CALIBRATION AND QUALITY CONTROL

Quality Control tests are used to ensure that the total system (analyzer, strips, MEMo Chip) is working properly and that the test results are accurate and reliable within the limits of the system. Users should run controls when results are questionable or to comply with their own facility’s quality control requirements. See the CardioCheck P+A User Guide for instructions on how to run controls. The CardioCheck P+A is factory calibrated before it is packaged. Use the Check Strip, supplied to verify that the analyzer’s electronics and optics are working properly. The Check Strip is NOT a Quality Control test. Please refer to the CardioCheck P+A User Guide for the proper procedure to be used to perform a Quality Control test.

EXPECTED VALUES

Glucose Expected Values
Blood glucose levels will vary from time to time depending on food consumed, activity levels, health status, medication dosages, stress or exercise. Your physician or healthcare professional will discuss “target values” (that is, highs and lows) specifically appropriate for you. A glucose level below 50 mg/dl (2.78 mmol/L) or above 240 mg/dl (13.56 mmol/L) may indicate a serious medical condition. If your test result should fall below 50 mg/dl (2.78 mmol/L) or exceed 240 mg/dl (13.56 mmol/L), you should contact your physician or healthcare professional as soon as possible. Expected values are for a fasting person, who does not have diabetes are: 70-105 mg/dl (3.9-5.8 mmol/L).

HDL Cholesterol Expected Values
1. Below 40 mg/dl (1.04 mmol/L) – low HDL (High risk for CHD*).
2. 40-60 mg/dl (1.04-1.55 mmol/L) and above – high HDL (Low risk for CHD*).
3. CHD – Coronary Heart Disease

Triglycerides Expected Values (for persons fasting for at least 9 hours)
1. Below 150 mg/dl (1.70 mmol/L) – normal.
2. 150-199 mg/dl (1.70-2.25 mmol/L) – borderline high.
3. 200-499 mg/dl (2.26-5.64 mmol/L) – high.
4. 500 mg/dl and above (5.65 mmol/L) – very high.

MEASURING RANGE

Metabolic Chemistry Panel Test Strips will display numeric results in the following ranges: Glucose: 0-2000 mg/dl (1.11-33.3 mmol/L); HDL Cholesterol: 25-100 mg/dl (0.65-2.59 mmol/L). Triglycerides: 50-500 mg/dl (0.57-5.56 mmol/L). Results below the range will read “<” (less than the measuring range). Results above the range will read “>” (greater than the measuring range).

IMPORTANT: If you get a result of “<” (less than) or “>” (greater than) an unexpected result for any test, test again with a new unused test strip.

LIMITATIONS OF THE PROCEDURE

Studies were performed to test for substances that may interfere with these tests. The results are below.

1. PRESERVATIVES: Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system. EDTA and heparin tubes are appropriate for collection of venous blood.
2. DRUGS: Dipeptidyl peptidase increases the results of HDL cholesterol and triglycerides.
3. METABOLITES: Excessively high degrees of ascorbic acid (Vitamin C) may decrease HDL and triglycerides results. Normal concentrations of Vitamin C did not effect the glucose results.
4. HEMOLYSIS: No hemolysis effect was observed for samples between 30% and 45% HCT.
5. ALTITUDE: Testing at altitudes up to 5200 feet has no effect on glucose results.
6. DEHYDRATION: Severe dehydration and excessive water loss may produce falsely low results.

Additional Considerations:
1. NEONATAL USE: There has been no data generated to validate the use of this system with neonatal blood specimens. Until such data become available, this test system should not be used on neonatal blood samples.
2. Cosmetics such as handcreams or lotions often contain glycerol. Use of these products may cause inaccurate results.
3. Displayed results are rounded.

