

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

k151545

**B. Purpose for Submission:**

Modification of the measuring range for HDL cholesterol analyte in Lipid Panel test strips due to a software modification.

**C. Measurand:**

HDL Cholesterol

**D. Type of Test:**

Quantitative, reflectance photometry measurement

**E. Applicant:**

Polymer Technology Systems, Inc.

**F. Proprietary and Established Names:**

CardioChek Home Test System  
CardioChek PA Home Test System  
CardioChek Plus Test System  
CardioChek PA Test System

**G. Regulatory Information:**

Product Code	Classification	Regulation Section	Panel
CHH	Class I, meets the limitation of exemption 21 CFR 862.9(c)(4)	21 CFR 862.1175 Cholesterol (total) test system	Chemistry (75)
LBR	Class I, meets the limitation of exemption 21 CFR 862.9(c)(4)	21 CFR 862.1475 Lipoprotein test system	Chemistry (75)
JGY	Class I, meets the limitation of exemption 21 CFR 862.9(c)(4)	21 CFR 862.1705 Triglyceride test system	Chemistry (75)

## H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

### CardioChek Home Test System

The CardioChek Home Test System (consisting of the CardioChek Home analyzer and CardioChek Home Lipid Panel test strips) is for the quantitative determination of total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in capillary whole blood from the fingertip and is intended to be used by a single person and should not be shared. This system is for in vitro diagnostic use only.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.

A Chol/HDL ration and estimated values for LDL (low density lipoprotein) cholesterol are calculated by the CardioChek Home Analyzer.

### CardioChek PA Home Test System

The CardioChek PA Home Test System (consisting of the CardioChek PA Home analyzer and CardioChek Home Lipid Panel test strips) is for the quantitative determination of total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in capillary whole blood from the fingertip and is intended to be used by a single person and should not be shared. This system is for in vitro diagnostic use only.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.

A Chol/HDL ration and estimated values for LDL (low density lipoprotein) cholesterol are calculated by the CardioChek PA Home Analyzer.

### CardioChek Plus Test System

The CardioChek Plus Test System (consisting of the CardioChek Plus analyzer and PTS Panels Lipid Panel test strips) is for the quantitative determination of total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in venous whole blood and capillary whole blood from the fingertip and is intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. This system is for in vitro diagnostic use only.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.

A Chol/HDL ration and estimated values for LDL (low density lipoprotein) cholesterol are calculated by the CardioChek Plus Analyzer.

### CardioChek PA Test System

The CardioChek PA Test System (consisting of the CardioChek PA analyzer and PTS Panels Lipid Panel test strips) is for the quantitative determination of total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in venous whole blood and capillary whole blood from the fingertip and is intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. This system is for in vitro diagnostic use only.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders.

A Chol/HDL ration and estimated values for LDL (low density lipoprotein) cholesterol are calculated by the CardioChek PA Analyzer.

3. Special conditions for use statement(s):

CardioChek Home Test System and CardioChek PA Home Test System

- For over the counter use
- For single patient use only
- Not for use on neonates
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CardioChek Plus Test System and CardioChek PA Test System

- For prescription use only
- For multiple patient use
- Not for use on neonates

For in vitro diagnostic use only.

4. Special instrument requirements:

For use on the CardioChek Home analyzer, the CardioChek PA Home analyzer, the CardioChek Plus analyzer and the CardioChek PA analyzer

**I. Device Description:**

The PTS Panels Lipid Panel test strips and the CardioChek Home Lipid Panel test strips are used with the CardioChek Home analyzer, the CardioChek PA Home analyzer, the CardioChek Plus analyzer and the CardioChek PA analyzer to measure total cholesterol, HDL cholesterol and triglycerides in whole blood. The test strips utilize enzymatic methods on a dry strip that is read by reflectance photometry. The test strips are packaged in a vial with a MEMo Chip (contains lot specific test strip information) and instructions.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

