CardioChek® Plus

Comparison Study Summary

September 18, 2015

1 PROTOCOL

This study was conducted on September 18, 2015 in Columbia, Maryland. It consisted of 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 Roche Cobas Integra 400 (Integra), the LabCorp Roche Cobas 8000 (Cobas) and the Cholestech LDX (LDX) using ninety six (96) participants. Forty seven (47) participants were drawn fasting and forty nine (49) were not fasting.

Three stations were set up at the test site. Each station was operated by a site RN. Each RN performed a fingerstick and dosed the eGlu strip on the CardioChek® Plus analyzer, the finger was then wiped and the first of two (2) 40µl capillary tubes were collected. The first and second capillary tubes were alternated between the CardioChek® Plus and the LDX.

Immediately following the fingerstick, the participant had a venipuncture performed by one of the two LabCorp phlebotomists. One (1) red top serum clot tube and one (1) green top lithium heparin tube was collected from each participant. The red top tubes were allowed to clot for 30 minutes and centrifuged. Each serum sample was split into two aliquots. One set of serum aliquots was sent to the LabCorp for analysis on the Roche Cobas. The second set of aliquots was transported overnight to PTS Diagnostics for analysis on the Roche Integra. The green top tubes were used for precision testing.

	Testing Range
Total Cholesterol	132-301
HDL Cholesterol	29-111
Triglyceride	30-414
Glucose	58-225

Testing range based on Roche Integra testing

All results are in mg/dL

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 LDX test system, the Roche Integra, and the LabCorp Cobas.

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

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

Average of Paired % Biases (mg/dL)			
vs Integra	**Cobas**	**CardioChek Plus**	**LDX**
Total Cholesterol	0.5%	-3.9%	-3.5%
HDL Cholesterol	0.1%	-8.1%	-9.0%
Triglycerides	6.3%	3.9%	-0.5%
Glucose	2.1%	2.1%	2.4%

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

Average of Paired % Biases (mg/dL)		
vs Cobas	**CardioChek Plus**	**LDX**
Total Cholesterol	-4.3%	-4.0%
HDL Cholesterol	-8.2%	-9.1%
Triglycerides	-1.9%	-6.0%
Glucose	0.0%	0.4%

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 values. ISO 2003 Guidelines were also displayed for glucose.

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 Integra	**Cobas**	**CardioChek Plus**	**LDX**
N	95	94	94
Slope	1.01	0.99	0.90
Intercept	-1.7	-5.4	11.8
R	0.995	0.962	0.937
vs Cobas		**CardioChek Plus**	**LDX**
Slope		0.97	0.89
Intercept		-3.1	12.9
R		0.960	0.943

Total Cholesterol Predicted Biases (mg/dL)						
Integra	**Cobas**	**% bias**	**CardioChek Plus**	**% bias**	**LDX**	**% bias**
160	161	0.4%	153	-4.3%	156	-2.5%
200	201	0.6%	193	-3.6%	192	-4.0%
240	242	0.7%	232	-3.2%	228	-5.0%
280	282	0.8%	272	-2.9%	264	-5.7%
Average % bias		**0.6%**		**-3.5%**		**-4.3%**

Total Cholesterol Predicted Biases (mg/dL)				
vs Cobas	**CardioChek Plus**	**% Bias**	**LDX**	**% Bias**
160	153	-4.6%	155	-2.9%
200	192	-4.2%	191	-4.5%
240	231	-3.9%	227	-5.6%
280	270	-3.7%	262	-6.4%
Average % bias		**-4.1%**		**-4.8%**

