510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K231974

B Applicant

PHC Corporation

C Proprietary and Established Names

PATHFAST®hs-cTnI-II

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
MMI	Class II	21 CFR 862.1215 - Creatine Phosphokinase/Creatine Kinase Or Isoenzymes Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modification of an existing device

B Measurand:

Troponin I

C Type of Test:

Quantitative, chemiluminescent enzyme immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
PATHFAST®hs-cTnI-II is an in vitro diagnostic test for the quantitative measurement of cardiac Troponin I (cTnl) in heparinized or EDTA whole blood and plasma. Measurements of cardiac Troponin I are used as an aid in the diagnosis of acute myocardial infarction (AMI). PATHFAST® hs-cTnI-II is for use in clinical laboratory or point of care (POC) settings.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:

PATHFAST Analyzer

IV Device/System Characteristics:

A Device Description:

Same as K100130

B Principle of Operation:

Same as K100130

V Substantial Equivalence Information:

A Predicate Device Name(s):
PATHFAST cTnI-II test

B Predicate 510(k) Number(s):
K100130

C Comparison with Predicate(s):

Device & Predicate Device(s):	K231974	K100130
Device Trade Name	PATHFAST®hs-cTnI-II	PATHFAST cTnI-II
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the quantitative measurement of cardiac Troponin I (cTnI) in heparinized or EDTA	Same

Device & Predicate Device(s):	K231974	K100130
	whole blood and plasma. Measurements of cardiac Troponin I are used as an aid in the diagnosis of acute myocardial infarction (AMI). For use in clinical laboratory or point of care (POC) settings.	
Methodology	Chemiluminescent enzyme immunoassay	Same
General Device Characteristic Differences		
Reportable range	4.1 to 50,000 ng/L	0.019 to 50 ng/mL

VI Standards/Guidance Documents Referenced:

CLSI EP6 2nd Edition: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI EP17-A2: Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Previously established in K100130.

2. Linearity:

   Linearity studies using EDTA and lithium heparin whole blood and plasma samples were designed and analyzed following the recommendations in the Guideline CLSI EP6 2nd Edition: Evaluation of the Linearity of Quantitative Measurement Procedures.

   EDTA whole blood and plasma samples, and lithium heparin whole blood and plasma samples with low and high cTnI values were mixed to produce up to 12 levels with concentrations ranging from 1 to 64,500 ng/L. Three dilution series of each sample matrix were prepared and tested with three different lots of reagents (one lot for each dilution series). Each level was tested in replicates of three. The maximum deviation from linearity observed in the study across all sample matrices was 9.7%.

The studies support that the device is linear from 4.1 to 50,000 ng/L.

3. Analytical Specificity/Interference:

   Previously established in K100130.

4. Assay Reportable Range:

   The measuring range of the PATHFAST hs-cTnI-II is from 4.1 ng/L to 50,000 ng/L.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Unchanged from K100130.

6. Detection Limit:

   The limit of blank (LoB) was determined by testing four lots of reagents and four blank samples. The limit of detection (LoD) for EDTA and lithium heparin whole blood and plasma was determined by testing 4 low level samples and four lots of reagents for each sample matrix.

   The limit of quantitation (LoQ) study was conducted using EDTA and lithium heparin whole blood and plasma samples at concentrations expected to be around the proposed LoQ. The LoQ was determined by testing six samples per sample type and two reagent lots.

   The LoB was calculated using the classical approach using nonparametric analysis as described in CLSI EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures. The LoD was calculated per the classical approach using parametric analysis as described in the CLSI EP17-A2 Guideline. The LoQ was determined based on a precision performance goal of less than 20 % CV.

   The results of the study support the assay LoQ of 4.1 ng/L.

	EDTA (ng/L)		LiHep (ng/L)	
	WB	Plasma	WB	Plasma
LoB	1.466	1.466	1.466	1.466
LoD	2.991	2.958	2.942	3.002
LoQ	4.1	4.1	4.1	4.1

7. Assay Cut-Off:

   See K100130

B Comparison Studies:

1. Method Comparison with Predicate Device:

   See K100130

2. Matrix Comparison:

   See K100130

C Clinical Studies:

1. Clinical Sensitivity:

   See K100130

2. Clinical Specificity:

   See K100130

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

D Clinical Cut-Off:

See K100130

E Expected Values/Reference Range:

See K100130

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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