CardioChek® Plus

Comparison Study Summary

Springs Memorial Hospital
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Lancaster, SC 29720
(803) 286-1480

February 10, 2016

1 PROTOCOL

This evaluation was conducted on February 10, 2016 at Springs Memorial Hospital in Lancaster, SC. It consisted of a comparative analysis of the CardioChek® Plus analyzer using CardioChek® Plus Lipid + eGlu® Smart Bundle™ test strips. The study compared fingerstick samples on the CardioChek® Plus analyzer to serum samples tested on Springs Memorial Hospital's Beckman Coulter DxC 660i (DxC). Thirty-three (33) participants were tested, twenty-nine (29) 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 will be utilized for the glucose calculations.

At the test site, a Springs Memorial Hospital employee performed a venipuncture blood draw and collected one (1) serum separator gold top tube and one (1) lithium heparin, whole blood dark green top tube. The serum was used for analysis on the reference analyzers, and the whole blood for the precision studies. The serum separator tube was allowed to clot after collection, centrifuged, and then analyzed on the Beckman DxC analyzer at Springs Memorial Hospital. An aliquot was removed from each serum separator tube, placed in a shipping envelope with ice packs and delivered to PTS Diagnostics for next day analysis on the Roche Cobas Integra 400 Plus (Integra).

Immediately following the venous draw, the participant had a fingerstick performed by either a PTS Diagnostics employee (designated by samples starting with "A") or a properly trained Springs Memorial Hospital employee (designated by samples starting with "B"). The first drop of blood was dosed to the electrochemical glucose test strip on the CardioChek Plus analyzer. The drop of blood was wiped from the finger and a 40µl PTS Diagnostics™ capillary tube was collected and dosed to the lipid panel test strip.

	Testing Range
Total Cholesterol	144 – 263
HDL Cholesterol	36 – 95
Triglyceride	44 – 321
Fasting Glucose	83 – 172

Testing range based on Roche Cobas Integra 400 plus analyzer
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, Roche Cobas Integra 400 plus analyzer and the Beckman Coulter DxC 660i 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 **Integra** analyzer. ((Comparator Result – Integra Lab Result) ÷ Integra Lab Result) *100) are as follows:

Average of Paired % Biases		
vs. Integra	**DxC**	**CardioChek Plus Analyzer**
Total Cholesterol	3.4%	-0.7%
HDL Cholesterol	-0.8%	-5.0%
Triglycerides	1.0%	5.5%
Fasting Glucose	4.2%	1.3%

The average difference calculated from the actual individual paired percent Bias with the **DxC** analyzer.

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

Average of Paired % Biases	
vs. DxC	**CardioChek Plus Analyzer**
Total Cholesterol	-3.8%
HDL Cholesterol	-1.3%
Triglycerides	4.0%
Fasting Glucose	-2.8%

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. Predicted bias data was not provided for glucose due to the lack of values spanning the dynamic range of the assay.

Actual predicted % differences with the reference analyzers are calculated as:

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

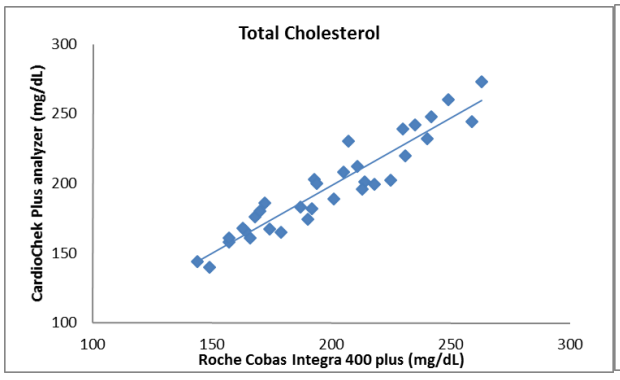
3 TOTAL CHOLESTEROL

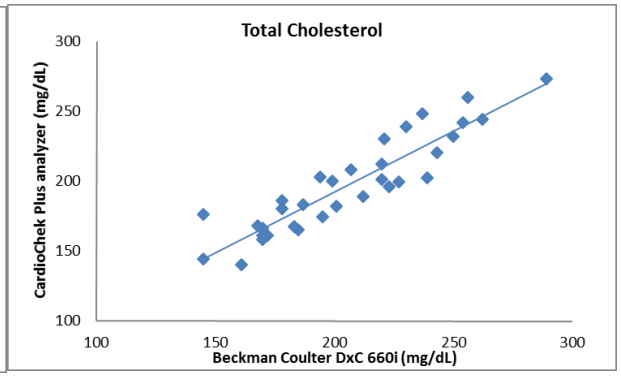
Total Cholesterol (mg/dL)		
vs. Integra	**DxC**	**CardioChek Plus Analyzer**
N	33	33
Slope	1.06	0.97
Intercept	-4.3	3.7
R	0.976	0.945
vs. DxC		**CardioChek Plus Analyzer**
Slope		0.87
Intercept		17.9
R		0.916

Total Cholesterol Predicted Biases (mg/dL)				
Integra	**DxC**	**% Bias**	**CardioChek Plus analyzer**	**% Bias**
160	165	3.0%	159	-0.4%
200	207	3.5%	198	-0.8%
240	249	3.9%	237	-1.1%
280	292	4.1%	276	-1.4%
	Average % Bias	**3.6%**		**-0.9%**

Total Cholesterol Predicted Biases (mg/dL)		
DxC	**CardioChek Plus Analyzer**	**% Bias**
160	157	-1.7%
200	192	-3.9%
240	227	-5.4%
280	262	-6.5%
	Average % Bias	**-4.4%**

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





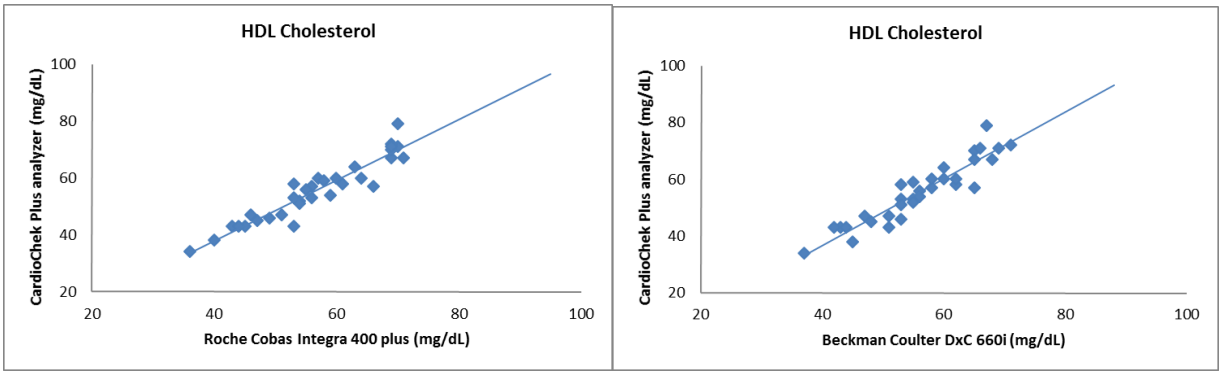
4 HDL CHOLESTEROL

HDL Cholesterol (mg/dL)		
vs. Integra	**DxC**	**CardioChek Plus Analyzer**
N	33	32
Slope	0.86	1.06
Intercept	7.5	-4.6
R	0.983	0.944
vs. DxC		**CardioChek Plus Analyzer**
Slope		1.18
Intercept		-10.4
R		0.932

HDL Cholesterol Predicted Biases (mg/dL)				
Integra	**DxC**	**% Bias**	**CardioChek Plus Analyzer**	**% Bias**
40	42	4.5%	38	-5.2%
60	59	-1.7%	59	-1.3%
80	76	-4.9%	81	0.6%
100	93	-6.7%	102	1.8%
	Average % Bias	**-2.2%**		**-1.0%**

HDL Cholesterol Predicted Biases (mg/dL)		
DxC	**CardioChek Plus Analyzer**	**% Bias**
40	37	-8.3%
60	60	0.4%
80	84	4.7%
100	107	7.3%
	Average % Bias	**1.0%**