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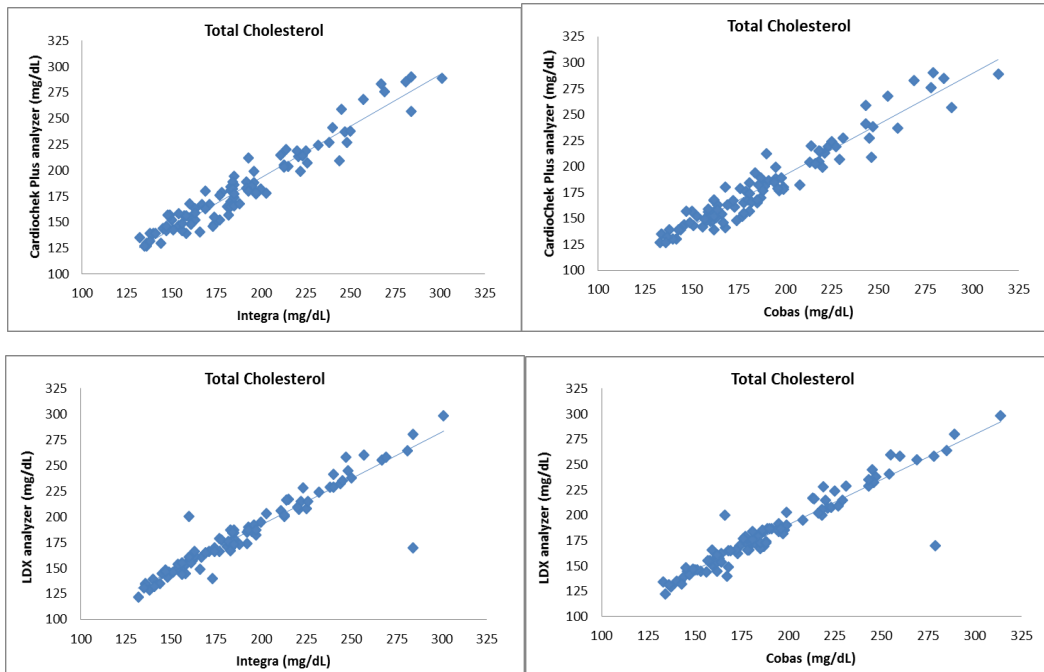
4 HDL CHOLESTEROL

HDL Cholesterol (mg/dL)			
vs Integra	**Cobas**	**CardioChek Plus**	**LDX**
N	95	94	93
Slope	0.99	0.91	0.82
Intercept	0.5	0.5	4.8
R	0.997	0.946	0.872
vs Cobas		**CardioChek Plus**	**LDX**
Slope		0.92	0.83
Intercept		0.2	4.1
R		0.946	0.872

HDL Cholesterol Predicted Biases (mg/dL)						
Integra	**Cobas**	**% bias**	**CardioChek Plus**	**% bias**	**LDX**	**% bias**
40	40	0.4%	37	-7.7%	38	-5.8%
60	60	0.0%	55	-8.1%	54	-9.8%
80	80	-0.2%	73	-8.4%	71	-11.8%
100	100	-0.3%	92	-8.5%	87	-13.0%
Average % bias		**0.0%**		**-8.2%**		**-10.1%**

HDL Cholesterol Predicted Biases (mg/dL)				
vs Cobas	**CardioChek Plus**	**% Bias**	**LDX**	**% Bias**
40	37	-7.9%	37	-6.3%
60	55	-8.1%	54	-9.7%
80	73	-8.2%	71	-11.4%
100	92	-8.2%	88	-12.5%
Average % bias		**-8.1%**		**-10.0%**

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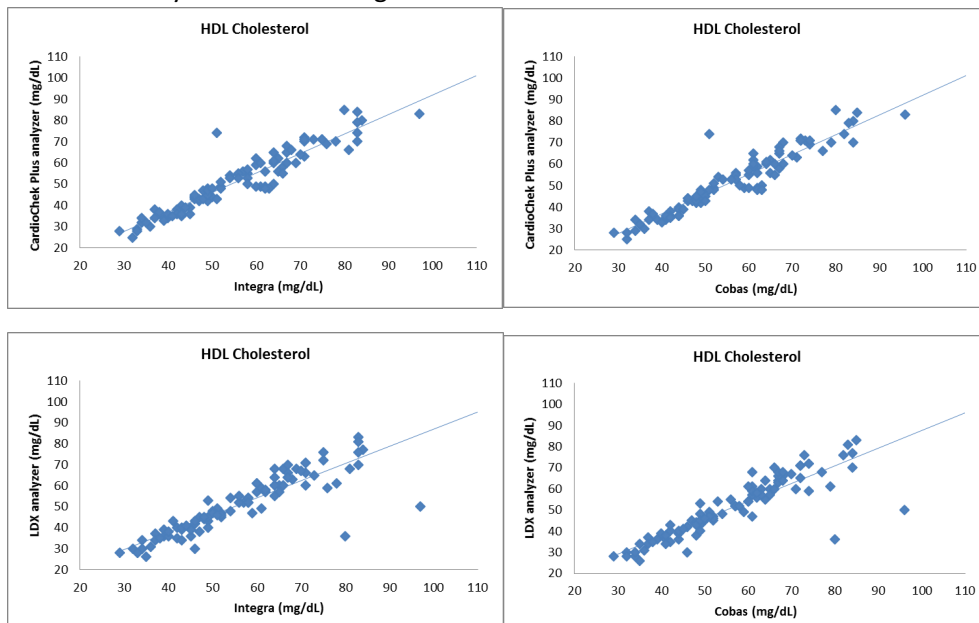
5 TRIGLYCERIDES

