Novant – Thomasville Medical Center

CardioChek® Plus | A1CNow®+ SYSTEM

Comparison Study Summary

Novant – Thomasville Medical Center
207 Old Lexington Road
Thomasville, NC 27360

April 21, 2016

1 PROTOCOL

This evaluation was conducted on April 20th, 2016 at Thomasville Medical Center in Thomasville, NC. It consisted of a comparative analysis of the CardioChek® Plus analyzer using CardioChek® Plus lipid panel + eGLU® Smart Bundle™ test strips and the A1CNow®+ system. The study compared fingerstick samples on the CardioChek® Plus analyzer and plasma samples tested on Thomasville Medical Center's Roche Cobas 6000 analyzer (Cobas) and Quest Diagnostics' Beckman Coulter AU5400 analyzer (AU5400). The study also compared fingerstick samples on the A1CNow system to whole blood venous samples tested on the Cobas at Thomasville Medical Center and the Tosoh analyzer (Tosoh) at PTS Diagnostics in Sunnyvale, CA. Forty (40) participants were tested, fifteen (15) of whom were fasting.

Due to expanding capillary-venous glycemic gradients as blood glucose increases after eating, for the purpose of this evaluation, only fasting patients and glucose spikes will be utilized for the glucose calculations.

At the test site, a Thomasville Medical Center employee performed a venipuncture blood draw and collected one (1) lithium heparin, plasma separator light green top tube, two (2) lithium heparin, whole blood dark green top tubes, and one (1) EDTA, whole blood lavender top tube. All tubes were inverted and thoroughly mixed. The lithium heparin light green top tube was centrifuged and split into two aliquots. The first plasma aliquot was transferred to the laboratory at Thomasville Medical Center for lipid and glucose analysis on the Cobas and the second plasma aliquot was sent to Quest Diagnostics via courier for analysis on the AU5400. The EDTA tube was transferred to the Thomasville Medical Center's laboratory for HbA1c analysis on the Cobas. One dark green tube was placed in a shipping envelope with ice packs and shipped via overnight courier to PTS Diagnostics in Sunnyvale, CA for next day HbA1c analysis on the Tosoh. One dark green tube of each sample was drawn for glucose spikes and the CardioChek Plus precision study.

After venipuncture, a PTS Diagnostics employee performed a fingerstick on each participant. The first drop of blood was dosed to the electrochemical glucose test strip on a CardioChek Plus analyzer. The residual blood was wiped from the finger using gauze and a 40µL PTS Diagnostics capillary tube was collected and the blood sample was applied to the lipid panel strip. The residual blood was wiped from the finger and a 5µL blood sample was collected for the A1CNow system using the blood collector provided in the kit.

1 PROTOCOL (CONTINUED)

Six (6) glucose sample spikes were made using glucose spiking solution from PTS Diagnostics. These samples were prepared to cover the dynamic range of the glucose. After the glucose spiking solution was added to the whole blood, the samples were allowed to equilibrate at room temperature. After 30 minutes, the electrochemical glucose strip on the CardioChek Plus analyzer was dosed using a transfer pipette. The remaining sample was immediately centrifuged and the plasma was transferred to the Thomasville Medical Center's laboratory for analysis on the Cobas.

	Testing Range
Total Cholesterol (mg/dL)	124 – 265
HDL Cholesterol (mg/dL)	29 – 105
Triglycerides (mg/dL)	44 – 397
Fasting Glucose (mg/dL)	85 – 117
Spiked Glucose (mg/dL)	176 - 475
HbA1c %	4.9 – 8.6

The lipid and glucose testing range is based on the Beckman Coulter AU5400 analyzer
Spiked glucose testing range is based on the Roche Cobas 6000 analyzer
HbA1c testing range is based on the Tosoh analyzer

2 RESULTS (CARDIOCHEK PLUS ANALYZER)

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, Roche Cobas 6000 analyzer and the Beckman Coulter AU5400 analyzer.

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 **AU5400** analyzer. ((Comparator Result – AU5400 Lab Result) ÷ AU5400 Lab Result) * 100) are as follows:

Average of Paired % Biases		
vs. AU5400	**Cobas**	**CardioChek Plus Analyzer**
Total Cholesterol	6.3%	-2.5%
HDL Cholesterol	-1.6%	-9.3%
Triglycerides	-1.8%	-2.6%
Fasting Glucose (spikes not included)	2.8%	3.3%

The average difference calculated from the actual individual paired percent bias with the **Cobas** analyzer.