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



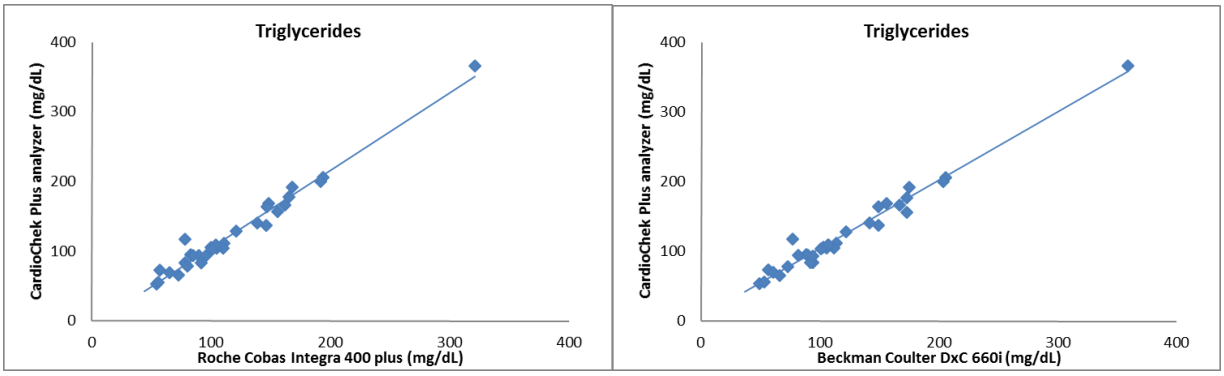
5 TRIGLYCERIDES

Triglycerides (mg/dL)		
vs. Integra	DxC	CardioChek Plus Analyzer
N	33	31
Slope	1.13	1.11
Intercept	-11.7	-6.7
R	0.997	0.985
vs. DxC		CardioChek Plus Analyzer
Slope		0.98
Intercept		5.3
R		0.985

Triglycerides Predicted Biases (mg/dL)				
Integra	DxC	% Bias	CardioChek Plus Analyzer	% Bias
100	101	1.4%	105	4.7%
150	158	5.3%	160	6.9%
200	215	7.3%	216	8.1%
250	271	8.5%	272	8.7%
	Average % Bias	**5.6%**		**7.1%**

Triglycerides Predicted Biases (mg/dL)		
DxC	CardioChek Plus Analyzer	% Bias
100	103	3.4%
150	152	1.7%
200	202	0.8%
250	251	0.2%
	Average % Bias	**1.5%**

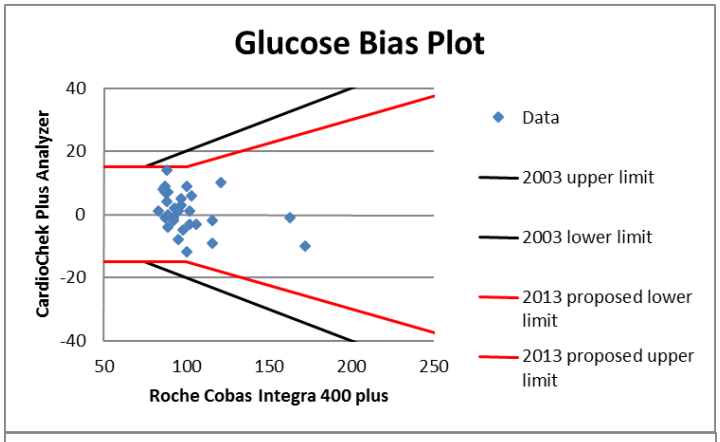
Predicted biases are based strictly on the linear regression line of the data collected.

