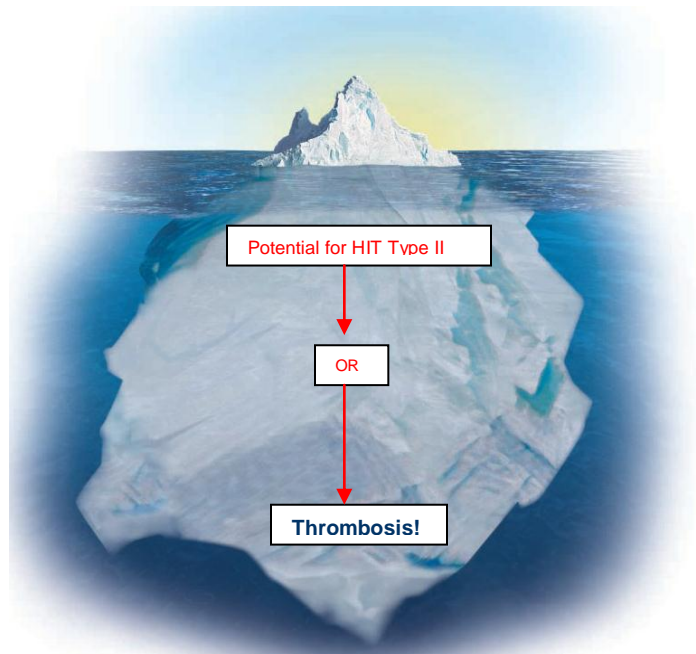


# **PIFA HEPARIN / PF4** *Rapid assay*

*Accurate detection of HIT Antibodies just got easier...and faster!*



Manufactured in the USA by  
Health-Chem Diagnostics LLC  
US FDA & ISO Approved facility  
3341 SW 15<sup>th</sup> Street, Pompano Beach, FL 33069 – USA  
Tel: (954) 979-3845 – Fax: (954) 979-7997 –  
[www.healthchemdiagnostics.com](http://www.healthchemdiagnostics.com)

Quality Award: FM 77504  
FDA Registration # 1048532

# **PIFA HEPARIN / PF4** *Rapid assay*

## ***The rapid manual assay that delivers accurate results in minutes!***

### **Accurate**

Performance comparable to GTI ELISA... without the wait!

### **Easy**

- ✚ CLIA classified – moderate complexity
- ✚ One piece construction, no special instrumentation
- ✚ Easy to read results windows
- ✚ Facilitates near-patient testing of an individual, FRESH Serum specimen

### **Fast**

Simple test procedure takes 5 steps, 10 minutes

For technical Assistance, product information or to order the, **PIFA HEPARIN / PF4**

*please call (954) 979-3845. Purchase orders may be faxed to (954) 979-7997.  
PIFA/Heparin/PF4 Rapid Assay Sleeve contains 6 miniReactor Devices.*

### **References**

1. Amiral, J., F. Bridey, M. Dreyfus, A. M. Vissoc, E. Fressinaud, M. Wolf, and D. Meyer. 1992. Platelet factor 4 complexed to heparin is the target for antibodies generated in heparin-induced thrombocytopenia. *Thromb. Haemost.* 68:95-96.
2. Amiral, J., F. Bridey, M. Wolf, C. Boyer-Neumann, E. Fressinaud, A. M. Vissac, E. Peynaud-Debayle, M. Dreyfus, and D. Meyer. 1995. Antibodies to macromolecular platelet factor 4-heparin complexes in heparin-induced thrombocytopenia: a study of 44 cases. *Thromb. Haemost.* 73:21-28.
3. Greinacher, A., and T. E. Warkentin. 2001. Treatment of heparin-induced thrombocytopenia: an overview, p. 291-322. *In* T. E. Warkentin and A. Greinacher (ed.), *Heparin-induced thrombocytopenia.*, 2nd ed. Marcel Dekker, New York, N.Y.
4. Warkentin TE, Greinacher A, eds. *Heparin-induced thrombocytopenia*, 3rd ed. New York: Marcel Dekker, Inc. 2004, 53, 205, 271, 295.
5. Brieger DB, Mak K-H, Kottke-Marchant K, Topol EJ. Heparin-induced thrombocytopenia. *J Am Coll Cardiol.* 1998;31:1449-1459.
6. Warkentin TE, Kelton JG. A 14-year study of heparin-induced thrombocytopenia. *Am J Med.* 1996;101:502-507.
7. King DJ, Kelton JG. Heparin-associated thrombocytopenia. *Ann Intern Med.* 1984;100:535-540.
8. McGarry L, Thompson D, Weinstein M, and Goldhaber S. 2004. Cost Effectiveness of Thromboprophylaxis With a Low-Molecular-Weight Heparin Versus Unfractionated Heparin in Acutely Ill Medical Inpatients. *Am J Manag Care.* 10:632-642.
9. Lubenow N, Kempf R, Eichner A, Eichler P, Carllson LE, Greinacher A. Heparin-induced thrombocytopenia: temporal pattern of Thrombocytopenia in relation to initial use and reexposure to heparin. *Chest* 2002; 122:37-42.
10. PIFA® Heparin/Platelet Factor 4 Package Insert, Data on file.

