CardioChek® P·A

Comparison Study Summary

April 23, 2019

1 PROTOCOL

This evaluation was conducted on April 23, 2019 at PTS Diagnostics in Indianapolis, IN. It consisted of a comparative analysis of the CardioChek® PA analyzer using PTS Panels® Lipid Panel and PTS Panels® Total Cholesterol test strips. The study compared fingerstick and venous samples on two CardioChek® PA analyzers to serum samples tested on a Roche Cobas Integra 400 plus (Integra) at PTS Diagnostics and on a Beckman AU5400 (AU5400) by Quest Diagnostics. Twenty (20) participants were tested.

At the test site, a PTS Diagnostics employee performed a venipuncture blood draw and collected one (1) lithium heparin whole blood green top tube and one (1) serum clot red top tube. The serum tube for each participant was allowed to clot for 30 minutes and then centrifuged. The serum was then split into two aliquots. The first aliquot was packaged and transported to Quest Diagnostics for analysis on the Beckman AU5400. The second aliquot was immediately processed for analysis at PTS Diagnostics on the Integra 400 plus. The lithium heparin whole blood tube was retained in the testing area for use in venous testing and in the precision analysis.

Immediately following the blood draw, a fingerstick was performed by a PTS Diagnostics employee. The first drop of blood was wiped from the finger with gauze, a 40µL PTS Collect capillary tube was collected, and the sample was applied to the Lipid Panel test strip on the CardioChek PA (SN 3202266) analyzer. The residual blood was wiped from the finger and a 15µL PTS Collect capillary tube was collected and applied to the total Cholesterol test strip on the CardioChek PA (SN 3232886) analyzer.

Immediately following the fingerstick analysis, the lithium heparin whole blood was analyzed on both of the CardioChek PA analyzers. Using a precision pipette, a 40 µL sample of blood was applied to the lipid panel test strip on the CardioChek PA (SN 3202266) analyzer. Using a second precision pipette, a 15µL sample was applied to the total cholesterol test strip on the CardioChek PA (SN 3232886) analyzer.

The precision study was completed using the whole blood collected in the lithium heparin tubes. Three samples which represented a low, mid, and high value for total cholesterol, HDL cholesterol, and triglycerides were run ten (10) times each on each CardioChek PA analyzer using a precision pipette.

1 PROTOCOL, CONTINUED

The following table lists the ranges of Integra results for the samples tested.

All results are in mg/dL

Analytes	Testing Range
Total Cholesterol	101 – 264
HDL Cholesterol	31 – 92
Triglycerides	33 – 316

2 RESULTS - LIPID PANEL TEST STRIPS, (FINGERSTICK)

Evaluation by Average Difference

The following graphs and tables show the detailed analyses of the relationship of the results from the CardioChek PA Test System, Quest Diagnostics' Beckman AU5400 analyzer, and the PTS Diagnostics' Roche Cobas Integra 400 plus analyzer.

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

Total cholesterol:	± 10%
HDL cholesterol:	± 12%
Triglycerides:	± 15%

The average difference calculated from the actual individual paired % Bias to the **Integra** analyzer.
i.e.: ((**AU5400** – Integra Lab Result) ÷ Integra Lab Result) *100 are as follows:

Average of % Bias vs. Integra		
vs. Integra	**AU5400**	**CardioChek PA SN 3202266**
Total Cholesterol	2.8%	-1.2%
HDL Cholesterol	0.0%	3.4%
Triglycerides	6.9%	-6.3%

The average difference calculated from the actual individual paired % Bias to the **AU5400** analyzer.
i.e.: ((**CardioChek PA** – AU5400 Lab Result) ÷ AU5400 Lab Result) *100 are as follows:

Average of % Bias vs. AU5400	
vs. AU5400	**CardioChek PA SN 3202266**
Total Cholesterol	-3.7%
HDL Cholesterol	3.6%
Triglycerides	-12.1%

NOTE: This value is the average difference of all results; differences between individual results are expected to vary both below and above the average.

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. This data is then used to calculate the predicted biases for each analyte at specific clinical decision values. Actual predicted % differences with the reference analyzers are calculated as:
((Comparator Result – Reference Lab Result) ÷ Reference Lab Result) *100 = % Bias

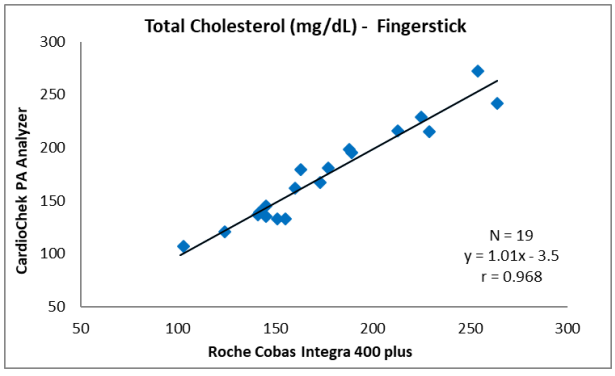
3 TOTAL CHOLESTEROL - LIPID PANEL TEST STRIPS, (FINGERSTICK)

