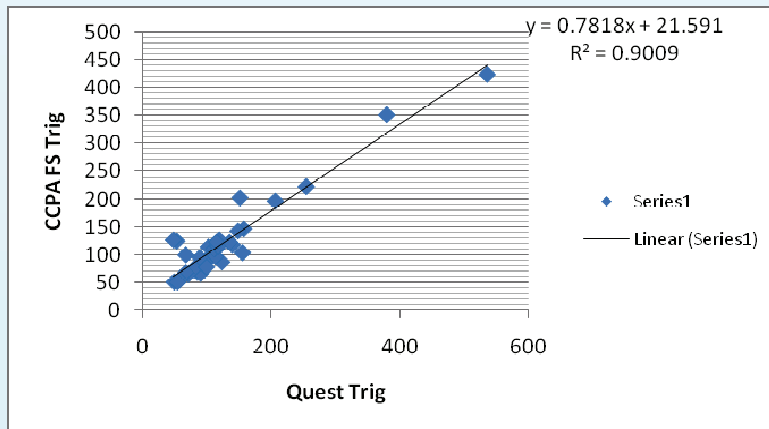
CLINICAL APPLICATION		
QUEST	CCPA	% DIFF
160	175	9.13%
200	213	6.50%
240	251	4.75%
280	290	3.50%
Average Deviation		5.97%

HDL Cholesterol Summary: CardioChek PA #3



CLINICAL APPLICATION		
QUEST	CCPA	% DIFF
40	39	-1.75%
60	61	1.17%
80	82	2.63%
100	104	3.50%
Average Deviation		1.39%

Triglycerides Summary: CardioChek PA #3



CLINICAL APPLICATION		
QUEST	CCPA	% DIFF
100	100	-0.50%
150	139	-7.67%
200	178	-11.25%
250	217	-13.40%
Average Deviation		-8.20%

Conclusion:

This study demonstrates that results obtained by three CardioChek PA point-of-care instruments will provide accurate measurements for Cholesterol, HDL Cholesterol, and Triglycerides when compared to results from a reference laboratory.



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