Triglycerides (mg/dL)			
vs Integra	Cobas	CardioChek Plus	LDX
N	95	87	82
Slope	1.03	1.01	1.00
Intercept	2.7	2.1	-0.5
R	0.999	0.992	0.986
vs Cobas		CardioChek Plus	LDX
Slope		0.98	0.97
Intercept		-0.1	-3.0
R		0.991	0.988

Triglycerides Predicted Biases (mg/dL)						
Integra	Cobas	% bias	CardioChek Plus	% bias	LDX	% bias
100	106	5.7%	103	2.9%	99	-0.6%
150	157	4.8%	153	2.2%	149	-0.5%
200	209	4.4%	204	1.8%	199	-0.4%
250	260	4.1%	254	1.6%	249	-0.4%
Average % bias		**4.7%**		**2.2%**		**-0.5%**

Triglycerides Predicted Biases (mg/dL)				
vs Cobas	CardioChek Plus	% Bias	LDX	% Bias
100	98	-2.5%	94	-6.1%
150	146	-2.5%	142	-5.1%
200	195	-2.4%	191	-4.6%
250	244	-2.4%	239	-4.3%
Average % bias		**-2.5%**		**-5.1%**

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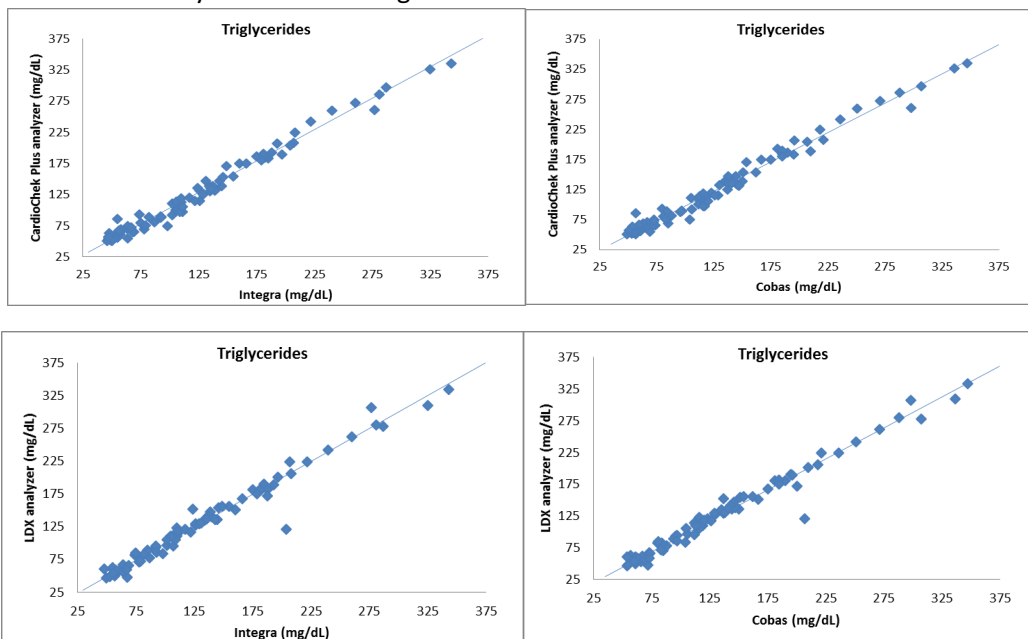
6 GLUCOSE

Glucose (mg/dL)			
vs Integra	**Cobas**	**CardioChek Plus**	**LDX**
N	89	88	88
Slope	1.00	0.84	0.96
Intercept	1.7	15.5	5.7
R	0.998	0.908	0.948
vs Cobas		**CardioChek Plus**	**LDX**
Slope		0.84	0.95
Intercept		14.3	4.5
R		0.905	0.944

Glucose Predicted Biases (mg/dL)						
Integra	**Cobas**	**% bias**	**CardioChek Plus**	**% bias**	**LDX**	**% bias**
100	102	1.8%	100	-0.2%	102	1.6%
150	152	1.2%	142	-5.4%	150	-0.3%
200	202	1.0%	184	-8.0%	197	-1.3%
250	252	0.8%	226	-9.5%	245	-1.8%
Average % bias		**1.2%**		**-5.8%**		**-0.5%**