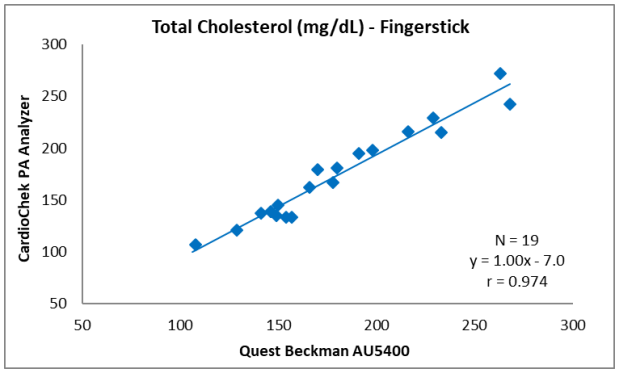
Total Cholesterol (mg/dL)		
vs. Integra	**AU5400**	**CardioChek PA SN 3202266**
N	20	19
Slope	1.01	1.01
Intercept	3.0	-3.5
Correlation Coefficient (r)	0.999	0.968
vs. AU5400		**CardioChek PA SN 3202266**
N		19
Slope		1.00
Intercept		-7.0
Correlation Coefficient (r)		0.974

Total Cholesterol Predicted Biases (mg/dL)				
Integra	**AU5400**	**% Bias**	**CardioChek PA SN 3202266**	**% Bias**
160	164	2.7%	158	-1.2%
200	205	2.4%	198	-0.8%
240	245	2.1%	239	-0.5%
280	285	1.9%	279	-0.3%
	Average % bias	**2.3%**		**-0.7%**

Total Cholesterol Predicted Biases (mg/dL)		
AU5400	**CardioChek PA SN 3202266**	**% Bias**
160	154	-4.0%
200	194	-3.1%
240	234	-2.5%
280	274	-2.1%
	Average % bias	**-2.9%**

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





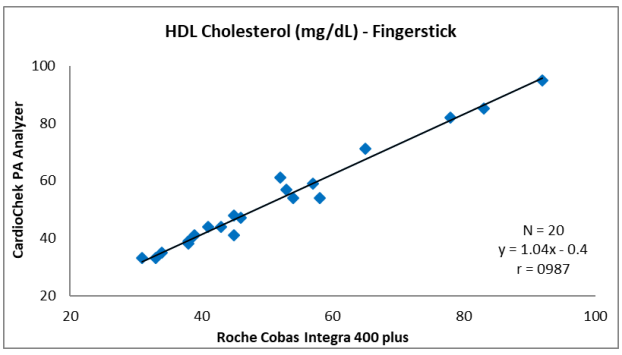
4 HDL CHOLESTEROL - LIPID PANEL TEST STRIPS, (FINGERSTICK)

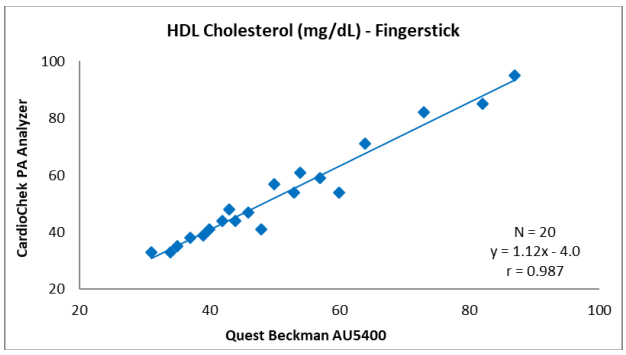
HDL Cholesterol (mg/dL)		
vs. Integra	**AU5400**	**CardioChek PA SN 3202266**
N	20	20
Slope	0.92	1.04
Intercept	3.9	-0.4
Correlation Coefficient (r)	0.994	0.987
vs. AU5400		**CardioChek PA SN 3202266**
N		20
Slope		1.12
Intercept		-4.0
Correlation Coefficient (r)		0.977

HDL Cholesterol Predicted Biases (mg/dL)				
Integra	**AU5400**	**% Bias**	**CardioChek PA SN 3202266**	**% Bias**
40	41	1.6%	41	3.3%
60	59	-1.7%	62	3.6%
80	77	-3.3%	83	3.8%
100	96	-4.3%	104	3.9%
	Average % bias	**-1.9%**		**3.7%**

HDL Cholesterol Predicted Biases (mg/dL)		
AU5400	**CardioChek PA SN 3202266**	**% Bias**
40	41	2.0%
60	63	5.3%
80	86	6.9%
100	108	7.9%
	Average % bias	**5.5%**