((Comparator Result – Cobas Lab Result) ÷ Cobas Lab Result) * 100) are as follows:

Average of Paired % Biases	
vs. Cobas	**CardioChek Plus Analyzer**
Total Cholesterol	-8.3%
HDL Cholesterol	-8.3%
Triglycerides	-1.4%
Fasting Glucose (spikes included)	-0.7%

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 spanning the dynamic range of the assay. Actual predicted percent differences with the reference analyzers are calculated as:

((Comparator Result – Reference Lab Result) ÷ Reference Lab Result) X100)

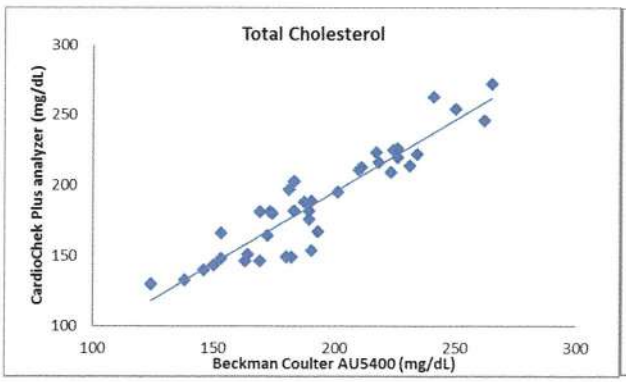
3 TOTAL CHOLESTEROL

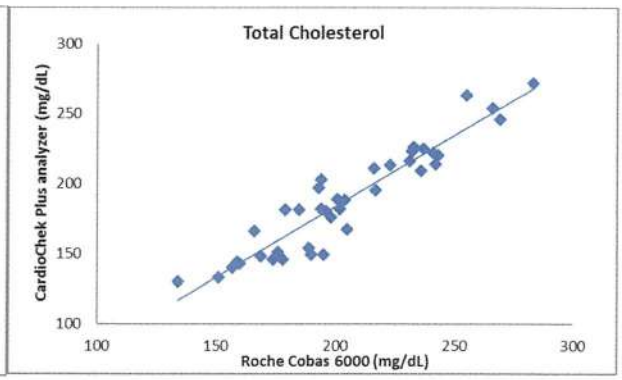
Total Cholesterol (mg/dL)		
vs. AU5400	Cobas	CardioChek Plus Analyzer
N	38	39
Slope	1.01	1.02
Intercept	10.6	-8.2
R	0.994	0.930
vs. Cobas		CardioChek Plus Analyzer
N		39
Slope		1.01
Intercept		-19.2
R		0.942

Total Cholesterol Predicted Biases (mg/dL)				
AU5400	Cobas	% Bias	CardioChek Plus Analyzer	% Bias
160	172	7.3%	155	-3.3%
200	212	6.0%	196	-2.2%
240	252	5.1%	236	-1.6%
280	292	4.5%	277	-1.1%
	Average % bias	**5.7%**		**-2.0%**

Total Cholesterol Predicted Biases (mg/dL)		
Cobas	CardioChek Plus Analyzer	% Bias
160	143	-10.6%
200	184	-8.2%
240	224	-6.6%
280	265	-5.5%
	Average % bias	**-7.7%**

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





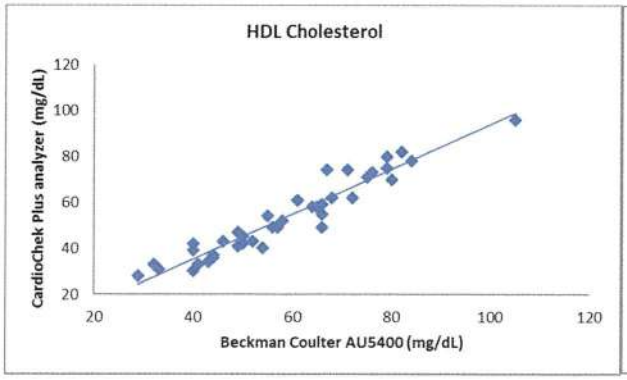
4 HDL CHOLESTEROL

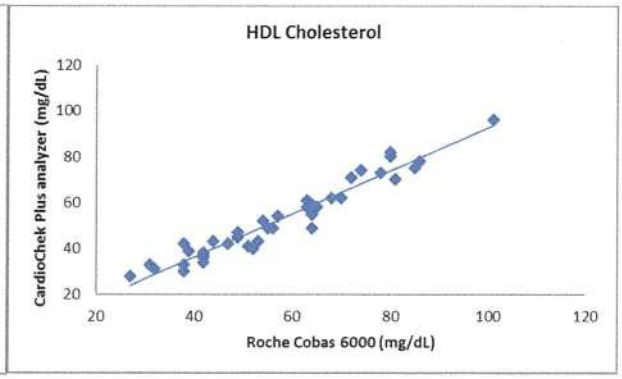
HDL Cholesterol (mg/dL)		
vs. AU5400	**Cobas**	**CardioChek Plus Analyzer**
N	38	39
Slope	1.03	0.98
Intercept	-2.4	-3.8
R	0.993	0.959
vs. Cobas		**CardioChek Plus Analyzer**
N		39
Slope		0.94
Intercept		-1.3
R		0.970