Glucose Predicted Biases (mg/dL)				
vs Cobas	**CardioChek Plus**	**% Bias**	**LDX**	**% Bias**
100	98	-1.8%	100	-0.2%
150	140	-6.6%	147	-1.7%
200	182	-9.0%	196	-2.5%
250	224	-10.4%	243	-2.9 %
Average % bias		**-7.0%**		**-1.8%**

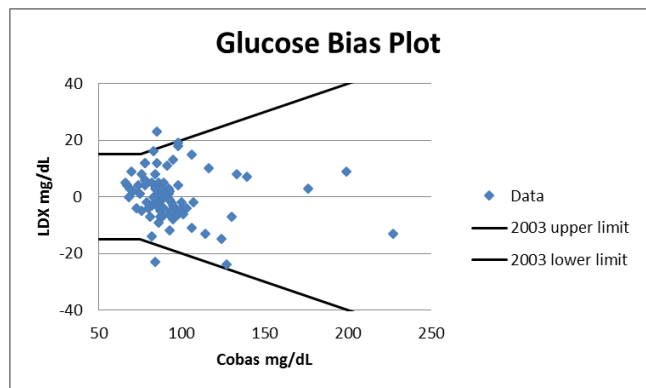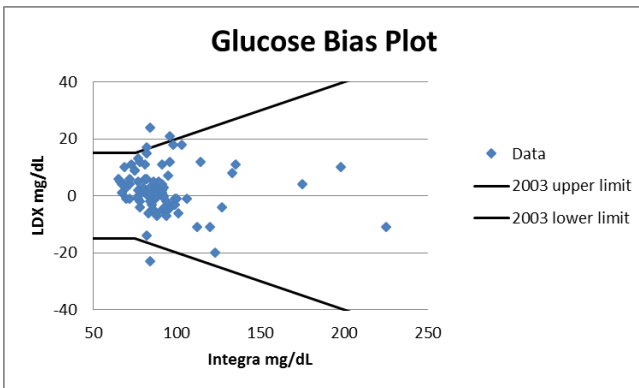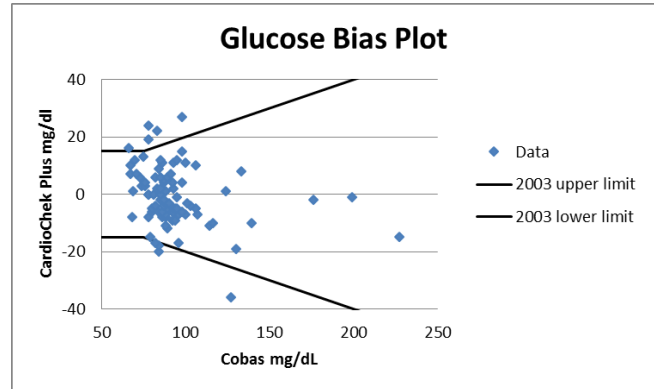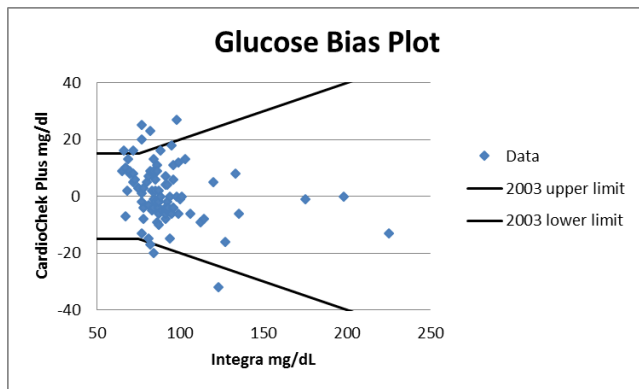Predicted biases are based strictly on the linear regression line of the data collected
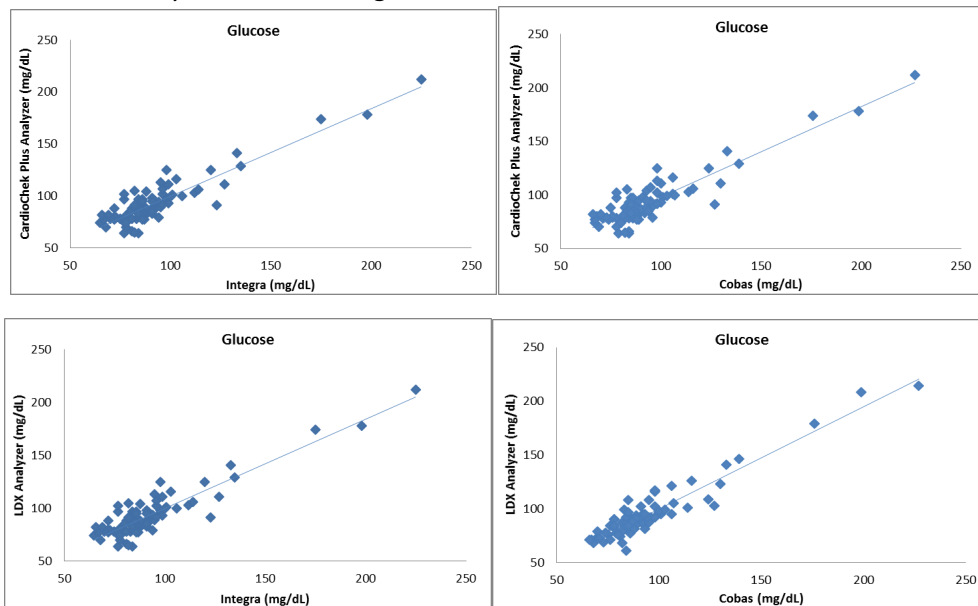
6   GLUCOSE, CONTINUED