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





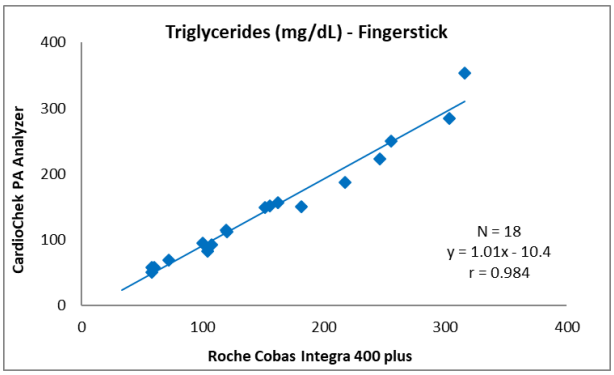
5 TRIGLYCERIDES - LIPID PANEL TEST STRIPS, (FINGERSTICK)

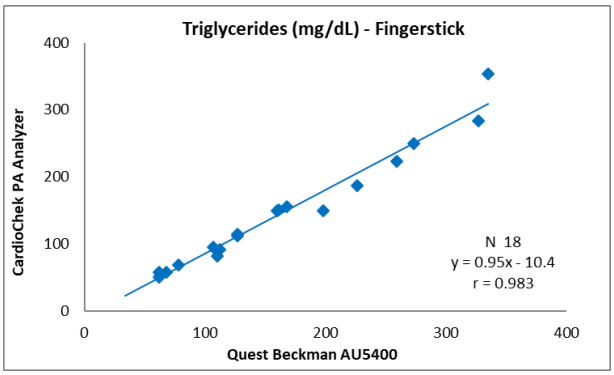
Triglycerides (mg/dL)		
vs. Integra	**AU5400**	**CardioChek PA SN 3202266**
N	20	18
Slope	1.06	1.01
Intercept	0.6	-10.4
Correlation Coefficient (r)	1.000	0.984
vs. AU5400		**CardioChek PA SN 3202266**
N		18
Slope		0.95
Intercept		-10.4
Correlation Coefficient (r)		0.983

Triglycerides Predicted Biases (mg/dL)				
Integra	**AU5400**	**% Bias**	**CardioChek PA SN 3202266**	**% Bias**
100	107	6.6%	91	-9.0%
150	160	6.4%	142	-5.5%
200	213	6.3%	192	-3.8%
250	266	6.2%	243	-2.8%
	Average % bias	**6.4%**		**-5.3%**

Triglycerides Predicted Biases (mg/dL)		
AU5400	**CardioChek PA SN 3202266**	**% Bias**
100	85	-15.0%
150	133	-11.6%
200	180	-9.8%
250	228	-8.8%
	Average % bias	**-11.3%**

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





6 RISK CLASSIFICATION - LIPID PANEL TEST STRIPS, (FINGERSTICK)

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 (bottom tables 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 PA and the reference laboratory results**.** In no instance was a "2 Category Difference" observed in this clinical evaluation for total cholesterol, HDL cholesterol or triglycerides.

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

Risk Classification Agreement Between Methods and Integra								
	Total Cholesterol			HDL Cholesterol		Triglycerides		
All Samples	Agree	1 Cat Diff	2 Cat Diff	Agree	1 Cat Diff	Agree	1 Cat Diff	2 Cat Diff
AU5400	20	0	0	19	1	20	0	0
CardioChek PA SN 3202266	20	0	0	19	1	18	2	0

Risk Classification Agreement Between Methods and AU5400								
	Total Cholesterol			HDL Cholesterol		Triglycerides		
All Samples	Agree	1 Cat Diff	2 Cat Diff	Agree	1 Cat Diff	Agree	1 Cat Diff	2 Cat Diff
CardioChek PA SN 3202266	20	0	0	20	0	18	2	0

7 RESULTS - LIPID PANEL TEST STRIPS, (VENOUS)

Evaluation by Average Difference

The following graphs and tables show the detailed analyses of the relationship of the results from the CardioChek PA Test System, Quest Diagnostics' Beckman AU5400 analyzer, and the PTS Diagnostics' Roche Cobas Integra 400 plus analyzer.

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

Total cholesterol:	± 10%
HDL cholesterol:	± 12%
Triglycerides:	± 15%

The average difference calculated from the actual individual paired % Bias to the **Integra** analyzer. i.e.: ((**AU5400** – Integra Lab Result) ÷ Integra Lab Result) *100 are as follows:

Average of % Bias vs. Integra		
vs. Integra	**AU5400**	**CardioChek PA SN 3202266**
Total Cholesterol	2.8%	2.4%
HDL Cholesterol	0.0%	5.3%
Triglycerides	6.9%	-3.0%

The average difference calculated from the actual individual paired % Bias to the **AU5400** analyzer. i.e.: ((**CardioChek PA** – AU5400 Lab Result) ÷ AU5400 Lab Result) *100 are as follows:

Average of % Bias vs. AU5400	
vs. AU5400	**CardioChek PA SN 3202266**
Total Cholesterol	-0.1%
HDL Cholesterol	5.1%
Triglycerides	-9.0%

NOTE: This value is the average difference of all results; differences between individual results are expected to vary both below and above the average.

