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)

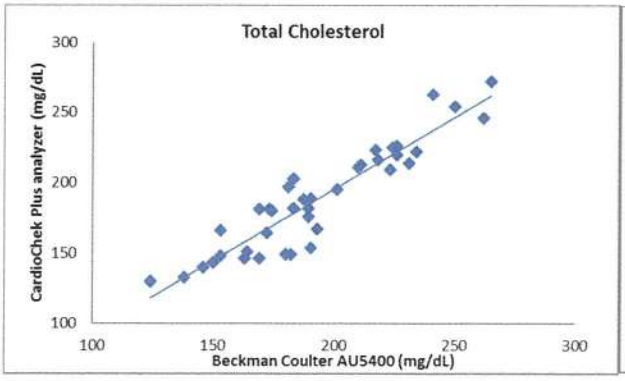
# 3 TOTAL CHOLESTEROL

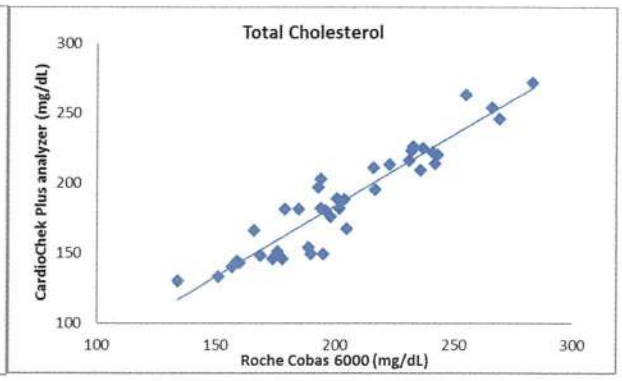
| Total Cholesterol (mg/dL) | | |
|---|---|---|
| vs. AU5400 | Cobas | CardioChek Plus Analyzer |
| N | 38 | 39 |
| Slope | 1.01 | 1.02 |
| Intercept | 10.6 | -8.2 |
| R | 0.994 | 0.930 |
| vs. Cobas | | CardioChek Plus Analyzer |
| N | | 39 |
| Slope | | 1.01 |
| Intercept | | -19.2 |
| R | | 0.942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

| 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.



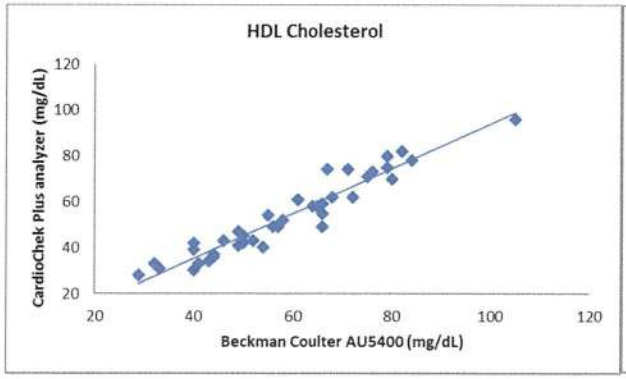
# 4 HDL CHOLESTEROL

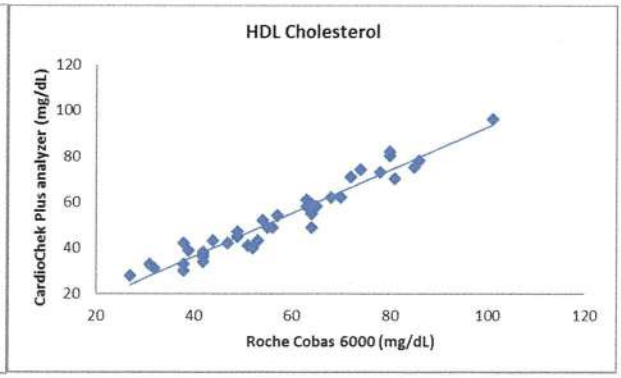
| HDL Cholesterol (mg/dL) | | |
|---|---|---|
| vs. AU5400 | Cobas | CardioChek Plus Analyzer |
| N | 38 | 39 |
| Slope | 1.03 | 0.98 |
| Intercept | -2.4 | -3.8 |
| R | 0.993 | 0.959 |
| vs. Cobas | | CardioChek Plus Analyzer |
| N | | 39 |
| Slope | | 0.94 |
| Intercept | | -1.3 |
| R | | 0.970 |

| 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.



