



**Polymer Technology Systems, Inc.
CardioChek® PA
VS
Method X
Bias Study Plus Precision Study
Evaluation Protocol**

Recommended Evaluation Protocol – Bias plus Precision

Scope

The purpose of this protocol is to provide a tool for comparing the CardioChek PA system versus another point-of-care (POC) or laboratory method. The protocol is set up to compare Lipid Panel results (Total Cholesterol, HDL Cholesterol and Triglycerides), but can be duplicated for any specific analyte in a side-by-side comparison.

Expected Results

1. Bias Study:

If this side-by-side evaluation is performed on the same venous blood samples, the expectation is that the average deviation of CardioChek results will be within $\pm 10\%$ of results of the CRMLN-certified in vitro diagnostic method for cholesterol, $\pm 12\%$ for HDL and $\pm 15\%$ for triglycerides.

2. Precision Study:

If this evaluation is performed on the same venous blood sample, the expectation is that the Coefficient of Variation (CV) of CardioChek results performed will be within $\pm 10\%$ for cholesterol, $\pm 10\%$ for HDL and $\pm 10\%$ for triglycerides.

Personnel / Training

As a CLIA-waived system, the CardioChek PA has been demonstrated to produce good laboratory results when used by operators with no previous experience with the system. However, while the system is easy to use, it is important that users follow recommended operational procedures and techniques. Improper technique in sample collection, storage and handling of test strips or general use of the products may affect both accuracy and precision of results.

Before testing, it is very important for the CardioChek PA operator to read all instructions especially the package insert that comes with the test strips and the User Guide that is packaged with the CardioChek. PTS Customer Service is available toll-free at 877-870-5610 to answer questions regarding the CardioChek system.

Set up

Insert fresh batteries in the analyzer. Ensure the optical window (glass) is clean (re-clean if necessary as indicated in the User Guide).

Use a CardioChek Check Strip to verify that the meter's electronics and optics are functioning properly.

Run Multi-Chemistry Controls (Level 1 and Level 2) and HDL Controls (Level 1 and Level 2) to verify the meter, strip and MEMo Chip are functioning properly together. The Multi-Chemistry control will generate values for the cholesterol and triglycerides. The HDL Control provides values for HDL cholesterol only.

Patient Selection

A minimum of 20 patients should be used so that the data is statistically relevant. The assay ranges for the patients selected should encompass the dynamic range of the CardioChek Lipid Panel assays and be distributed as indicated in the table below.

Sample Distribution Table

TEST	MEASURING RANGE	BIN 1 RANGE % Samples	BIN 2 RANGE % Samples	BIN 3 RANGE % Samples	BIN 4 RANGE % Samples	BIN 5 RANGE % Samples
Total Cholesterol	100-400 mg/dL	100-160 mg/dL 15%	161-199 mg/dL 25%	200-239 mg/dL 25%	240-280 mg/dL 25%	>280 mg/dL 10%
HDL Cholesterol	15-100 mg/dL	15-35 mg/dL 15%	36-45 mg/dL 25%	46-55 mg/dL 25%	56-70 mg/dL 25%	>70 mg/dL 10%
Triglycerides	50-500 mg/dL	50-100 mg/dL 15%	101-150 mg/dL 25%	151-200 mg/dL 25%	201-300 mg/dL 25%	>300 mg/dL 10%

Samples

Venous sample: Using a lithium heparin (green top) blood collection tube, collect fresh whole blood. Do not use blood collection tubes without anticoagulant (clot tubes, which include red top and SST) or tubes containing other anticoagulants or preservatives. Do not use samples that are hemolyzed. Test the samples within one hour after collection. Mix the samples well by gently inverting (to avoid hemolysis) the collection tube 7-8 times before testing.

IMPORTANT: The CardioChek is a whole blood analyzer. Serum and plasma are not appropriate samples for the CardioChek.

Testing Procedure and Data Collection for Bias Study

For each of the patients use the following procedure:

1. Turn on the CardioChek PA. Insert the MEMO Chip for the lot of Lipid Panel strips being used. Insert a Lipid Panel Test Strip into the analyzer.
2. The display should read APPLY SAMPLE. If the CardioChek displays RUN TEST, press the Enter button to get to APPLY SAMPLE display
3. Gently mix the venous blood sample in the blood collection tube. Remove the stopper and insert a CardioChek 40µL capillary into the tube to collect a 40µL blood sample for the Lipid Panel. When complete, replace the stopper.
4. Make sure APPLY SAMPLE is displayed. Dispense the blood sample onto the blood application window of the test strip. (The CardioChek PA will automatically begin testing the sample.)
5. When the CardioChek PA displays the results (CHOL, HDL, TRIG), record on the attached bias study data form. To test the next sample, press Enter button so the display reads INSERT STRIP.
6. Turn the used test strip over and confirm that the three reaction circles on the back side of the test strip are completely and evenly colored. If not, retest with a fresh unused test strip. Note in the comments section of the data form if there was insufficient sample placed on the strip or that the strip was unevenly colored.
7. Run the same venous sample on the CRMLN-certified in vitro diagnostic method, following the user instructions.
8. Record the CRMLN-certified in vitro diagnostic method values on the chart provided.

Analysis of the Bias Study

1. On the attached bias study data sheets, record the values for Total Cholesterol, HDL Cholesterol and Triglycerides determined by the CardioChek System and the CRMLN-certified in vitro diagnostic method.
2. Deviation Calculations. For each patient sample, calculate the deviation and % deviation of the CardioChek result from the CRMLN-certified method result using the following formulas:

CardioChek Value – CRMLN-certified in vitro diagnostic method Value = Deviation.

(Deviation / CRMLN-certified in vitro diagnostic method Value) x 100 = % Deviation

Note: If the CardioChek value is greater than the CRMLN-certified in vitro diagnostic method, the deviation will be a positive (+) number. If the CardioChek value is less than the CRMLN-certified in vitro diagnostic method, the deviation will be a negative (-) number. Results that are clearly in error should be excluded from the analysis, but should be noted in the comments and explained to the best of the operator's ability.

3. Average Deviation Calculation. Determine the average ("mean") percent deviation of all the sample results by adding the percent deviations for each sample and dividing by the number of samples.
4. Interpretation. The CardioChek System is performing acceptably if the mean deviation for all the results is within:

Total Cholesterol	± 10%
HDL Cholesterol	12%
Triglycerides	± 15%

Testing Procedure and Data Collection for Precision Study

Select one venous patient sample and test that same sample 20 times. Optimally, the sample selected would have assay values that are close to these targets:

Total Cholesterol = 200mg/dL

HDL Cholesterol = 50mg/dL

Triglycerides = 150mg/dL

1. Run the sample as indicated above in the bias study and record the results on the attached precision study data form. To test the sample again, press Enter button so the display reads INSERT STRIP.
2. Turn the used test strip over and confirm that the three reaction circles on the back side of the test strip are completely and evenly colored. If not, retest with a fresh unused test strip. Note in the comments section of the data form if there was insufficient sample placed on the strip or that the strip was unevenly colored.

Analysis of the Precision Study

1. On the attached precision study data sheet, record the 20 replicates of the same sample. For a lipid panel, this would be for Total Cholesterol, HDL Cholesterol and Triglycerides determined by the CardioChek System.

2. Calculations. For the 20 replicates of the same patient sample, calculate the mean, standard deviation (SD), and coefficient of variation (CV).
3. Interpretation. The CardioChek System is performing acceptably if the coefficients of variation (CV's) from this precision study are within:

Total Cholesterol	± 10%
HDL Cholesterol	10%
Triglycerides	± 10%