HDL Cholesterol Predicted Biases (mg/dL)				
AU5400	**Cobas**	**% Bias**	**CardioChek Plus Analyzer**	**% Bias**
40	39	-3.1%	35	-11.9%
60	59	-1.1%	55	-8.7%
80	80	-0.1%	74	-7.1%
100	100	0.5%	94	-6.2%
	Average % bias	**-1.0%**		**-8.5%**

HDL Cholesterol Predicted Biases (mg/dL)		
Cobas	**CardioChek Plus Analyzer**	**% Bias**
40	36	-9.3%
60	55	-8.3%
80	74	-7.7%
100	93	-7.4%
	Average % bias	**-8.2%**

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





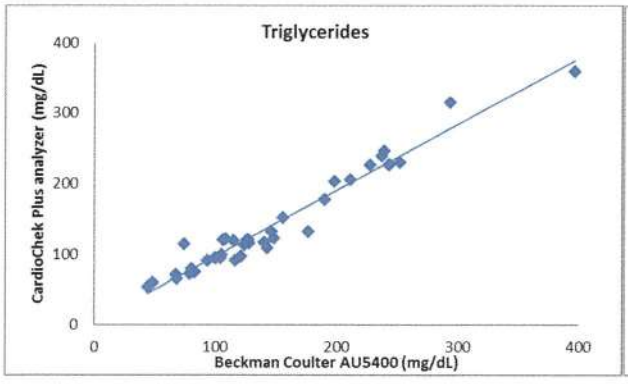
5 TRIGLYCERIDES

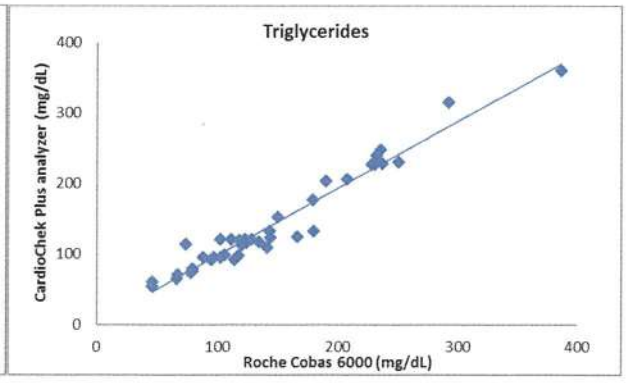
Triglycerides (mg/dL)		
vs. AU5400	**Cobas**	**CardioChek Plus Analyzer**
N	39	39
Slope	0.98	0.93
Intercept	0.5	3.3
R	0.998	0.977
vs. Cobas		**CardioChek Plus Analyzer**
N		39
Slope		0.95
Intercept		2.6
R		0.973

Triglycerides Predicted Biases (mg/dL)				
AU5400	**Cobas**	**% Bias**	**CardioChek Plus Analyzer**	**% Bias**
100	98	-1.8%	97	-3.2%
150	147	-2.0%	144	-4.3%
200	196	-2.0%	190	-4.9%
250	245	-2.1%	237	-5.2%
	Average % bias	**-2.0%**		**-4.4%**

Triglycerides Predicted Biases (mg/dL)		
Cobas	**CardioChek Plus Analyzer**	**% Bias**
100	98	-2.2%
150	145	-3.1%
200	193	-3.5%
250	241	-3.8%
	Average % bias	**-3.2%**

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





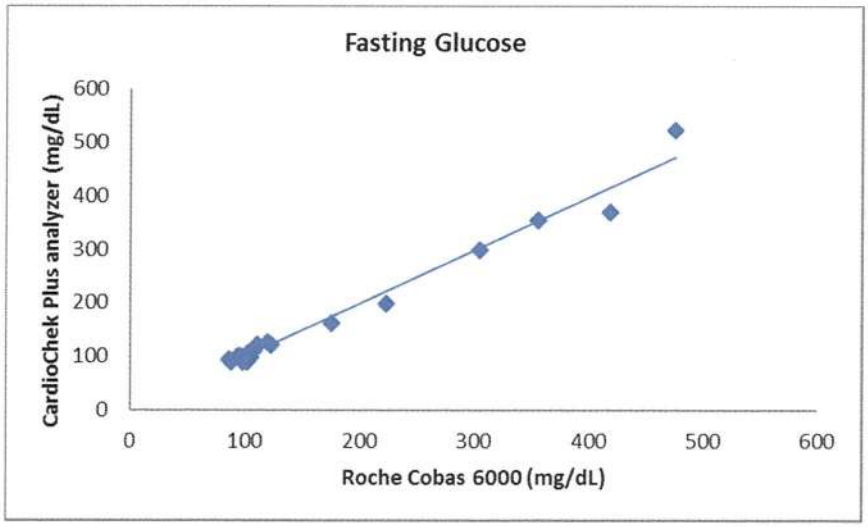
6 FASTING GLUCOSE

Fasting Glucose (mg/dL): Spikes only included with Cobas reference		
vs. AU5400	Cobas	CardioChek Plus Analyzer
N	15	15
Slope	1.12	1.17
Intercept	-9.0	-13.7
R	0.987	0.883
vs. Cobas		CardioChek Plus Analyzer
N		21
Slope		0.99
Intercept		-1.1
R		0.989