PERFORMANCE CHARACTERISTICS

1. ACCURACY: Glucose results were compared to a commercially available hexokinase method.

PTS PANELS: Glucose vs. Commercially Available Glucose System
Number of patients = 120
slope = 0.951
y-intercept = 5.36
r = 0.992
Results from clinical studies comparing the PTS PANELS Test Strips to the Cholesterol Reference Method Laboratory Network (CRMLN) are listed below:

PTS PANELS HDL Cholesterol vs. Ablin-Kendall method run by a CRMLN laboratory
n = 67 samples
range of samples tested: <25 to 80 mg/dl
y = 1.16x – 4.1
r = 0.93

PTs PANELS Triglycerides vs. CRMLN reference method
n = 111 samples
range of samples tested: 80 to 481 mg/dl
y = 0.97x + 2.8
r = 0.97

The Metabolic Chemistry Panel Test Strips were run by professionals on a CardioCheck P+A and the results were compared to results from a commercially available automated laboratory analyzer. The results are listed by test as follows:

Glucose Comparison
n = 108 samples
range of samples tested: 51 to 557 mg/dl
y = 0.89x + 14.4
r = 0.992

HDL Cholesterol Comparison
n = 95 samples
range of samples tested: 26 to 89 mg/dl
y = 0.93x + 6.7
r = 0.903

2. PRECISION: Twenty replicates of various levels of whole blood were tested using the Metabolic Chemistry Panel Test Strips. The following results were obtained:

<table>
<thead>
<tr>
<th>Glucose No. of Samples</th>
<th>20</th>
<th>20</th>
<th>20</th>
<th>20</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Glucose Conc. (mg/dL)</td>
<td>34.7</td>
<td>73.7</td>
<td>105.9</td>
<td>185.0</td>
<td>226.7</td>
</tr>
<tr>
<td>Std. Deviation (mg/dL)</td>
<td>3.01</td>
<td>4.04</td>
<td>4.59</td>
<td>7.85</td>
<td>2.93</td>
</tr>
<tr>
<td>Coefficient of Variation (%)</td>
<td>8.67</td>
<td>5.48</td>
<td>4.33</td>
<td>4.10</td>
<td>3.63</td>
</tr>
</tbody>
</table>

This means that the variation between test strips is not greater than 8.7%.

HDL Cholesterol
<table>
<thead>
<tr>
<th>No. of Observations</th>
<th>20</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean HDL Conc. (mg/dL)</td>
<td>35.7</td>
<td>68.7</td>
</tr>
<tr>
<td>Std. Deviation (mg/dL)</td>
<td>2.87</td>
<td>5.53</td>
</tr>
<tr>
<td>Coefficient of Variation (%)</td>
<td>8.04</td>
<td>8.05</td>
</tr>
</tbody>
</table>

Triglycerides
<table>
<thead>
<tr>
<th>No. of Observations</th>
<th>20</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Triglycerides Conc. (mg/dL)</td>
<td>86.2</td>
<td>152.6</td>
</tr>
<tr>
<td>Std. Deviation (mg/dL)</td>
<td>5.78</td>
<td>6.33</td>
</tr>
<tr>
<td>Coefficient of Variation (%)</td>
<td>6.71</td>
<td>4.15</td>
</tr>
</tbody>
</table>

INTERFERENCE: See Limitations Section.

CLIA INFORMATION (US only)

Complexity Categorization: Waived

AVAILABILITY

REFCAT NO. DESCRIPTION 1708 CardioCheck P+A Analyzer 2400 Metabolic Chemistry Panel Test Strips, 15 count 2408 Metabolic Chemistry Panel Test Strips, 3 count 0721 PTS PANELS Multi-Chemistry Control – Level 1 & Level 2 0722 PTS PANELS HDL Cholesterol Controls – Level 1 & Level 2

REFERENCES


CUSTOMER SERVICE

Customer Service is available to answer questions regarding the CardioCheck P+A and Metabolic Chemistry Panel Test Strips. Outside Customer Service hours, please contact your healthcare professional. (877) 670-9810 8 a.m. – 5 p.m. EST. M-F toll-free inside the US (317) 670-5810, FAX (317) 570-5598 E-mail: infoquest@cardiocheck.com

The CardioCheck P+A and PTS PANELS Metabolic Chemistry Panel Test Strips are manufactured in the US by Polymer Technology Systems, Inc., Indianapolis, IN 46226.

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AUTHORIZED EUROPEAN REPRESENTATIVE per IVDD 98/79/EC

MDSS
Schiffgraben 41
D-30159 Hannover
Germany

Explanation of Symbols

- Use By/ Expiration date
- Catalog number
- Batch Code/ Lot number
- Manufacturer
- Store at/Temperature limitation