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. This data is then used to calculate the predicted biases for each analyte at specific clinical decision values. Actual predicted % differences with the reference analyzers are calculated as:
((Comparator Result – Reference Lab Result) ÷ Reference Lab Result) *100 = % Bias

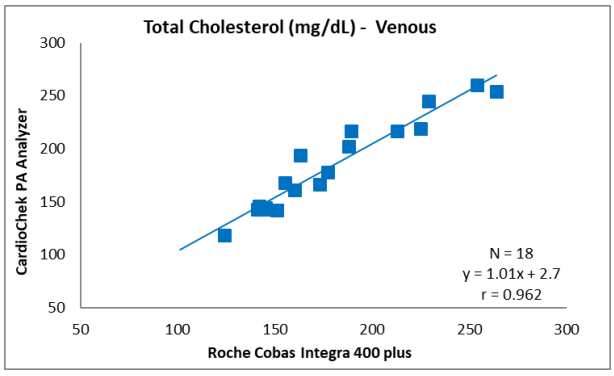
8 TOTAL CHOLESTEROL - LIPID PANEL TEST STRIPS, (VENOUS)

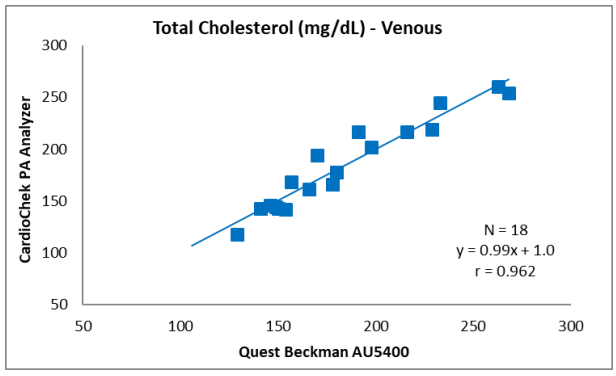
Total Cholesterol (mg/dL)		
vs. Integra	**AU5400**	**CardioChek PA SN 3202266**
N	20	18
Slope	1.01	1.01
Intercept	3.0	2.7
Correlation Coefficient (r)	0.999	0.962
vs. AU5400		**CardioChek PA SN 3202266**
N		18
Slope		0.99
Intercept		1.0
Correlation Coefficient (r)		0.962

Total Cholesterol Predicted Biases (mg/dL)				
Integra	**AU5400**	**% Bias**	**CardioChek PA SN 3202266**	**% Bias**
160	164	2.7%	164	2.6%
200	205	2.4%	205	2.3%
240	245	2.1%	245	2.1%
280	285	1.9%	285	1.9%
	Average % bias	**2.3%**		**2.2%**

Total Cholesterol Predicted Biases (mg/dL)		
AU5400	**CardioChek PA SN 3202266**	**% Bias**
160	160	0.1%
200	200	-0.1%
240	240	-0.2%
280	279	-0.2%
	Average % bias	**-0.1%**

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





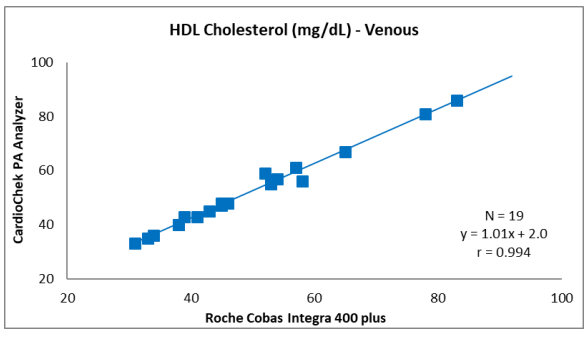
9 HDL CHOLESTEROL - LIPID PANEL TEST STRIPS, (VENOUS)

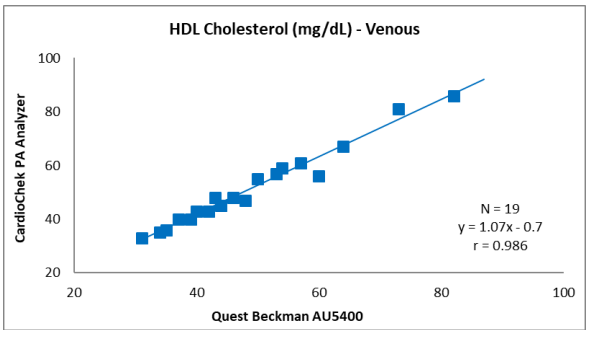
HDL Cholesterol (mg/dL)		
vs. Integra	**AU5400**	**CardioChek PA SN 3202266**
N	20	19
Slope	0.92	1.01
Intercept	3.9	2.0
Correlation Coefficient (r)	0.994	0.994
vs. AU5400		**CardioChek PA SN 3202266**
N		19
Slope		1.07
Intercept		-0.7
Correlation Coefficient (r)		0.986