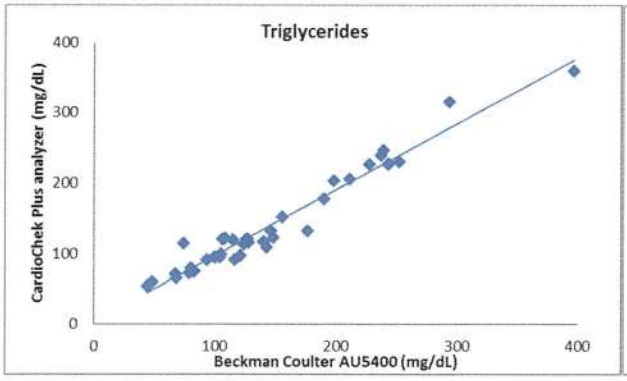
# 5 TRIGLYCERIDES

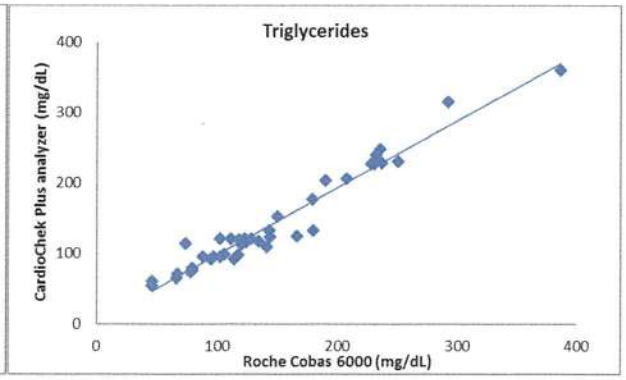
| Triglycerides (mg/dL) | | |
|---|---|---|
| vs. AU5400 | Cobas | CardioChek Plus Analyzer |
| N | 39 | 39 |
| Slope | 0.98 | 0.93 |
| Intercept | 0.5 | 3.3 |
| R | 0.998 | 0.977 |
| vs. Cobas | | CardioChek Plus Analyzer |
| N | | 39 |
| Slope | | 0.95 |
| Intercept | | 2.6 |
| R | | 0.973 |

| 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.



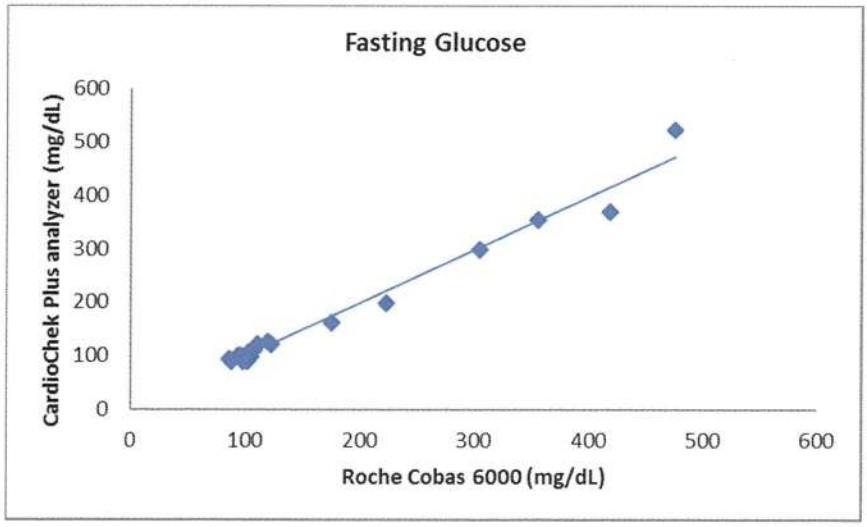
# 6 FASTING GLUCOSE

| 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% |

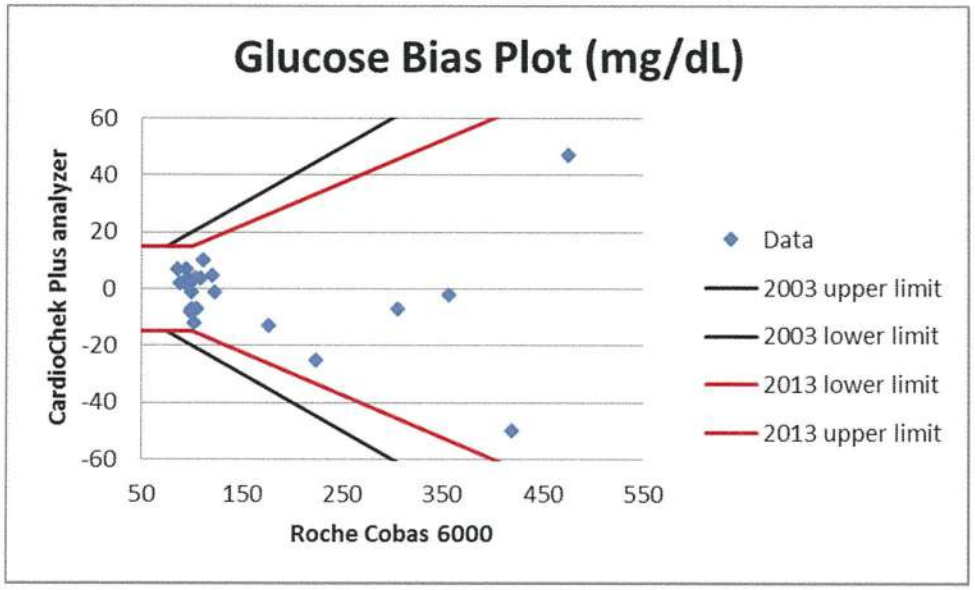
Predicted biases are based strictly on the linear regression line of the data collected.