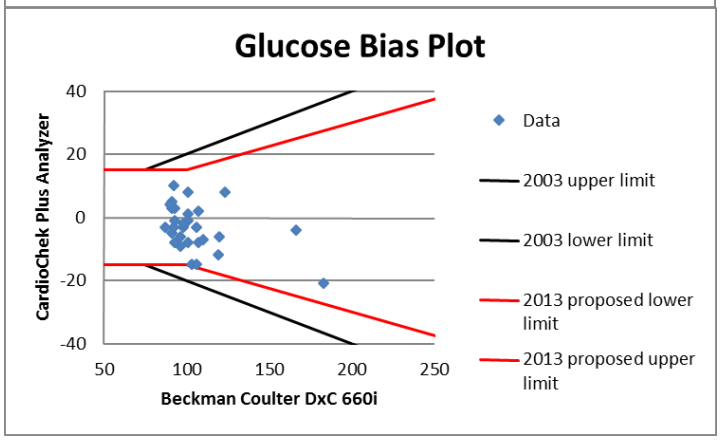


6 FASTING GLUCOSE

Fasting Glucose (mg/dL)		
vs. Integra	**DxC**	**CardioChek Plus Analyzer**
N	29	29
Slope	1.03	0.89
Intercept	1.6	12.0
R	0.993	0.951
vs. DxC		**CardioChek Plus Analyzer**
Slope		0.85
Intercept		12.3
R		0.941

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

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 (3) test systems was rated as a one (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 Agreement Between Methods and Integra										
	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**
DxC	29	4	0	33	0	30	3	0	29	0
CardioChek Plus Analyzer	26	7	0	32	1	29	4	0	28	1

Risk Classification Agreeement Between CardioChek Plus Analyzer and DxC										
	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	24	9	0	32	1	32	1	0	28	1

8 PRECISION

CardioChek Plus Analyzer SN 5125266				
Sample ID	A-2	A-2	A-2	A-2
Analyte	Cholesterol	HDL	Triglyceride	eGlucose
1	246	65	119	120
2	249	67	118	120
3	252	65	106	115
4	249	65	119	117
5	236	66	115	120
6	249	69	109	117
7	242	69	109	115
8	254	67	110	127
9	260	62	109	123
10	259	62	112	120
Number	10	10	10	10
Average	249.6	65.7	112.6	119.4
SD	7.3	2.5	4.8	3.7
%CV	2.9	3.7	4.3	3.1

CardioChek Plus Analyzer SN 5125266				
Sample ID	A-4	A-4	A-4	A-4
Analyte	Cholesterol	HDL	Triglyceride	eGlucose
1	237	47	149	106
2	229	48	145	107
3	217	48	147	104
4	228	48	151	103
5	223	44	149	106
6	215	43	164	97
7	214	45	162	106
8	232	48	142	104
9	228	47	141	101
10	231	46	150	99
Number	10	10	10	10
Average	225.4	46.4	150	103.3
SD	7.8	1.8	7.6	3.3
%CV	3.5	4.0	5.1	3.2

8 PRECISION, CONTINUED

CardioChek Plus Analyzer SN 5125266				
Sample ID	B-3	B-3	B-3	B-3
Analyte	Cholesterol	HDL	Triglyceride	eGlucose
1	192	35	167	104
2	202	33	165	101
3	195	35	156	107
4	207	34	162	107
5	192	36	165	105
6	185	35	156	103
7	194	34	160	103
8	189	34	160	103
9	202	34	154	105
10	191	33	160	103
Number	10	10	10	10
Average	194.9	34.3	160.5	104.1
SD	6.8	0.9	4.3	1.9
%CV	3.5	2.8	2.7	1.8

9 RAW DATA: CHOLESTEROL (mg/dL)

Sample #	Integra	Beckman DxC	CardioChek Plus Analyzer
A-1	192	201	182
A-2	259	262	244
A-3	205	207	208
A-4	231	243	220
A-5	179	185	165
A-6	201	212	189
A-7	187	187	183
A-8	193	194	203
A-9	164	170	166
A-10	157	170	158
A-11	211	220	212
A-12	168	145	176
A-13	225	239	202
A-14	249	256	260
A-15	230	230	239
A-16	242	237	248
A-17	263	289	273
A-18	172	178	186
A-19	235	254	242
B-1	194	199	200
B-2	144	145	144
B-3	190	195	174
B-4	218	227	199
B-5	163	168	168
B-6	207	221	230
B-7	157	172	161
B-8	174	183	167
B-9	214	220	201
B-10	166	170	161
B-11	213	223	196
B-12	149	161	140
B-13	240	250	232
B-14	170	178	180