Fasting Glucose Predicted Biases (mg/dL): Spikes included		
Cobas	CardioChek Plus Analyzer	% Bias
100	98	-1.6%
150	148	-1.3%
200	198	-1.1%
250	248	-1.0%
	Average % bias	-1.2%

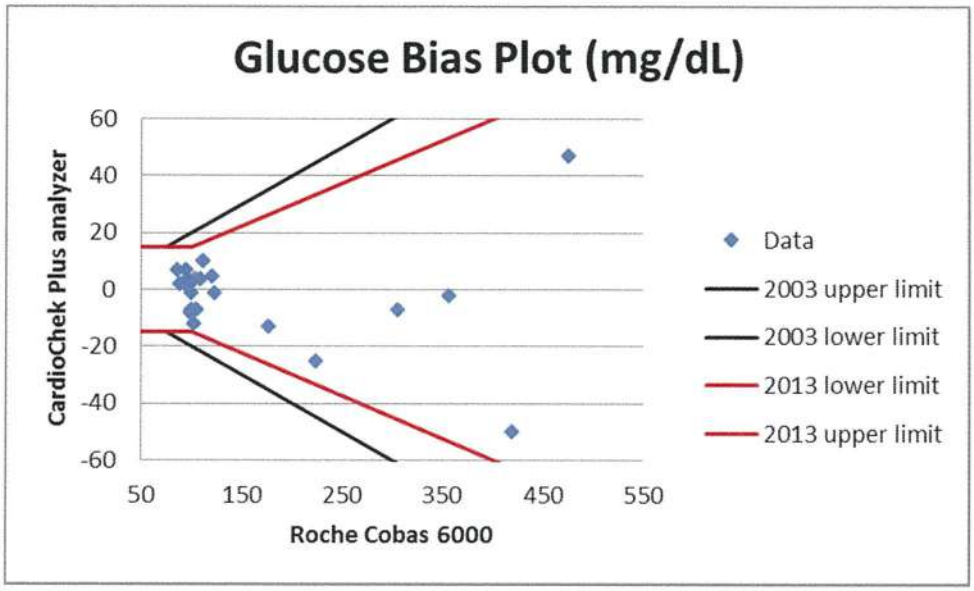
Predicted biases are based strictly on the linear regression line of the data collected.

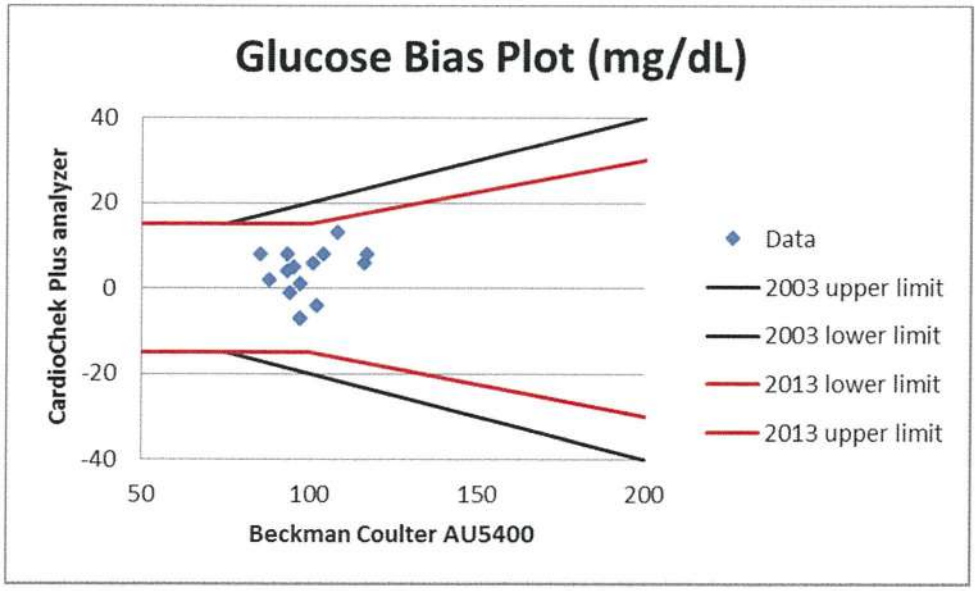
Predicted Biases only calculated with the Cobas due to insufficient samples spanning the dynamic range for the AU5400.



