

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

A. 510(k) Number:

K052697

B. Purpose for Submission:

To obtain clearance for the Heparin/Platelet Factor 4 Antibody Serum Panel controls

C. Measurand:

Heparin PF4 Antibody

D. Type of Test:

Assayed control

E. Applicant:

Akers Biosciences, Inc.

F. Proprietary and Established Names:

Heparin/Platelet Factor 4 Antibody Serum Panel

G. Regulatory Information:

1. Regulation section:

21 CFR 864.5425

2. Classification:

Class II

3. Product code:

GGN

4. Panel:

81 Hematology

H. Intended Use:

1. Intended use(s):

The Heparin/Platelet Factor 4 Antibody Serum Panel is an assayed control, intended for use as a serum QC control to monitor and evaluate precision and accuracy of the (qualitative) PIFA[®] Heparin/PF4 Antibody Assay. Included are both confirmed positive and negative control panel members.

The panel members enable the users to evaluate their PIFA[®] Heparin PF4 Antibody Assay test systems and provide comprehensive data for comparative analysis.

2. Indication(s) for use:

Assayed controls available for use as a QC panel for routine quality checks or as a qualification panel enabling users to evaluate their PIFA[®] Heparin PF4 Antibody Assay test systems providing comprehensive data for comparative analysis.

3. Special conditions for use statement(s):

Serum control panel members are identified as positive and negative. These are selected for specific use on the PIFA Heparin PF4 Antibody Assay test.

4. Special instrument requirements:

I. Device Description:

The Heparin/Platelet Factor 4 Antibody Serum Panel is a well-defined serum sample identified as a positive or negative sample against the PIFA[®] Heparin/Platelet Factor 4 Antibody Assay.

The panels are assembled from its repository of frozen serum samples, with reactivity as determined by the GTI[®] PF4 Enhanced ELISA test. No preservatives are added. Samples are chosen to provide a broad range of reactivity and to include samples with both low and high antibody levels.

Two types of kit configurations are available:

Two-Member QC Panel – consists of one positive and one negative serum each approximately 150 µl in volume. Reagents normally used for routine quality checks and to help identify whether technical errors or reagent failures have occurred.

Multi-Member Qualification Panel – consists of 10 positive and two negative sera each approximately 150 µl in volume. Reagents are normally used for qualifying and evaluating their PIFA[®] Heparin PF4 Antibody Assay test systems where a broad

range of reactivity levels is desired. They provide comprehensive data for comparative analysis in regard to sensitivity, specificity, reproducibility and lot-to-lot variability. Data for comparative values on all panel members are available for reference only.

J. Substantial Equivalence Information:

1. Predicate device name(s):

GTI[®] PF4[®] ELISA Assay

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

K983379

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Characteristic	Heparin PF4 Antibody Serum Panel	GTI PF4 ENHANCED[®] ELISA (controls provided with test)
Test type for control use	Qualitative	Qualitative
Sample Matrix	Serum	Serum
Testing Environment	Professional	Professional
Test Determination for Positive	≥ 0.40	≥ 0.40
Test Determination for Negative	≤ 0.40	≤ 0.40

Differences		
Item	Device	Predicate
Characteristic	Heparin PF4 Antibody Serum Panel	GTI PF4 ENHANCED[®] ELISA (controls provided with test)
Indications for Use	Assayed controls available for use as a QC panel for routine quality checks or as a qualification panel enabling users to evaluate their PIFA [®] Heparin PF4 Antibody Assay test systems providing comprehensive data for comparative analysis.	Assayed controls included with each test. Run to help determine if technical errors or reagent failures have occurred.
Positive Control Determination Level (OD)	≥ 0.50	≥ 1.80

Differences		
Item	Device	Predicate
reading)		
Negative Control Determination Level (OD reading)	≤ 0.32	≤ 0.30

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

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision

Prior to use for testing, a single-use aliquot is thawed in a 37° C water bath. The GTI® PF4® Enhanced ELISA Assay is initially utilized to characterize each serum member.

Five serum samples were tested within the course of a 24-hour period by a single laboratory technician. Each serum sample was tested 10 times on both assays. The PIFA® Heparin/PF4 Rapid Assay provides a qualitative (positive/negative) results that consistently correlates with the O.D. values received when samples were run on the GTI® PF4® ELISA Assay.

GTI® PF4 Enhanced® ELISA Assay

	Positive	Negative
PIFA® H/PF4 Rapid Assay Positive	30	0
Negative	0	20

b. Linearity/assay reportable range:

Not applicable

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

A stability study and reproducibility study were conducted in conjunction to test the ability of the Heparin/Platelet Factor 4 Antibody Serum Panel to remain stable after a number of freeze-thaw cycles.

Six specimens, each identified with an individual lot number, were utilized for the study covering positive and negative samples. Five vials of each sample were prepared for testing and observed over the course of five days by a single laboratory technician. Initially, all samples (n=30), were stored under deep freeze conditions. On day one of the study, the 30 vials were quick-thawed by submersion into a 37° C water bath.

A single vial of each identified specimen was utilized on a specific testing interval. From a single vial, two aliquots from each of the six specimens were tested on the PIFA[®] Heparin/PF4 Rapid Assay. After the tests were completed, the vials utilized for the test interval were segregated from those not tested and all vials were flash-frozen. The vials formerly utilized were kept in deep-freeze conditions for the remainder of the study. The same procedure was performed on each test interval period thereafter until the five days were complete. At the end of the five days, all vials were retrieved from deep-freeze conditions, quick-thawed, and utilized in the same manner through testing with the GTI[®] PF4[®] Enhanced ELISA Assay.

From testing each of the characterized samples in duplicate over a period of five days through a varying number of freeze-thaw cycles, the Heparin/Platelet Factor 4 Antibody Serum Panel consistently produced expected results from the PIFA[®] Heparin/PF4 Rapid Assay. In addition, the results consistently correlated with the O.D. values received when samples were run on the GTI[®] assay, indicating the ability of the serum panel member to remain stable through numerous freeze-thaw cycles. The PIFA[®] Heparin/PF4 Rapid Assay package insert states that more than one additional freeze-thaw cycle must be validated by the user.

GTI[®] PF4 Enhanced[®] ELISA Assay

		Positive	Negative
PIFA[®] H/PF4 Rapid Assay	Positive	40	0
	Negative	0	20

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

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):

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The PIFA[®] Heparin/PF4 Rapid Assay provides a qualitative (positive or negative) result. A “positive” identified serum panel has O.D. values greater than or equal to 0.500 as determined on the GTI[®] PF4 ELISA Assay. A “negative” identified serum panel has O.D. values less than or equal to 0.320 as determined on the GTI[®] PF4 ELISA Assay.

N. Proposed Labeling:

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

O. Conclusion:

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