Glucose ISO Guidelines

Glucose evaluated according to the current 2003 ISO Standard:

Values < 75 mg/dL ±15 mg/dL

Values ≥ 75 mg/dL ± 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 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 and the reference laboratory result. There were no instances a "2 Category Difference" observed in this clinical evaluation for Total Cholesterol, HDL Cholesterol, Triglycerides, or Glucose.

Risk Classification									
Categories	**Total Cholesterol (mg/dL)**			**HDL Chol (mg/dL)**		**Triglycerides (mg/dL)**			**Glucose (mg/dL)**	
Compared	<200	200 - 240	>240	<40	≥40	<150	150 - 200	>200	<126	≥126

Risk Classification Agreement Between Methods and Integra										
	Total Cholesterol			**HDL Cholesterol**		**Triglycerides**			**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**
Cobas	94	1	0	94	1	90	5	0	88	1
CardioChek Plus	86	8	0	84	10	84	3	0	87	1
LDX	87	6	1	83	10	77	4	1	86	2

Risk Classification Agreement Between Methods and Cobas										
	Total Cholesterol			**HDL Cholesterol**		**Triglycerides**			**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**
CardioChek Plus	88	7	0	84	11	85	3	0	87	2
LDX	87	7	1	83	11	79	3	1	86	3

8 PRECISION

CardioChek Plus analyzer SN 5123036 (mg/dL)				
Sample ID	6	6	6	6
Analyte	CHOL	HDL	TRIG	eGLU
1	210	81	98	77
2	210	81	99	75
3	210	80	107	79
4	202	81	95	74
5	206	81	98	80
6	218	80	97	78
7	199	82	97	78
8	201	80	102	72
9	195	75	99	72
10	209	79	91	72
Number	10	10	10	10
Average	206	80	98.3	75.7
SD	6.8	1.9	4.2	3.1
%CV	3.3	2.4	4.3	4.1

CardioChek Plus analyzer SN 5123036 (mg/dL)				
Sample ID	11	11	11	11
Analyte	CHOL	HDL	TRIG	eGLU
1	149	32	110	84
2	154	36	111	89
3	147	36	111	82
4	145	32	110	78
5	148	35	107	83
6	152	37	107	78
7	148	34	106	80
8	144	32	100	78
9	151	33	111	82
10	141	37	109	84
Number	10	10	10	10
Average	147.9	34.4	108.2	81.8
SD	3.9	2.1	3.4	3.5
%CV	2.6	6.0	3.2	4.3

CardioChek Plus analyzer SN 5123036 (mg/dL)			
Sample ID	22	22	22	22
Analyte	CHOL	HDL	TRIG	eGLU
1	244	58	253	95
2	250	60	266	96
3	244	59	250	97
4	253	57	237	91
5	243	57	249	95
6	258	56	259	88
7	251	56	241	90
8	248	59	253	94
9	248	60	267	90
10	252	60	266	89
Number	10	10	10	10
Average	249.1	58.2	254.1	92.5
SD	4.7	1.6	10.5	3.2
%CV	1.9	2.8	4.1	3.5