6 FASTING GLUCOSE (CONTINUED)

Glucose ISO Guidelines
Glucose evaluated according to the current 2003 ISO Standard:
Values up to 75 mg/dL ±15mg/dL
Values ≥75 mg/dL ± 20%





7 Risk Classification (CardioChek Plus Analyzer)

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 total cholesterol results of 199 and 200 mg/dL on the three 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 result 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 (mg/dL)										
Categories Compared	Total Cholesterol			HDL Cholesterol		Triglycerides			Fasting Glucose	
	<200	200 - 240	>240	<40	≥40	<150	150 - 200	>200	<126	≥126

Risk Classification Agreeement Between Methods and AU5400										
	Total Cholesterol			HDL Cholesterol		Triglycerides			Fasting 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	31	7	0	34	4	39	0	0	15	0
CardioChek Plus Analyzer	37	2	0	33	6	37	2	0	15	0

Risk Classification Agreement Between CardioChek Plus and Cobas										
	Total Cholesterol			HDL Cholesterol		Triglycerides			Fasting 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 Analyzer	30	9	0	34	5	37	3	0	21	0

8 PRECISION

CardioChek Plus Analyzer SN 5129995				
Sample ID	2	2	2	19
Analyte (mg/dL)	Cholesterol	HDL	Triglyceride	eGlucose
1	152	47	247	140
2	150	48	224	140
3	146	48	251	144
4	147	47	249	148
5	147	48	241	141
6	140	47	252	142
7	150	46	237	145
8	146	46	223	146
9	150	46	220	144
10	147	46	232	146
Number	10	10	10	10
Average	147.5	46.9	237.6	143.6
SD	3.3	0.9	12.3	2.8
%CV	2.3	1.9	5.2	1.9

CardioChek Plus Analyzer SN 5129995				
Sample ID	12	12	12	12
Analyte (mg/dL)	Cholesterol	HDL	Triglyceride	eGlucose
1	200	74	87	95
2	198	76	82	95
3	218	73	85	89
4	194	71	88	96
5	220	81	82	94
6	212	74	85	95
7	208	74	87	92
8	196	75	84	98
9	206	77	83	94
10	204	74	82	100
Number	10	10	10	10
Average	205.6	74.9	84.5	94.8
SD	9.0	2.7	2.3	3.0
%CV	4.4	3.6	2.7	3.2

8 PRECISION, CONTINUED

CardioChek Plus Analyzer SN 5131256				
Sample ID	15	15	15	15
Analyte (mg/dL)	Cholesterol	HDL	Triglyceride	eGlucose
1	277	71	115	104
2	290	70	113	93
3	252	74	122	97
4	276	72	116	102
5	284	67	124	103
6	257	70	122	92
7	266	75	123	100
8	270	71	121	98
9	273	72	129	102
10	276	71	127	92
Number	10	10	10	10
Average	272.1	71.3	121.2	98.3
SD	11.5	2.2	5.2	4.6
%CV	4.2	3.1	4.3	4.7

9 RESULTS (A1CNOW SYSTEM)

Evaluation by Average Difference

The following graphs and tables show the detailed analyses of the relationship of the results from the A1CNow System, Tosoh analyzer and the Roche Cobas 6000 analyzer.

The difference between the A1CNow 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:

HbA1c: ± 6%

The average difference calculated from the actual individual paired % Bias with the **Tosoh** analyzer. ((Comparator Result – Tosoh Lab Result) ÷ Tosoh Lab Result) * 100) are as follows:

Average of Paired % Biases		
vs. Tosoh	**Cobas**	**A1CNow System**
HbA1c %	-3.3%	-0.4%

The average difference calculated from the actual individual paired % Bias with the **Cobas** analyzer. ((Comparator Result – Cobas Lab Result) ÷ Cobas Lab Result) * 100) are as follows:

Average of Paired % Biases	
vs. Cobas	**A1CNow System**
HbA1c %	3.2%

Analyte Summary

The summary of the linear regression and predicted bias data is shown on the following page for HbA1c. This data is then used to calculate the predicted bias at specific clinical decision values spanning the dynamic range of the assay on the Tosoh. Actual predicted percent differences with the reference analyzers are calculated as:

((Comparator Result – Reference Lab Result) ÷ Reference Lab Result) *100)

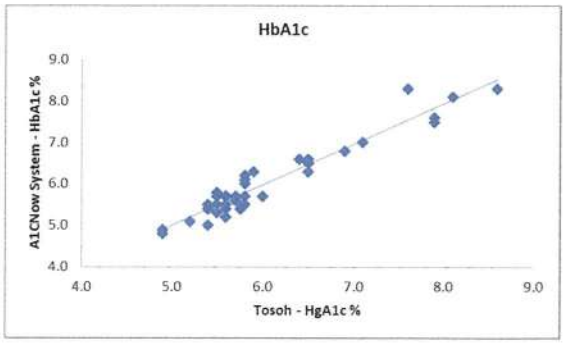
9 HbA1c % (A1CNow System)