CardioChek Plus Test System and CardioChek Home Test System  
CardioChek Test System

2. Predicate 510(k) number(s):

k140068  
k023558

3. Comparison with predicate:

<b>Similarities</b>		
Item	Candidate Devices	Predicate Device
	The CardioChek Home Test System The CardioChek PA Home Test System The CardioChek Plus Test System The CardioChek PA Test System	k140068 CardioChek Plus Test System and CardioChek Home Test System
Intended Use	For the quantitative determination of total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides	Same
Test Principle	Quantitative, reflectance photometry measurement	Same
Result Calculations	Test strips require a lot specific memory chip for result calculation, which are included in the same package with the test strips	Same

<b>Differences</b>		
Item	Candidate Devices	Predicate Device
	The CardioChek Home Test System The CardioChek PA Home Test System The CardioChek Plus Test System The CardioChek PA Test System	k140068 CardioChek Plus Test System and CardioChek Home Test System
Measuring range for HDL cholesterol	20-120 mg/dL	15-100 mg/dL
Test strips	Lipid Panel	Lipid Panel, eGLU, Glucose

**K. Standard/Guidance Document Referenced (if applicable):**

Clinical Laboratory Standards Institute (CLSI) EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline; 2003.

**L. Test Principle:**

The PTS Panels Lipid Panel test strips and the CardioChek Home Lipid Panel test strips are identical except the CardioChek Home Lipid Panel test strips are for over-the-counter use. The test strips utilize enzymatic methods on a dry strip that is read by reflectance photometry. The test strip contains three sets of dry components, which are dry test strip reagents one set for each analyte (total cholesterol, HDL cholesterol and triglycerides). A single application of whole blood flows laterally to dose each set of analyte specific membranes once the blood is applied to the test strip. The red blood cells are separated by the test strip such that only the serum or plasma reaches the reaction membranes. The color resulting from the enzymatic reaction is read by the analyzers by reflectance. The reflectance is compared to the calibration curve stored in the memory chip and converted into concentration and displayed by the analyzer.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

The CardioChek Home analyzer is the same as the CardioChek Plus analyzer but is labeled for home use; the performance studies for the CardioChek Plus are applicable for the CardioChek Home analyzer. The CardioChek PA Home analyzer is the same as the CardioChek PA analyzer but is labeled for home use; the performance studies for the CardioChek PA are applicable for the CardioChek PA Home analyzer.

*a. Precision/Reproducibility:*

Precision studies were performed using 3 Lithium heparin venous whole blood samples tested 8 times by 2 operators using 5 of each type of analyzer (CardioChek PA and CardioChek Plus) in 2 runs beginning 3 hours apart.

CardioChek PA/ CardioChek PA Home	HDL Level 1	HDL Level 2	HDL Level 3
N	80	80	80
Mean (mg/dL)	38.3	62.4	106.0
SD (mg/dL)	1.65	2.26	4.2
CV%	4.3	3.6	4.0

CardioChek Plus/ CardioChek Home	HDL Level 1	HDL Level 2	HDL Level 3
N	80	80	80
Mean (mg/dL)	39.5	63.3	108.3
SD (mg/dL)	1.63	2.66	5.24
CV%	4.1	4.2	4.8

*b. Linearity/assay reportable range:*

The linearity study followed recommendations in CLSI EP06-A. The linearity was evaluated using three lots of Lipid Panel test strips on each type of analyzer (CardioChek PA/CardioChek PA Home and CardioChek Plus/CardioChek Home) and a series of 10 HDL cholesterol concentration levels in whole blood that spanned the reportable range of the test. The statistical analysis of the 2nd and 3rd order regressions indicated statistically significant non-linear components but the maximum deviation from nonlinearity was 10% within the claimed interval. The linearity was adequate across the reportable range (20 to 120 mg/dL).