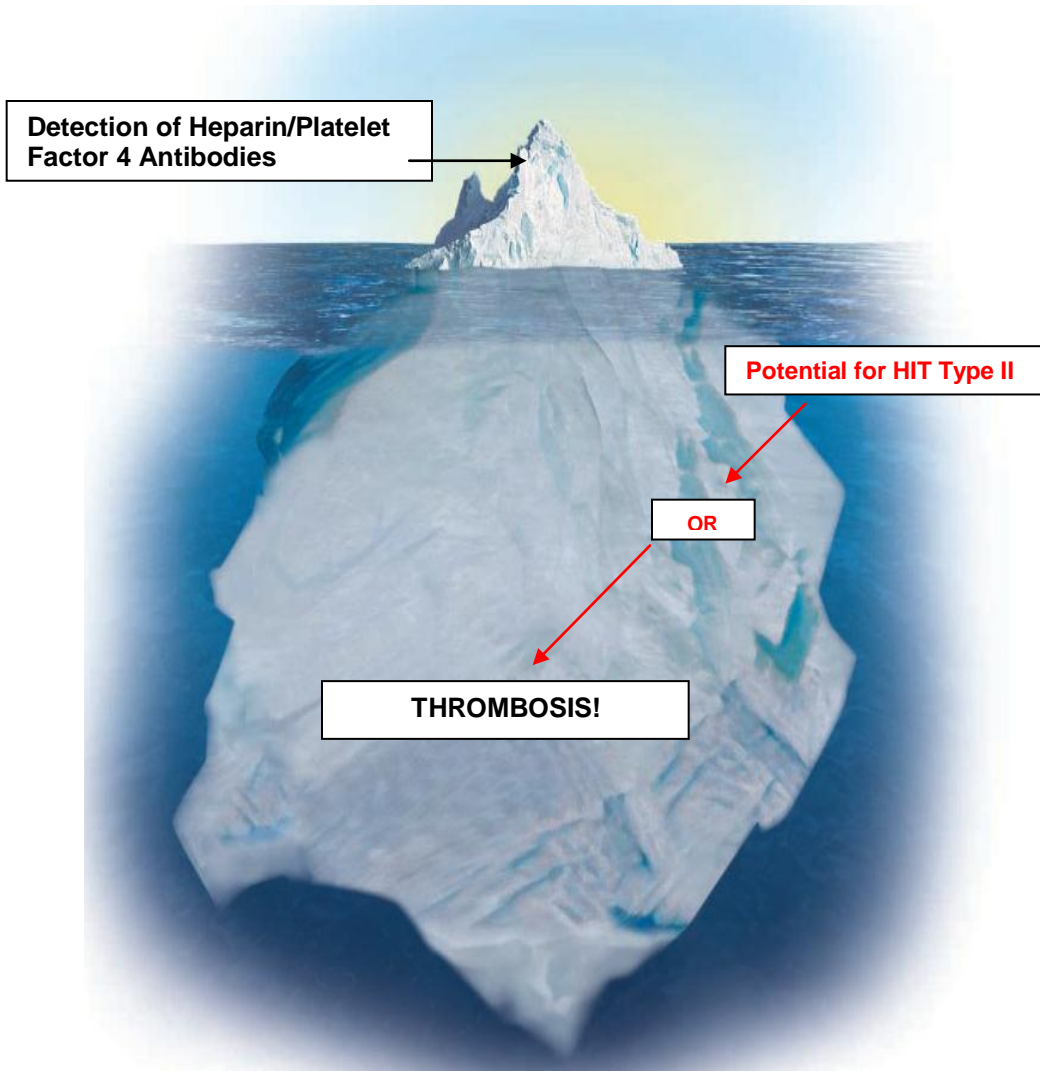
**Health-Chem Diagnostics LLC** has been, for many years, developing proprietary, *in vitro* diagnostic technology that accelerates the rate at which clinicians can obtain single patient test results, with the same level of accuracy as traditional, often time-consuming testing methods.