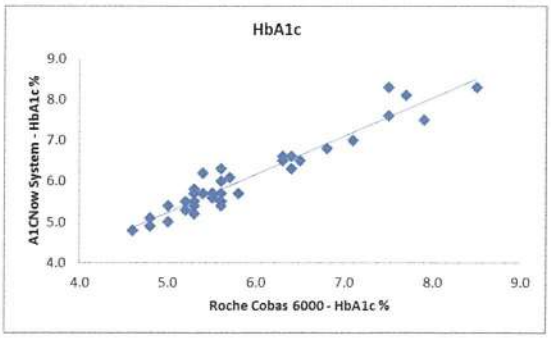
HbA1c %		
vs. Tosoh	Cobas	A1CNow System
N	39	40
Slope	1.03	0.98
Intercept	-0.4	0.1
R	0.991	0.965
vs. Cobas		A1CNow System
N		39
Slope		0.94
Intercept		0.5
R		0.960

HbA1c % Predicted Biases				
Tosoh	Cobas	% Bias	A1CNow System	% Bias
4.0	3.7	-6.3%	4.0	0.4%
5.7	5.5	-3.6%	5.7	-0.3%
6.5	6.3	-2.8%	6.5	-0.5%
7.0	6.8	-2.4%	7.0	-0.6%
	Average % bias	-3.8%		-0.2%

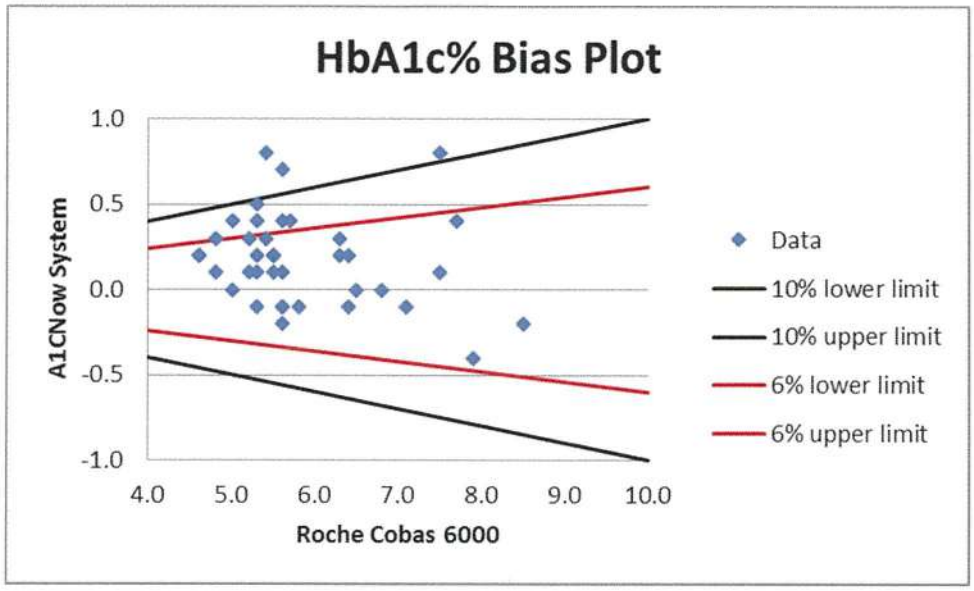
HbA1c Predicted Biases		
Cobas	A1CNow System	% Bias
4.0	4.3	7.3%
5.7	5.9	3.2%
6.5	6.6	2.1%
7.0	7.1	1.5%
	Average % bias	3.5%

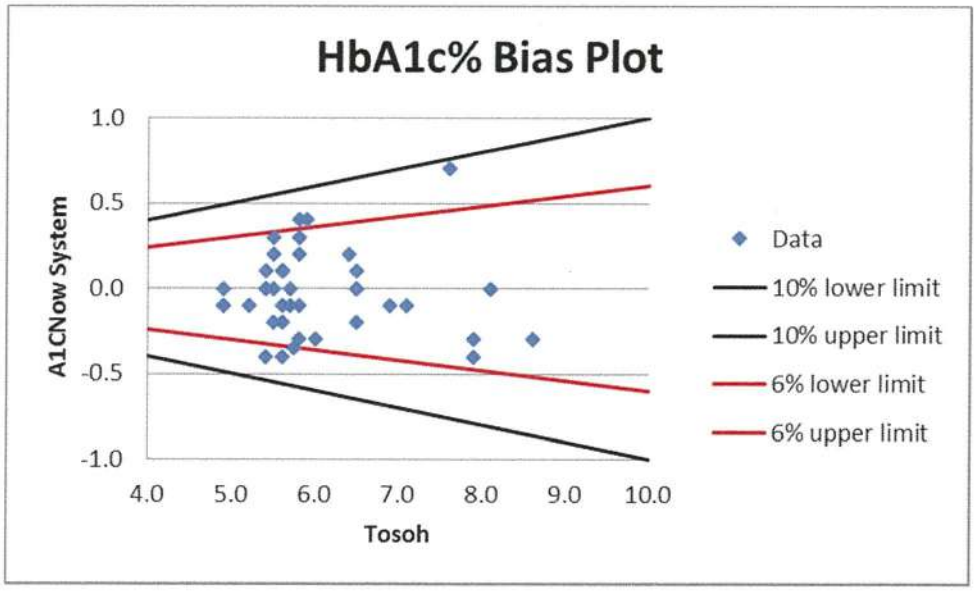
Predicted biases are based strictly on the linear regression line of the data collected.