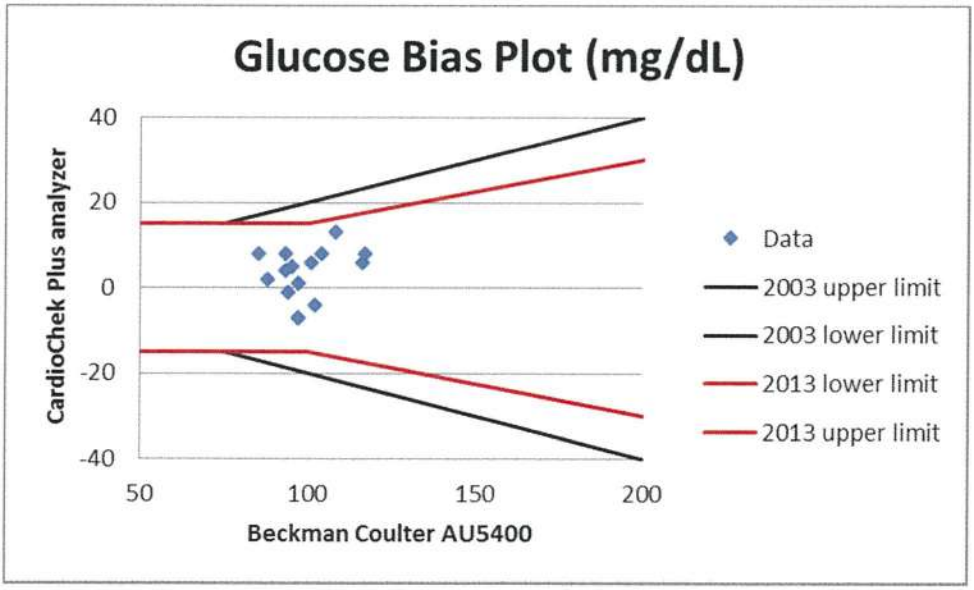
Predicted Biases only calculated with the Cobas due to insufficient samples spanning the dynamic range for the AU5400.



# 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)

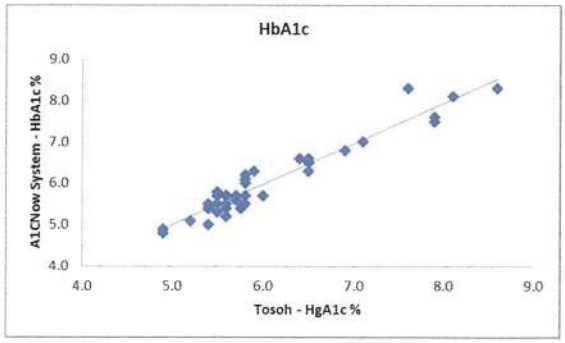
# 9 HbA1c % (A1CNow System)

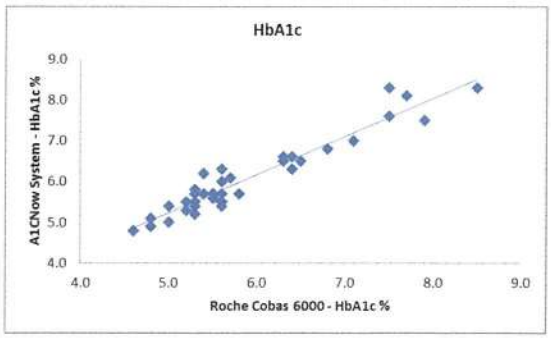
| HbA1c % | | |
|---|---|---|
| **vs. Tosoh** | **Cobas** | **A1CNow System** |
| **N** | 39 | 40 |
| **Slope** | 1.03 | 0.98 |
| **Intercept** | -0.4 | 0.1 |
| **R** | 0.991 | 0.965 |
| **vs. Cobas** | | **A1CNow System** |
| **N** | | 39 |
| **Slope** | | 0.94 |
| **Intercept** | | 0.5 |
| **R** |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