HDL Cholesterol Predicted Biases (mg/dL)				
Integra	**AU5400**	**% Bias**	**CardioChek PA SN 3202266**	**% Bias**
40	41	1.6%	42	6.0%
60	59	-1.7%	63	4.3%
80	77	-3.3%	83	3.5%
100	96	-4.3%	103	3.0%
	Average % bias	**-1.9%**		**4.2%**

HDL Cholesterol Predicted Biases (mg/dL)		
AU5400	**CardioChek PA SN 3202266**	**% Bias**
40	42	4.8%
60	63	5.4%
80	85	5.7%
100	106	5.8%
	Average % bias	**5.4%**

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





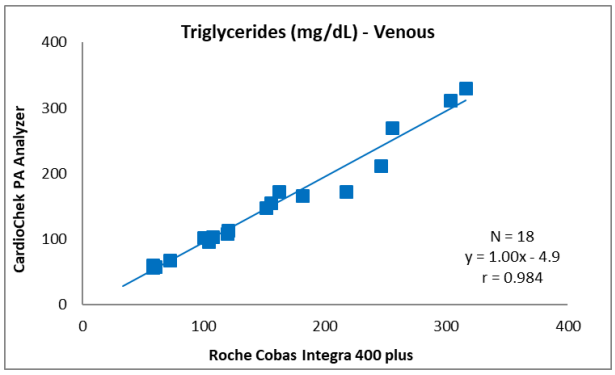
10 TRIGLYCERIDES - LIPID PANEL TEST STRIPS, (VENOUS)

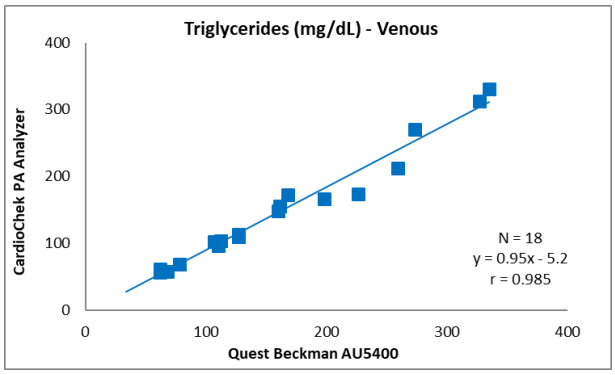
Triglycerides (mg/dL)		
vs. Integra	**AU5400**	**CardioChek PA SN 3202266**
N	20	18
Slope	1.06	1.00
Intercept	0.6	-4.9
Correlation Coefficient (r)	1.000	0.984
vs. AU5400		**CardioChek PA SN 3202266**
N		18
Slope		0.95
Intercept		-5.2
Correlation Coefficient (r)		0.985

Triglycerides Predicted Biases (mg/dL)				
Integra	**AU5400**	**% Bias**	**CardioChek PA SN 3202266**	**% Bias**
100	107	6.6%	95	-4.6%
150	160	6.4%	146	-2.9%
200	213	6.3%	196	-2.1%
250	266	6.2%	246	-1.6%
	Average % bias	**6.4%**		**-2.8%**

Triglycerides Predicted Biases (mg/dL)		
AU5400	**CardioChek PA SN 3202266**	**% Bias**
100	89	-10.6%
150	137	-8.9%
200	184	-8.1%
250	231	-7.5%
	Average % bias	**-8.8%**

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





11 RISK CLASSIFICATION - LIPID PANEL TEST STRIPS, (VENOUS)

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 (bottom tables 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 PA and the reference laboratory result**.** In no instance was a "2 Category Difference" observed in this clinical evaluation for total cholesterol, HDL cholesterol or triglycerides.

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

Risk Classification Agreement Between Methods and Integra								
	Total Cholesterol			HDL Cholesterol		Triglycerides		
All Samples	Agree	1 Cat Diff	2 Cat Diff	Agree	1 Cat Diff	Agree	1 Cat Diff	2 Cat Diff
AU5400	20	0	0	19	1	20	0	0
CardioChek PA SN 3202266	17	3	0	17	3	18	2	0

Risk Classification Agreement Between Methods and AU5400								
	Total Cholesterol			HDL Cholesterol		Triglycerides		
All Samples	Agree	1 Cat Diff	2 Cat Diff	Agree	1 Cat Diff	Agree	1 Cat Diff	2 Cat Diff
CardioChek PA SN 3202266	17	3	0	18	2	18	2	0