10 RAW DATA: HDL CHOLESTEROL (mg/dL)

Sample #	Integra	Beckman DxC	CardioChek Plus Analyzer
A-1	56	55	53
A-2	63	60	64
A-3	49	53	46
A-4	51	51	47
A-5	66	65	57
A-6	43	43	43
A-7	69	68	67
A-8	56	58	57
A-9	61	62	58
A-10	64	62	60
A-11	70	69	71
A-12	55	56	56
A-13	54	55	52
A-14	95	88	>100
A-15	57	58	60
A-16	69	65	70
A-17	40	45	38
A-18	71	65	67
A-19	53	53	53
B-1	69	71	72
B-2	59	56	54
B-3	36	37	34
B-4	46	47	47
B-5	45	44	43
B-6	53	53	58
B-7	58	55	59
B-8	47	48	45
B-9	70	67	79
B-10	44	42	43
B-11	53	51	43
B-12	54	53	51
B-13	60	60	60
B-14	69	66	71

Indicates that the sample ran outside of the measuring range of the CardioChek Plus Analyzer for HDL.

11 RAW DATA: TRIGLYCERIDE (mg/dL)

Sample #	Integra	Beckman DxC	CardioChek Plus Analyzer
A-1	90	90	94
A-2	111	114	111
A-3	110	112	104
A-4	168	175	192
A-5	54	49	53
A-6	105	106	104
A-7	44	37	56
A-8	78	77	117
A-9	121	122	128
A-10	83	89	95
A-11	57	57	73
A-12	78	94	83
A-13	92	92	83
A-14	148	156	168
A-15	100	103	105
A-16	194	206	206
A-17	321	359	366
A-18	65	61	69
A-19	104	107	109
B-1	80	73	78
B-2	96	94	93
B-3	162	167	166
B-4	101	101	103
B-5	165	173	177
B-6	147	149	164
B-7	49	47	60
B-8	139	142	140
B-9	146	149	137
B-10	56	53	55
B-11	156	173	156
B-12	73	66	65
B-13	192	204	200
B-14	85	82	94

Indicates that the sample ran outside of the testing measuring range for triglycerides and was not included in calculations.

12 RAW DATA: GLUCOSE (mg/dL)

Sample #	Integra	Beckman DxC	CardioChek Plus Analyzer
A-1	103	107	109
A-2	116	119	107
A-3	87	91	96
A-4	100	103	88
A-5	102	107	99
A-6	116	120	114
A-7	87	91	86
A-8	97	101	102
A-9	97	101	100
A-10	89	92	89
A-11	106	110	103
A-12	92	106	91
A-13	69	72	83
A-14	88	93	92
A-15	89	93	96
A-16	93	98	95
A-17	172	183	162
A-18	95	96	87
A-19	99	101	99
B-1	88	92	102
B-2	102	106	103
B-3	100	101	109
B-4	95	98	96
B-5	98	101	93
B-6	163	166	162
B-7	83	87	84
B-8	121	123	131
B-9	87	91	94
B-10	86	90	94
B-11	92	96	90
B-12	70	72	88
B-13	89	93	85
B-14	89	91	80

Indicates non-fasting participants.

13 Overview of Evaluation

Evaluation Site
Springs Memorial Hospital
800 W. Meeting St.
Lancaster, SC 29720

Technical Service Specialist (TSS)
Emily Suscha

Account Contacts
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April Mathis, MT
Assistant Administrative Laboratory Director
April_Mathis@CHS.net
(803) 286-1648

Third Party Comparison: (X-axis)
Springs Memorial Hospital: Beckman Coulter DxC 660i
PTS Diagnostics: Roche Cobas Integra 400 plus

Reagents Used
CardioChek Plus Smart Bundle Pack: Lot Q513
Multi-Chemistry controls: Lot MC23
HDL Cholesterol controls: Lot HC21

Accuracy Instruments: (Y-axis)
CardioChek Plus analyzer: SN 5125266 v.1.07
CardioChek Plus analyzer: SN 5122627 v.1.07

Precision Instrument:
CardioChek Plus analyzer: SN 5125266 v.1.07

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 analysis, 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 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.

Lee B. Springer Ph.D.
Director of Clinical Laboratory Medicine — 2/12/2016

PTS Diagnostics Approval Signature: — Date

TB000049 r0 03/16