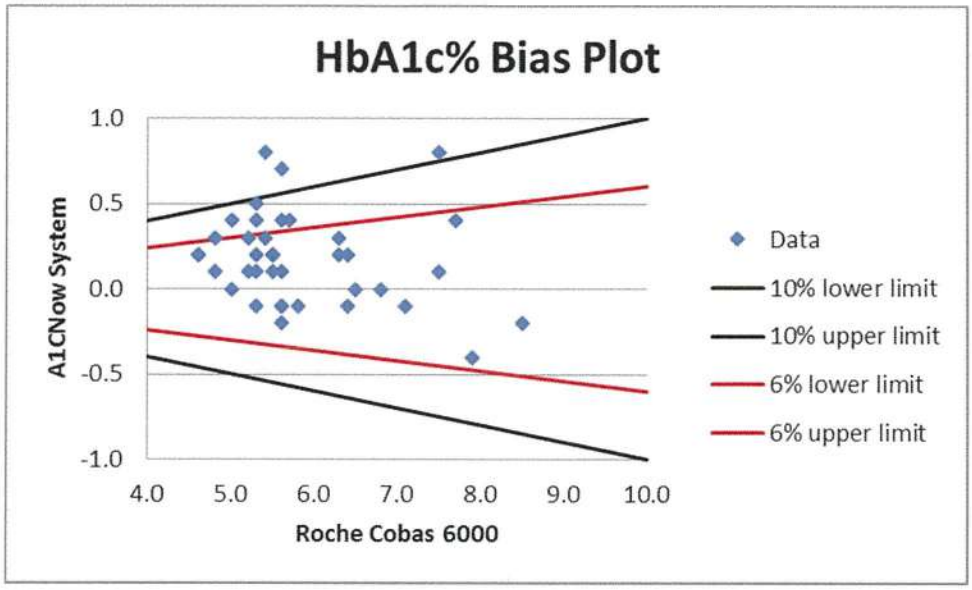
| HbA1c Predicted Biases | | |
|---|---|---|
| **Cobas** | **A1CNow System** | **% Bias** |
| **4.0** | 4.3 | 7.3% |
| **5.7** | 5.9 | 3.2% |
| **6.5** | 6.6 | 2.1% |
| **7.0** | 7.1 | 1.5% |
| | **Average % bias** | **3.5%** |

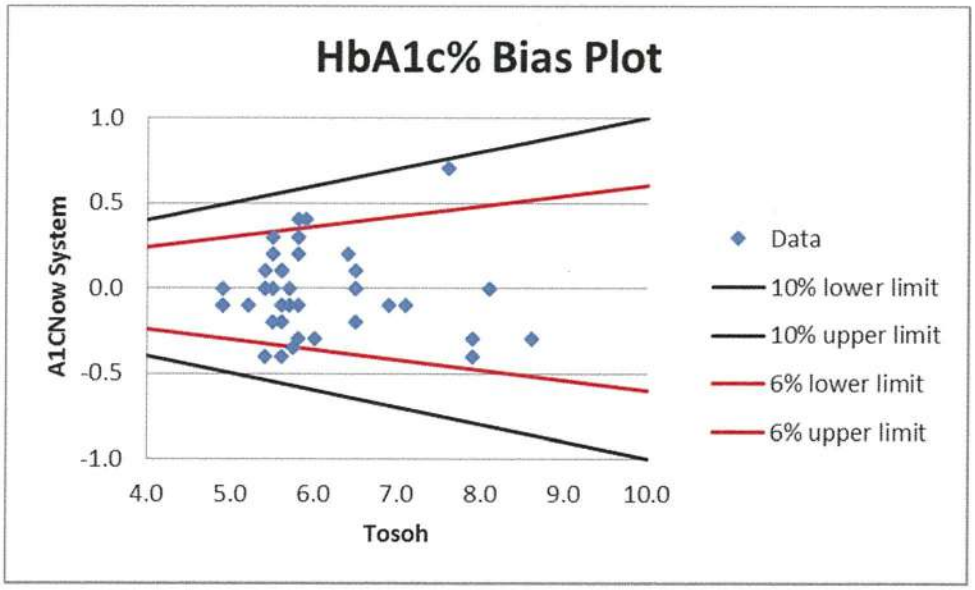
Predicted biases are based strictly on the linear regression line of the data collected.



# 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
207 Old Lexington Road
Thomasville, NC 27360

**Technical Service Specialist (TSS)**

Emily Suscha
Corina Lindke

**Account Contacts**

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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