9 HbA1c % (A1CNow System, Continued)





10Risk Classification (A1CNow System)

Each result was categorized based on traditional risk categories for HbA1c (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 HbA1c % results of 5.6% and 5.7% on the three 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 A1CNow system and the reference laboratory result. In no instance was a "2 Category Difference" observed in this clinical evaluation for HbA1c %.

Risk Classification (HbA1c %)			
Categories Compared	HbA1c %		
	<5.7	5.7 – 6.4	≥6.5

Risk Classification Agreement Between Methods and Tosoh			
	HbA1c %		
All Samples	Agree	1 Cat Diff	2 Cat Diff
Cobas	28	11	0
A1CNow	30	10	0

Risk Classification Agreement Between A1CNow System and Cobas			
	HbA1c %		
All Samples	Agree	1 Cat Diff	2 Cat Diff
A1CNow	26	13	0

11RAW DATA: CHOLESTEROL (mg/dL)

Sample #	Cobas	AU5400	CardioChek Plus Analyzer
1	153	166	166
2	146	157	140
3	164	176	151
4	183	194	203
5	211	223	213
6	262	269	246
7	231	242	214
8	181	193	197
9	234	241	222
10	189	198	176
11	265	283	272
12	210	216	211
13	173	185	181
14	169	178	146
15	250	266	254
16	190	201	189
17	223	236	209
18	224	237	225
19	180	190	149
20	174	196	180
21	218	231	216
22	201	217	195
23	182	195	149
24	193	205	167
25	169	179	181
26	217	232	223
27	226	243	220
28	189	202	182
29	187	204	188
30	226	233	226
31	172	N/A	164
32	138	151	133
33	241	255	263
34	190	189	154
35	124	134	130
36	150	160	143
37	153	169	148
38	163	174	146
39	183	194	182
40	N/A	159	144

Data for sample 31 - cholesterol was not provided from the Cobas.

Sample 40 was not sent to Quest for analysis.

12RAW DATA: HDL CHOLESTEROL (mg/dL)

Sample #	Cobas	AU5400	CardioChek Plus Analyzer
1	76	78	73
2	50	49	45
3	40	38	30
4	71	74	74
5	82	80	82
6	56	56	49
7	64	63	58
8	29	27	28
9	80	81	70
10	65	65	58
11	105	101	96
12	79	80	80
13	84	86	78
14	43	42	34
15	72	70	62
16	79	85	75
17	66	64	49
18	66	64	59
19	52	53	43
20	57	55	49
21	68	68	62
22	49	51	41
23	41	38	33
24	54	52	40
25	61	63	61
26	46	44	43
27	58	54	52
28	75	72	71
29	66	64	55
30	44	42	37
31	67	N/A	74
32	55	57	54
33	40	38	42
34	50	47	42
35	33	32	31
36	44	42	36
37	40	39	39
38	32	31	33
39	49	49	47
40	N/A	42	38

Data for sample 31 - cholesterol was not provided from the Cobas.

Sample 40 was not sent to Quest for analysis.

13RAW DATA: TRIGLYCERIDE (mg/dL)

Sample #	Cobas	AU5400	CardioChek Plus Analyzer
1	48	46	60
2	239	236	247
3	156	150	152
4	128	124	116
5	126	123	120
6	124	120	113
7	121	117	97
8	108	102	121
9	105	106	99
10	80	79	79
11	146	143	132
12	93	95	91
13	74	74	114
14	68	66	65
15	115	118	119
16	44	46	54
17	83	79	75
18	140	134	117
19	148	144	123
20	99	97	95
21	198	190	203
22	127	128	120
23	143	141	109
24	79	78	73
25	67	67	71
26	227	228	227
27	211	208	206
28	100	102	95
29	116	114	91
30	243	231	227
31	104	88	95
32	106	111	120
33	293	292	315
34	190	179	177
35	243	237	228
36	176	180	132
37	252	251	230
38	237	232	239
39	397	386	360
40	N/A	166	124

Sample 40 was not sent to Quest for analysis.