9 RAW DATA – TOTAL CHOLESTEROL (mg/dL)

Sample #	Integra	Cobas	CardioChek Plus	LDX
1	215	213	204	217
2	183	187	170	169
3	167	162	167	161
4	177	177	152	179
5	185	184	194	179
6	196	195	188	184
7	144	142	130	135
8	158	162	139	145
9	181	178	165	171
10	221	221	213	207
11	174	174	148	170
12	185	191	186	187
13	132	134	135	122
14	284	279	290	170
15	238	231	227	229
16	145	146	144	145
17	150	153	152	145
18	154	160	147	150
19	157	159	156	151
20	147	145	142	148
21	136	140	130	135
22	247	260	237	258
23	185	180	168	173
24	183	181	184	173
25	192	198	169	185
26	250	247	238	238
27	213	218	205	200
28	140	144	139	139
29	225	223	219	208
30	160	166	154	200
31	195	194	185	186
32	223	219	214	228
33	183	185	165	167
34	NA	173	161	162
35	161	161	148	157
36	162	163	151	157
37	158	162	156	154
38	149	150	157	146
39	244	246	209	232
40	222	220	199	215

9 RAW DATA – TOTAL CHOLESTEROL (mg/dL), CONTINUED

Sample #	Integra	Cobas	CardioChek Plus	LDX
41	178	176	179	177
42	185	182	166	173
43	148	147	157	141
44	192	188	183	174
45	136	133	127	134
46	166	168	141	149
47	211	218	215	206
48	182	181	157	176
49	163	162	152	161
50	156	156	142	144
51	173	167	146	140
52	171	172	167	166
53	161	158	148	155
54	177	179	176	166
55	197	197	177	182
56	226	229	207	215
57	248	245	227	245
58	138	138	139	215
59	188	185	168	173
60	138	137	132	129
61	163	164	163	162
62	284	289	257	280
63	151	151	143	146
64	213	216	203	202
65	184	187	189	184
66	301	314	289	298
67	281	285	285	264
68	174	178	155	166
69	154	164	158	154
70	193	199	180	190
71	203	199	178	203
72	183	189	181	187
73	156	157	149	155
74	267	269	283	255
75	240	254	NA	241
76	185	181	174	184
77	184	186	182	185
78	147	149	146	147
79	141	143	139	132
80	232	225	224	224

9 RAW DATA – TOTAL CHOLESTEROL (mg/dL), CONTINUED

Sample #	Integra	Cobas	CardioChek Plus	LDX
81	169	168	180	165
82	257	255	268	260
83	163	159	159	166
84	214	214	220	216
85	193	190	212	187
86	169	169	163	165
87	240	243	241	229
88	160	162	168	161
89	185	188	177	173
90	196	195	199	192
91	200	208	182	195
92	197	196	179	187
93	245	243	259	235
94	269	278	276	258
95	220	227	219	209
96	135	136	127	131

Sample # 34 was spilled. Unable to run on Integra.

Sample # 58 is an outlier for LDX

Sample # 75 second capillary tube clotted.

10 RAW DATA – HDL CHOLESTEROL (mg/dL)

Sample #	Integra	Cobas	CardioChek Plus	LDX

1	67	67	65	64
2	83	84	70	70
3	65	65	56	60
4	64	63	50	60
5	46	46	44	42
6	84	84	80	77
7	61	59	49	49
8	47	48	42	38
9	39	39	34	36
10	43	44	40	39
11	40	41	34	36
12	49	49	42	43
13	71	71	63	60
14	80	80	85	36
15	71	68	70	66
16	52	52	49	47
17	58	60	55	54
18	37	37	38	37
19	29	29	28	28
20	67	67	58	66
21	39	40	33	39
22	64	61	65	68
23	36	36	30	31
24	52	52	48	45
25	34	35	32	34
26	33	34	29	28
27	57	57	56	52
28	58	60	57	54
29	54	53	54	54
30	56	57	55	52
31	32	32	25	30
32	66	67	58	68
33	35	35	32	26
34	NA	62	59	56
35	46	46	43	42
36	47	47	43	45
37	65	65	62	57
38	83	82	74	76
39	37	37	34	34
40	45	44	36	36

10 Raw Data – HDL Cholesterol (mg/dL), Continued

Sample #	Integra	Cobas	CardioChek Plus	LDX
41	60	61	62	61
42	81	77	66	68

43	51	51	74	49
44	38	38	37	35
45	50	49	44	48
46	45	44	39	39
47	64	64	60	64
48	42	42	38	40
49	49	49	48	40
50	60	61	59	57
51	62	62	49	58
52	48	48	43	44
53	69	68	60	68
54	52	52	51	46
55	68	67	66	63
56	58	57	53	52
57	42	42	36	35
58	63	62	48	<mark>52</mark>
59	76	74	69	59
60	49	50	45	45
61	71	72	72	71
62	43	41	35	34
63	64	64	61	55
64	34	34	34	30
65	46	46	44	30
66	46	48	45	43
67	40	41	36	38
68	48	49	47	45
69	71	72	71	71
70	41	42	35	43
71	43	44	36	40
72	111	114	95	<mark>>100</mark>
73	49	49	47	53
74	83	85	84	83
75	59	61	<mark>NA</mark>	47
76	58	58	50	52
77	50	51	48	47
78	70	70	64	67
79	62	63	48	57
80	75	73	71	76