12 PRECISION - LIPID PANEL TEST STRIPS

CardioChek PA SN 3202266			
Sample ID	757	757	757
Analyte	Cholesterol	HDL	Triglycerides
1	248	60	151
2	237	56	146
3	245	60	157
4	232	61	154
5	258	60	150
6	249	63	149
7	234	59	143
8	255	60	155
9	227	60	150
10	256	60	148
Number	10	10	10
Average	244.1	59.9	150.3
SD	11.0	1.7	4.2
%CV	4.5	2.9	2.8

CardioChek PA SN 3202266			
Sample ID	674	674	674
Analyte	Cholesterol	HDL	Triglycerides
1	130	34	293
2	116	32	321
3	136	33	303
4	126	32	316
5	131	32	331
6	131	31	299
7	124	33	329
8	127	33	303
9	132	33	269
10	115	32	284
Number	10	10	10
Average	126.8	32.5	304.8
SD	6.8	0.8	19.9
%CV	5.4	2.6	6.5

12 PRECISION - LIPID PANEL TEST STRIPS, CONTINUED

CardioChek PA SN 3202266			
Sample ID	131	131	131
Analyte	Cholesterol	HDL	Triglycerides
1	229	91	61
2	222	86	61
3	228	88	61
4	225	92	64
5	217	84	61
6	221	85	62
7	216	87	63
8	227	92	59
9	201	91	65
10	214	84	60
Number	10	10	10
Average	220.0	88.0	61.7
SD	8.5	3.3	1.8
%CV	3.9	3.7	3.0

13 RESULTS - TOTAL CHOLESTEROL TEST STRIPS, (FINGERSTICK)

Evaluation by Average Difference

The following graphs and tables show the detailed analyses of the relationship of the results from the CardioChek PA Test System, Quest Diagnostics' Beckman AU5400 analyzer, and the PTS Diagnostics' Roche Cobas Integra 400 plus analyzer.

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

Total cholesterol: ± 10%

The average difference calculated from the actual individual paired % Bias to the **Integra** analyzer.
i.e.: ((**AU5400** – Integra Lab Result) ÷ Integra Lab Result) *100 are as follows:

Average of % Bias vs. Integra		
vs. Integra	**AU5400**	**CardioChek PA SN 3232886**
Total Cholesterol	2.8%	-6.8%

The average difference calculated from the actual individual paired % Bias to the **AU5400** analyzer.
i.e.: ((**CardioChek PA** – AU5400 Lab Result) ÷ AU5400 Lab Result) *100 are as follows:

Average of % Bias vs. AU5400	
vs. AU5400	**CardioChek PA SN 3232886**
Total Cholesterol	-9.0%

NOTE: This value is the average difference of all results; differences between individual results are expected to vary both below and above the average.

Analyte Summaries

The summary of the linear regression and predicted bias data is shown on the following pages for Total Cholesterol. The regression statistics are displayed for each individual instrument used. This data is then used to calculate the predicted biases for each analyte at specific clinical decision values. Actual predicted % differences with the reference analyzers are calculated as:
((Comparison Analyzer Result – Reference Lab Result) ÷ Reference Lab Result) *100 = % Bias

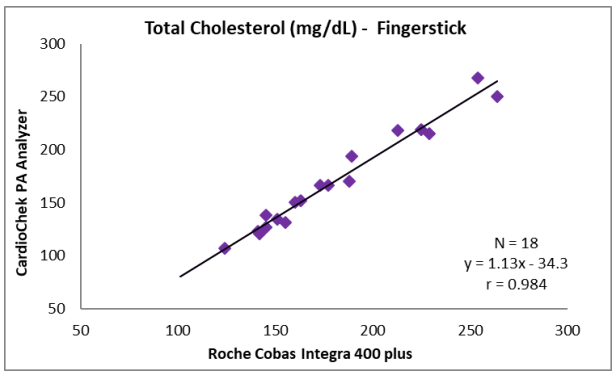
14 TOTAL CHOLESTEROL TEST STRIPS, (FINGERSTICK)

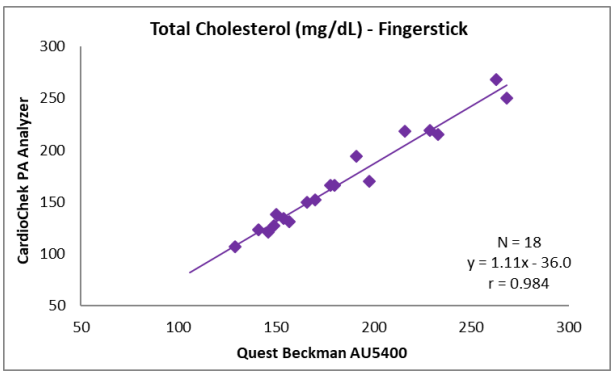
Total Cholesterol (mg/dL)		
vs. Integra	**AU5400**	**CardioChek PA SN 3232886**
N	20	18
Slope	1.01	1.13
Intercept	3.0	-34.3
Correlation Coefficient (r)	0.999	0.984
vs. AU5400		**CardioChek PA SN 3232886**
N		18
Slope		1.11
Intercept		-36.0
Correlation Coefficient (r)		0.984