2004 marks the introduction of two, rapid manual assays into the clinical laboratory marketplace, the PIFA® Heparin/PF4 Rapid Assay and the Lithium System. Both tests are:

- Uncomplicated to perform which can help reduce operator error and potentially eliminate the need to outsource laboratory services
- Designed to deliver accurate results in less than 10 minutes enabling physicians to make more immediate, well-informed treatment decisions
- Small in scale to accommodate the workspace limitations of many laboratories. ***Please see Package Insert for full product information.***

# PIFA HEPARIN / PF4 Rapid assay

Uncover the patient's H/PF4 antibody status *in minutes* to help navigate potential hazards of Heparin Therapy



# **PIFA HEPARIN / PF4** Rapid assay

## **HIT Antibodies**

### **Potential warning signs of serious complications**

**Heparin/Platelet Factor 4 (H/PF4) complexes seem to be the major determinant in the pathogenesis of HIT Type II** <sup>1,2,3</sup>

- **HIT antibodies are most frequently induced by Unfractionated Heparin (UFH) use following Cardiopulmonary Bypass Surgery (50%) and major Orthopedic Surgery (15%).**
- **HIT Type II is observed in 1% to 5% of patients treated with UFH**

**HIT Type II: an acute, immune-mediated process that may result in life- and limb-threatening Thrombosis**

- **Risk of Thrombosis in patients who develop HIT is at least 33-50%.**<sup>4,5</sup>
- **Subsequent risks of HIT with Thrombosis (HITT)** <sup>6,7</sup>
  - **Mortality: 30%**
  - **Limb Amputation: 20%**
- **HIT-associated thromboembolic events may increase hospital stays at a cost of at least \$8,000.**<sup>8</sup>

# **PIFA HEPARIN / PF4** *Rapid assay* **HIT Antibodies**

## ***The Importance of Laboratory Documentation***

**May help identify patients at risk for HIT prior to Heparin re-exposure**

**Recent Heparin treatment may affect the likelihood *and* time to onset of HIT**

- ✚ Rapid Onset! HIT may occur ***within minutes or hours*** of Heparin re-challenge, if patient is exposed to Heparin within the previous 100 days ***and*** H/PF4 antibodies are already circulating<sup>9</sup>
- ✚ Patients may not be aware of, or their medical records might not accurately document, a prior exposure within the past 3 months

**Crucial in determining the clinical scope of HIT Type II<sup>4</sup>**

Greater than 90% of HIT occurs between days 5 and 10 after initiation of Heparin therapy  
Diagnosis of HIT Type II should be based on two criteria:<sup>4</sup>

- ✚ Clinically evident abnormalities, most commonly thrombocytopenia, with or without thrombosis
- ✚ Detection of HIT antibodies

## ***The Drawbacks of Traditional Laboratory Techniques***

**Conventional testing methods like the Enzyme-Linked Immunosorbent Assay (ELISA) are time-consuming and labor-intensive**

- CLIA Classified – High Complexity
- Require special instrumentation
- Difficult to process single patient specimens efficiently and cost-effectively

**May generate retrospective data that cannot be integrated into time-sensitive, therapeutic decisions**

- Results are often delayed by hours or days, especially if the test must be outsourced to a reference laboratory

# **Accurate detection of HIT antibodies just got easier...and faster!**

## **Introducing PIFA® Heparin/PF4 Rapid Assay**

The rapid manual assay that delivers accurate results *in minutes!*

### **PIFA® - (Particle ImmunoFiltration Assay)**

#### **The Benefits**

##### **Accurate**

***Substantially equivalent to a commercially available ELISA technique (see chart below)***

- 179 single patient, Serum samples, originating from field sources, were tested blindly with respect to antibody status
- Clinical results verified by independent laboratories

##### **Easy**

- CLIA Classified – Moderate Complexity
- One piece construction, no special instrumentation
- Easy-to-read Results Windows
- Facilitates near-patient testing of an individual FRESH Serum specimen

##### **Fast**

***Simple test procedure takes 5 Steps, 10 minutes\****

1. Press the Tower down to dispense reagents into the Reaction Chamber
2. Add FRESH Serum to the Sample Well
3. Slide unit from side-to-side on a level surface for five seconds, wait one minute
4. Pull the Tower to the locked position, tilt unit approximately 45°, tap with finger on results flange until blue color appears in Reagent Window.
5. Wait five minutes. Read and record the result in the TEST Window.

*\*Please review product insert for detailed instructions.*

Study - Serum		GTI Elisa	
		Positive	Negative
PIFA	Positive	21	3
	Negative	2	153

Sensitivity: 91.3%

Specificity: 98.1%

Overall Agreement: 97.2%

	Time	Procedure
PIFA	Less than 10 minutes	5 Steps
GTI Elisa	At least 3 hours	26 Steps

#### **Reproducibility**

The reproducibility of the PIFA Heparin/PF4 Rapid Assay in detecting Heparin/PF4 antibodies was demonstrated by testing 10 aliquots of 5 specimens for inter-day evaluation and 10 aliquots of intra-day evaluation. Reproducibility of the PIFA Heparin/PF4 Rapid Assay was determined to be 100% in both studies.