10 Raw Data – HDL Cholesterol (mg/dL), Continued

Sample #	Integra	Cobas	CardioChek Plus	LDX
81	54	54	53	48
82	67	66	60	70
83	61	61	60	59
84	56	56	53	55
85	75	74	71	72
86	62	62	56	58
87	97	96	83	50
88	73	72	71	65
89	66	66	55	60
90	78	79	70	61
91	60	60	49	61
92	67	68	60	64
93	51	50	43	46
94	83	83	79	81
95	33	32	28	28
96	44	45	39	41

Sample # 34 was spilled. Unable to run on Integra.

Sample # 58 is an outlier for LDX

Sample # 75 second capillary tube clotted.

11 RAW DATA – TRIGLYCERIDE (mg/dL)

Sample #	Integra	Cobas	CardioChek Plus	LDX
1	109	112	109	114
2	50	57	51	<45
3	92	96	88	93
4	67	72	70	63
5	126	130	132	127
6	110	116	104	113
7	49	53	52	<45
8	78	85	69	71
9	102	106	92	97
10	111	117	97	115
11	117	123	120	121
12	207	221	208	224
13	38	44	<50	<45
14	204	207	204	121
15	126	129	115	129
16	63	67	71	62
17	50	54	59	47
18	287	307	297	278
19	140	145	134	140
20	53	55	61	49
21	55	61	56	61
22	277	298	261	307
23	145	150	139	136
24	129	137	125	129
25	185	195	183	190
26	343	347	335	334
27	110	119	113	110
28	47	54	54	<45
29	139	146	132	147
30	105	117	101	110
31	281	288	286	280
32	78	84	75	78
33	260	271	272	262
34	NA	66	63	53
35	134	135	139	135
36	107	112	101	96
37	42	47	<50	<45
38	34	38	<50	<45
39	155	162	154	156
40	131	138	147	131

11 RAW DATA – TRIGLYCERIDE (mg/dL), CONTINUED

Sample #	Integra	Cobas	CardioChek Plus	LDX
41	102	105	111	105
42	44	49	<50	<45
43	85	94	<50	89
44	208	218	225	206
45	87	88	81	78
46	160	167	175	151
47	74	80	93	82
48	188	181	193	181
49	143	144	147	136
50	109	116	97	105
51	57	61	61	50
52	92	97	90	95
53	55	57	86	63
54	82	84	89	83
55	58	60	66	53
56	182	185	184	180
57	122	126	115	117
58	46	49	51	180
59	48	51	<50	<45
60	51	55	53	<45
61	146	151	153	154
62	414	435	434	429
63	56	62	63	53
64	325	336	326	310
65	149	154	171	156
66	135	147	131	138
67	175	190	186	181
68	240	251	260	242
69	64	73	75	67
70	124	137	136	152
71	137	143	139	141
72	30	35	<50	<45
73	58	63	69	58
74	106	113	114	110
75	188	200	NA	172
76	69	74	65	66
77	166	175	175	168
78	75	81	80	85
79	47	54	57	<45
80	181	185	190	182

11 RAW DATA – TRIGLYCERIDE (mg/dL), CONTINUED

Sample #	Integra	Cobas	CardioChek Plus	LDX
81	56	60	67	54
82	110	116	119	123
83	48	54	63	61
84	47	51	57	<45
85	193	196	207	189
86	93	97	89	86
87	68	72	65	48
88	64	69	55	56
89	79	83	76	72
90	98	104	75	84
91	197	210	189	201
92	136	141	135	137
93	179	185	180	175
94	111	120	106	118
95	222	236	242	224
96	67	73	73	59

Sample # 34 was spilled. Unable to run on Integra.

Sample # 58 is an outlier for LDX

Sample # 75 second capillary tube clotted.