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*

*Traceability:*

PTS Lipid Panel test strips are calibrated using a commercially available CRMLN certified method. PTS Lipid Panel test strips were CRMLN certified for Total Cholesterol and HDL Cholesterol with both the CardioChek PA/CardioChek PA Home analyzer and CardioChek Plus/CardioChek Home analyzer.

*Stability:*

The shelf life and open vial stability protocols were reviewed and found to be acceptable.

*d. Detection limit:*

The change in measuring range is due to a software modification and had no impact on the detection limit therefore detection limit studies were not performed.

The measuring range for HDL on the test systems is 20-120 mg/dL.

e. *Analytical specificity:*

The change in measuring range is due to a software modification and had no impact on interferences therefore studies to evaluate potential interferences were not performed.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison:*

A method comparison study was performed using 2 CardioChek PA/CardioChek PA Home analyzers and 2 CardioChek Plus/CardioChek Home analyzers and 80 Lithium Heparin whole blood samples covering the HDL cholesterol range (21 to 112 mg/dL). None of the specimens were altered. A single replicate from the proposed devices and the predicate device were used in the analysis.

	n	Sample Range	Deming Regression Equation	r
CardioChek PA/ CardioChek PA Home	80	21-112 mg/dL	$y=0.930x+0.98$	0.980
CardioChek Plus/ CardioChek Home	80	21-112 mg/dL	$y=0.990x+0.55$	0.980

b. *Matrix comparison:*

The matrix comparison study was performed using 2 CardioChek PA and 2 CardioChek Plus analyzers and 40 blood samples of each sample type across the HDL cholesterol range (21 to 112 mg/dL). Individual results of each matrix comparison study were compared to the reference results and it was determined if the results were correctly classified per NCEP Working Group recommendations<sup>1</sup>.

CardioChek PA/ CardioChek PA Home	n	correctly classified	% correctly classified results
Fingerstick whole blood	40	38	95.0
Venous Li Heparin whole blood	40	39	97.5
Venous K2EDTA whole blood	40	39	97.5

CardioChek Plus /CardioChek Home	n	correctly classified	% correctly classified results
Fingerstick whole blood	40	38	95.0
Venous Li Heparin whole blood	40	40	100
Venous K2EDTA whole blood	39	39	100

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<sup>1</sup> Warnick GR, Wood PD. National Cholesterol Education Program Recommendations For Measurement Of High-Density Lipoprotein Cholesterol: Executive Summary. Clin Chem 1995;41:1427-33.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable

b. *Clinical specificity:*

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

HDL Cholesterol Expected Values<sup>2</sup>

Below 40 mg/dL (1.04 mmol/L) – low HDL (High risk for CHD\*)

60 mg/dL (1.55 mmol/L) and above – high HDL (Low risk for CHD\*)

\*CHD - Coronary Heart Disease

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<sup>2</sup>US National Cholesterol Education Program (NCEP) 2001 Guidelines (ATP III NCEP Guidelines for CHD Risk. JAMA 2001, 285:2486-2509).

**N. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:**

Infection control studies:

The CardioChek PA/CardioChek PA Home analyzer materials are the same as the materials used in the CardioChek Plus/CardioChek Home analyzer, therefore the disinfection efficacy studies were only performed for the CardioChek Plus/CardioChek Home analyzer. The disinfection efficacy for the CardioChek Plus/CardioChek Home analyzer was reviewed in k140068. Disinfection efficacy studies were performed by an outside commercial testing laboratory and demonstrated complete inactivation of duck hepatitis B virus (HBV) with the chosen disinfectant, Super Sani-Cloth (EPA Registration #9480-4).

Robustness studies were performed on the CardioChek PA/CardioChek PA Home test system demonstrating that there was no change in performance for HDL, cholesterol and triglycerides or in external materials of the meters after 11,000 cleaning and disinfection cycles with Super Sani-Cloth. The robustness studies were designed to simulate 3 years of multiple-patient use and 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

**O. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**P. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.