Total Cholesterol Predicted Biases (mg/dL)				
Integra	**AU5400**	**% Bias**	**CardioChek PA SN 3232886**	**% Bias**
160	164	2.7%	147	-8.2%
200	205	2.4%	192	-3.9%
240	245	2.1%	237	-1.1%
280	285	1.9%	283	1.0%
	Average % bias	**2.3%**		**-3.0%**

Total Cholesterol Predicted Biases (mg/dL)		
AU5400	**CardioChek PA SN 3232886**	**% Bias**
160	148	-7.6%
200	188	-6.2%
240	227	-5.3%
280	267	-4.7%
	Average % bias	**-6.0%**

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





15 RISK CLASSIFICATION - TOTAL CHOLESTEROL TEST STRIPS, (FINGERSTICK)

Each result was categorized based on traditional risk categories for total cholesterol (top table below). From these analyses, a clinical agreement table was compiled (bottom tables 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 PA and the reference laboratory result**.** In no instance was a "2 Category Difference" observed in this clinical evaluation for total cholesterol.

Risk Classification (mg/dL)			
Categories Compared	**Total Cholesterol**		
	<200	200 - 240	>240

Risk Classification Agreement Between Methods and Integra			
	Total Cholesterol		
All Samples	**Agree**	**1 Cat Diff**	**2 Cat Diff**
AU5400	20	0	0
CardioChek PA SN 3232886	20	0	0

Risk Classification Agreement Between Methods and AU5400			
	Total Cholesterol		
All Samples	**Agree**	**1 Cat Diff**	**2 Cat Diff**
CardioChek PA SN 3232886	20	0	0

16 RESULTS - TOTAL CHOLESTEROL TEST STRIPS, (VENOUS)

Evaluation by Average Difference

The following graphs and tables show the detailed analyses of the relationship of the results from the CardioChek PA Test System, Quest Diagnostics' Beckman AU5400 analyzer, and the PTS Diagnostics' Roche Cobas Integra 400 plus analyzer.

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

Total cholesterol: ± 10%

The average difference calculated from the actual individual paired % Bias to the **Integra** analyzer. i.e.: ((**AU5400** – Integra Lab Result) ÷ Integra Lab Result) *100 are as follows:

Average of % Bias vs. Integra		
vs. Integra	**AU5400**	**CardioChek PA SN 3232886**
Total Cholesterol	2.8%	-4.7%

The average difference calculated from the actual individual paired % Bias to the **AU5400** analyzer. i.e.: ((**CardioChek PA** – AU5400 Lab Result) ÷ AU5400 Lab Result) *100 are as follows:

Average of % Bias vs. AU5400	
vs. AU5400	**CardioChek PA SN 3232886**
Total Cholesterol	-7.2%

NOTE: This value is the average difference of all results; differences between individual results are expected to vary both below and above the average.

Analyte Summaries

The summary of the linear regression and predicted bias data is shown on the following pages for Total Cholesterol. The regression statistics are displayed for each individual instrument used. This data is then used to calculate the predicted biases for each analyte at specific clinical decision values. Actual predicted % differences with the reference analyzers are calculated as:
((Comparison Analyzer Result – Reference Lab Result) ÷ Reference Lab Result) *100 = % Bias

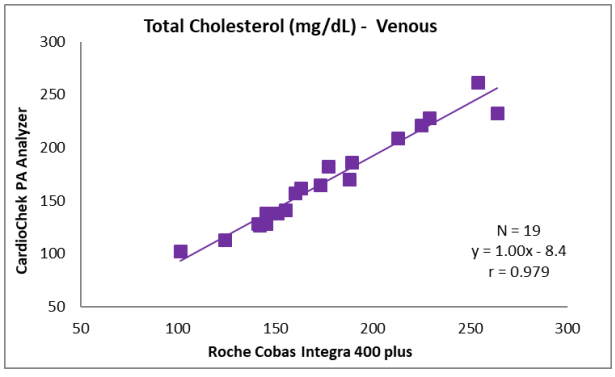
17 TOTAL CHOLESTEROL TEST STRIPS, (VENOUS)

