

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

A. 510(k) Number:

K040293

B. Purpose for Submission:

New assay

C. Analyte:

Platelet Factor 4 Antibodies

D. Type of Test:

Qualitative Particulate ImmunoFiltration Assay (PIFA)

E. Applicant:

Akers Laboratory Inc

F. Proprietary and Established Names:

HealthTEST® Heparin/Platelet Factor 4 Antibody Assay

G. Regulatory Information:

1. Regulation section:
21 CFR 864.7695
2. Classification:
Class II
3. Product Code:
LCO
4. Panel:
81 Hematology

H. Intended Use:

1. Intended use(s):
The HealthTEST® Heparin/Platelet Factor 4 Antibody Assay is a qualitative *in vitro* diagnostic device designed for the detection of antibodies to Platelet Factor 4 complexed to polyanionic compounds such as polystyrene.
2. Indication(s) for use:
The device is indicated for patients undergoing heparin therapy, who are at risk for developing heparin induced thrombocytopenia.
3. Special condition for use statement(s):
4. Special instrument Requirements:

I. Device Description:

The HealthTEST® Heparin/Platelet Factor 4 Antibody Assay consists of two components: a Mini-reactor device containing a membrane filtration system and a results window, and a dispenser containing reaction reagents.

The Mini-reactor contains a reaction well that allows the sample to react with the reagents. The sample is added to the reaction well followed by the reagents contained in the reagent dispenser. The reagents contain microparticles coated with purified PF-4 protein as well as additional enhancing agents designed to promote rapid agglutination of the particles in the presence of specific antibodies in the test sample.

Once the reagents have reacted with the sample in the reaction well, the reaction mixture automatically collects over the membrane filtration system. This system acts to filter agglutinated particles, while allowing non-agglutinated particles to pass through. Thus, as agglutinated, reactive sample will be trapped within the membrane. Since the dyed particles are trapped on this filter, no particles and hence no color, are able to migrate past the positive/negative line on the results window. Conversely, a non-agglutinated, non-reactive sample will pass through the membrane filter and into the wicking layers, and color will migrate past the positive/negative line.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Genetic Testing Institute PF4 ELISA Assay
2. Predicate K number(s):
K983379
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Detects antibodies to the heparin/PF4 complex in patient's circulation	Detects antibodies to the heparin?PF4 complex in patient's circulation
Assay Type	Serology	Serology
Analyte Detected	Antibody to PF-4 complexed with polyanionic compounds	Antibody to PF-4 complexed with polyanionic compounds
Differences		
Item	Device	Predicate
Sample matrix	Serum, plasma	Serum
Methodology	Immunoassay, Particulate ImmunoFiltration Assay (PIFA)	Immunoassay, Enzyme-linked Immunosorbent Assay (ELISA)
Throughput	Individual	Batch testing

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

The HealthTEST® Heparin/Platelet Factor 4 Antibody Assay is based on the particulate immunofiltration principle. Dyed microparticles coated with purified platelet factor-4 (PF-4) protein derived from platelet-rich plasma provide the visual signal for the results of the assay. The ability of agglutinated or non-agglutinated particles to move through a filter medium is the measure of the reactivity/non-reactivity of the test sample.

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

A study was performed using 5 replicates each of a positive and a negative patient control. The samples were tested daily for 4 consecutive days. Both serum and plasma was tested.

b. *Linearity/assay reportable range:*

n/a

c. *Traceability (controls, calibrators, or method):*

n/a

d. *Detection limit:*

n/a

e. *Analytical specificity:*f. *Assay cut-off:*

The assay cut-off value was determined using patient samples tested on the predicate device. The cut-off value was designed to coincide with the cut-off of the predicate device (0.4).

The cut-off was validated by running a correlation study of 26 patient samples within the assay 20% cut-off range of 0.32 to 0.48. The specificity of this study was 92.3% and the sensitivity was 100%. A second evaluation was completed on 23 samples. Specificity of this study was 86.9%, and the sensitivity was 100.0%.

2. Comparison studies:a. *Method comparison with predicate device:*

Study #1- Plasma

ELISA

		POS	NEG
HealthTEST	POS	21	15
	NEG	2	137

Specificity = 90.1%

Sensitivity = 91.3%
Overall agreement = 90.3%

Study #2- Serum

		ELISA	
		POS	NEG
HealthTEST	POS	21	3
	NEG	2	153

Specificity = 98.1%
Sensitivity = 91.3%
Overall agreement = 97.2%

b. Matrix comparison:

Fresh blood samples were drawn from 12 subjects in red top and EDTA purple to tubes and respectively processed into serum and plasma. Each pair of serum and plasma samples was evaluated with the HealthTEST® Heparin/Platelet Factor 4 Antibody Assay as directed by the package insert. Positive and negative patient controls were also ran.

Results demonstrated no difference between serum and plasma results.

3. Clinical studies:

a. Clinical sensitivity:

b. Clinical specificity:

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

4. Clinical cut-off:

5. Expected values/Reference range:
Negative

N. Conclusion:

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