12 RAW DATA – GLUCOSE (mg/dL)

Sample #	Integra	Cobas	CardioChek Plus	LDX
*1	96	98	92	92
*2	85	87	83	80
*3	92	92	96	95
*4	92	95	90	92
5	68	69	96	97
*6	87	88	89	81
*7	87	88	85	87
8	73	76	79	84
*9	81	82	88	87
10	98	101	98	95
11	77	78	97	90
12	120	124	125	109
*13	72	75	88	76
*14	78	78	70	90
15	89	89	84	94
*16	93	94	89	89
*17	94	96	79	92
*18	103	106	116	121
19	135	139	129	146
*20	84	85	97	108
*21	91	92	83	86
*22	101	106	101	95
23	175	176	174	179
24	98	98	125	116
*25	99	100	111	96
*26	92	93	87	92
*27	83	85	85	83
*28	84	87	92	82
29	83	86	78	77
*30	80	83	85	83
*31	99	100	93	98
32	91	92	86	93
*33	225	227	212	214
34	NA	88	80	84
*35	61	62	89	85
36	58	60	91	91
*37	72	74	77	78
*38	84	84	64	61
*39	100	103	99	99
*40	95	96	89	90

12 RAW DATA – GLUCOSE (mg/dL), CONTINUED

Sample #	Integra	Cobas	CardioChek Plus	LDX
*41	87	87	83	86
*42	68	69	70	72
*43	77	79	64	77
*44	84	84	93	87
45	61	62	79	86
*46	86	86	97	91
47	87	88	81	88
48	67	68	80	68
49	133	133	141	141
*50	82	83	105	99
*51	91	90	87	91
*52	112	114	103	101
*53	87	87	85	90
54	81	84	78	82
*55	75	78	78	84
56	77	78	102	82
*57	81	84	66	92
58	88	93	104	82
59	75	78	78	84
60	76	78	128	124
61	85	87	91	87
62	86	89	95	85
*63	84	86	80	85
64	70	71	78	73
65	94	95	94	87
*66	72	76	80	71
*67	95	98	113	102
*68	77	80	75	76
*69	77	82	78	79
*70	78	81	81	74
71	87	89	77	91
72	88	93	88	81
73	96	98	102	117
*74	70	73	79	69
75	82	87	NA	88
*76	85	85	87	82
77	96	98	92	92
78	65	67	74	71
79	67	67	77	71
80	84	85	83	84

12 RAW DATA – GLUCOSE (mg/dL), CONTINUED

Sample #	Integra	Cobas	CardioChek Plus	LDX
81	91	91	98	102
82	76	78	113	114
*83	82	82	65	68
84	78	80	74	76
85	96	95	107	108
86	91	94	85	92
87	198	199	178	208
88	82	85	91	97
89	66	66	82	71
90	69	70	82	79
91	127	130	111	123
92	91	93	95	95
93	106	107	100	105
94	86	88	77	81
95	123	127	91	103
96	114	116	106	126

* Indicates fasting samples

Samples 5, 35, 36, 45, 60, 82 were removed due to probability of extended time clotting of red blood cells prior to centrifugation.

Sample # 34 was spilled. Unable to run on Integra.

Sample # 58 is an outlier for LDX

Sample # 75 second capillary tube clotted.

13 OVERVIEW OF EVALUATION

Evaluation Site
Columbia, MD 21046

Technical Support Specialist (TSS)
Maria Shafai, MT (ASCP), POC (AACC)
Emily Suscha, POC (AACC)

Account Contact
Juley Jenkins
970-393-2705

Third Party Comparison: (X-axis)
Roche Cobas Integra 400
Roche Cobas 8000

Reagents Used
CardioChek Plus Smart Bundle Lot Q408
Multi-Chemistry Controls Lot: MC22
HDL Cholesterol Controls Lot: HC21

Accuracy Instruments: (Y-axis)
CardioChek Plus analyzer SN5122938
CardioChek Plus analyzer SN5123684
CardioChek Plus analyzer SN5123274

Precision Instruments:
CardioChek Plus analyzer SN 5123036

14 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 analyses, 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 Test System 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, and triglycerides. It is noted that some of the glucose measurements were not within the PTS Diagnostics expected range of performance. This could be attributed to the delay in removal of the serum from the red blood cells (centrifugation) of some samples (Six samples were removed). This type of delay will show an over recovery in capillary samples which was demonstrated in both point of care analyzers. The risk classification tables demonstrate that the CardioChek Plus 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 for all four analytes. In summation, the data as a whole demonstrates clinical equivalency between all methods used.

James H Anderson Jr MD	
James H Anderson Jr MD Medical Director	11MAR2016
PTS Diagnostics Approval Signature	Date

pts Diagnostics

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