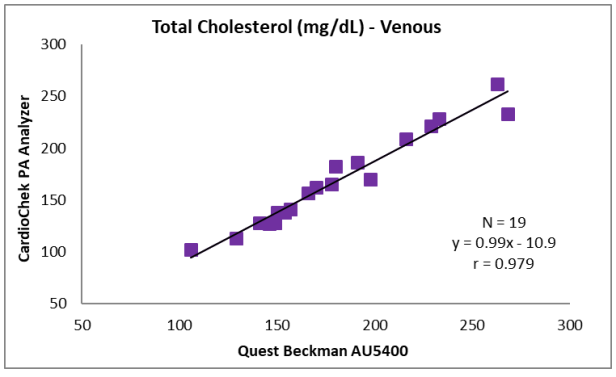
Total Cholesterol (mg/dL)		
vs. Integra	**AU5400**	**CardioChek PA SN 3232886**
N	20	19
Slope	1.01	1.00
Intercept	3.0	-8.4
Correlation Coefficient (r)	0.999	0.979
vs.AU5400		**CardioChek PA SN 3232886**
N		19
Slope		0.99
Intercept		-10.9
Correlation Coefficient (r)		0.979

Total Cholesterol Predicted Biases (mg/dL)				
Integra	**AU5400**	**% Bias**	**CardioChek PA SN 3232886**	**% Bias**
160	164	2.7%	152	-4.9%
200	205	2.4%	192	-3.9%
240	245	2.1%	232	-3.2%
280	285	1.9%	273	-2.7%
	Average % bias	**2.3%**		**-3.7%**

Total Cholesterol Predicted Biases (mg/dL)		
AU5400	**CardioChek PA SN 3232886**	**% Bias**
160	148	-7.6%
200	188	-6.2%
240	227	-5.3%
280	267	-4.7%
	Average % bias	**-6.0%**

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





18 RISK CLASSIFICATION - TOTAL CHOLESTEROL TEST STRIPS, (VENOUS)

Each result was categorized based on traditional risk categories for total cholesterol (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 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 PA and the reference laboratory result**.** In no instance was a "2 Category Difference" observed in this clinical evaluation for total cholesterol.

Risk Classification (mg/dL)			
Categories Compared	**Total Cholesterol**		
	<200	200 - 240	>240

Risk Classification Agreement Between Methods and Integra			
	Total Cholesterol		
All Samples	**Agree**	**1 Cat Diff**	**2 Cat Diff**
AU5400	20	0	0
CardioChek PA SN 3232886	19	1	0

Risk Classification Agreement Between Methods and AU5400			
	Total Cholesterol		
All Samples	**Agree**	**1 Cat Diff**	**2 Cat Diff**
CardioChek PA SN 3232886	19	1	0

19 PRECISION - TOTAL CHOLESTEROL TEST STRIPS

CardioChek PA SN 3232886			
Sample ID	757	674	38
Analyte	Cholesterol		
1	231	140	193
2	242	137	188
3	231	139	189
4	238	143	184
5	245	139	186
6	234	137	198
7	244	142	189
8	248	140	188
9	251	138	192
10	234	132	191
Number	10	10	10
Average	239.8	138.7	189.8
SD	7.2	3.1	3.9
%CV	3.0	2.2	2.1

20 OVERVIEW OF EVALUATION

Evaluation Site

PTS Diagnostics
7736 Zionsville Rd
Indianapolis, IN 46268

PTS Diagnostics Technical Support

Technical Support
(877) 870-5610
customerservice@ptsdiagnostics.com

Third Party Comparison: (X-axis)

PTS Diagnostics – Indianapolis, IN: Roche Cobas Integra 400 plus
Quest Diagnostics – Wood Dale, IL: Beckman AU5400

Reagents Used: Accuracy and Precision

PTS Lipid Panel Test Strip Lot: P906
PTS Total Cholesterol Test Strip Lot: C903
PTS Multi-Chemistry Controls: Lot MC32
PTS HDL Controls Lot: HC26

Accuracy Instruments: (Y-axis)

CardioChek PA analyzer: SN 3202266, v.2.64 (Lipid Panel Test Strips)
CardioChek PA analyzer: SN 3232886, v.2.64 (Total Cholesterol Test Strips)

Precision Instruments:

CardioChek PA analyzer: SN 3202266, v.2.64 (Lipid Panel Test Strips)
CardioChek PA analyzer: SN 3232886, v.2.64 (Total Cholesterol Test Strips)

21 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 (PTS Diagnostics Internal Evaluation)

In this evaluation, the CardioChek PA test system produced clinically equivalent values for total cholesterol, HDL cholesterol and triglycerides compared to those reported for the same patients' samples analyzed in a reference laboratory(s). The linear regression results between the methods indicate a good correlation between the CardioChek PA analyzer point-of-care method and the reference laboratory methods for total cholesterol, HDL cholesterol and triglycerides. The risk classification tables demonstrate that the CardioChek Plus analyzer accurately identifies patient risk category with a high level of correlation with reference methods. In summation, the data demonstrates clinical equivalency between all methods used.

James H. Anderson Jr., MD, FFPM, FACE
Medical Director

7 MAY 19

PTS Diagnostics Approval Signature — Date