14RAW DATA: GLUCOSE (mg/dL)

Sample #	Cobas	AU5400	CardioChek Plus Analyzer
1	85	86	93
2	93	94	101
3	116	123	122
4	95	96	100
5	117	120	125
6	94	100	93
7	97	99	98
8	97	102	90
9	102	105	98
10	148	149	136
11	110	108	117
12	101	103	107
13	104	103	99
14	88	88	90
15	110	111	123
16	93	96	97
17	97	98	90
18	91	91	87
19	134	136	145
20	93	93	112
21	80	81	98
22	97	98	94
23	98	98	94
24	82	82	82
25	83	82	83
26	92	93	97
27	112	113	104
28	104	108	112
29	88	89	92
30	100	104	106
31	108	111	121
32	151	148	148
33	162	165	158
34	140	139	132
35	123	127	136
36	314	316	299
37	85	89	91
38	91	95	97
39	202	212	236
40	N/A	117	115

16 RAW DATA: GLUCOSE (mg/dL) Continued

Sample #	Cobas	AU5400	CardioChek Plus Analyzer
GS-1*	475	N/A	522
GS-2*	356	N/A	354
GS-3*	176	N/A	163
GS-4*	419	N/A	369
GS-5*	305	N/A	298
GS-6*	223	N/A	198

Sample 40 was not sent to Quest for analysis.

Glucose Spike - Sample was only analyzed on Roche Cobas.

17 RAW DATA: HbA1c %

Sample #	Cobas	Tosoh	A1CNow System
1	5.0	5.4	5.0
2	5.4	5.5	5.7
3	6.4	6.4	6.6
4	5.0	5.4	5.4
5	6.3	6.5	6.5
6	5.6	5.6	5.5
7	5.5	5.6	5.7
8	5.3	5.6	5.7
9	5.6	5.8	5.5
10	6.5	6.5	6.5
11	5.2	5.5	5.3
12	5.6	5.8	5.4
13	4.8	5.2	5.1
14	5.2	5.5	5.5
15	5.3	5.5	5.8
16	5.3	5.6	5.2
17	5.5	5.7	5.6
18	5.3	5.4	5.4
19	5.5	5.7	5.7
20	5.3	5.4	5.5
21	4.6	4.9	4.8
22	5.6	5.8	6.0
23	5.8	6.0	5.7
24	4.8	4.9	4.9
25	4.6	4.9	4.8
26	5.4	5.8	6.2
27	5.6	5.6	5.7
28	5.6	5.9	6.3
29	5.7	5.8	6.1
30	N/A	5.6	5.4
31	6.4	6.5	6.3
32	7.7	8.1	8.1
33	8.5	8.6	8.3
34	7.1	7.1	7.0
35	6.8	6.9	6.8
36	7.5	7.9	7.6
37	7.5	7.6	8.3
38	6.3	6.5	6.6
39	7.9	7.9	7.5
40	5.5	5.8	5.7

Insufficient sample to analyze on the Cobas.

18 Overview of Evaluation

Evaluation Site
Novant – Thomasville Medical Center
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Technical Service Specialist (TSS)
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Third Party Comparison: (X-axis)
Thomasville Medical Center: Roche Cobas 6000 (Lipid panel, glucose, HbA1c)
Quest Diagnostics: Beckman Coulter AU5400 (Lipid panel, glucose)
PTS Diagnostics: Tosoh (HbA1c)

Reagents Used
CardioChek Plus Smart Bundle Pack: Lot Q603
Multi-Chemistry Controls: Lot MC23
HDL Cholesterol Controls: Lot HC22
A1CNow system: Lot 1525327
Nova-One Diagnostics HbA1c Controls: 5286H004

Accuracy Instruments: (Y-axis)
CardioChek Plus analyzer: SN 5129995 v.1.08
A1CNow System: Lot 1525327

Precision Instruments:
CardioChek Plus analyzer: SN 5129995 v.1.08
CardioChek Plus analyzer: SN5131256 v.1.08

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

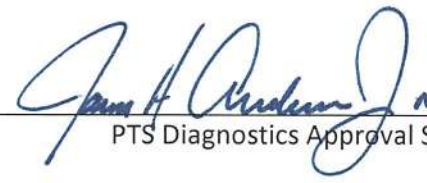
Data Summary

CardioChek Plus Test System

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 analyzer point-of-care method and the reference laboratory method(s) for total cholesterol, HDL cholesterol, triglycerides, and glucose. The risk classification tables demonstrate that the CardioChek Plus analyzer 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 analyzer for all four analytes. In summation, the data as a whole demonstrate clinical equivalency between all methods used.

A1CNow + Test System

The A1CNow + test system produced clinically equivalent values for hemoglobin A1C 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 A1CNow + analyzer point-of-care method and the reference laboratory method(s) for hemoglobin A1C. The risk classification tables demonstrate that the A1CNow + analyzer accurately identifies patient risk category with a high level of correlation with reference methods. In summation, the data as a whole demonstrate clinical equivalency between all methods used.



PTS Diagnostics Approval Signature:

13 MAY 16

Date

TB000050 r0 05/16