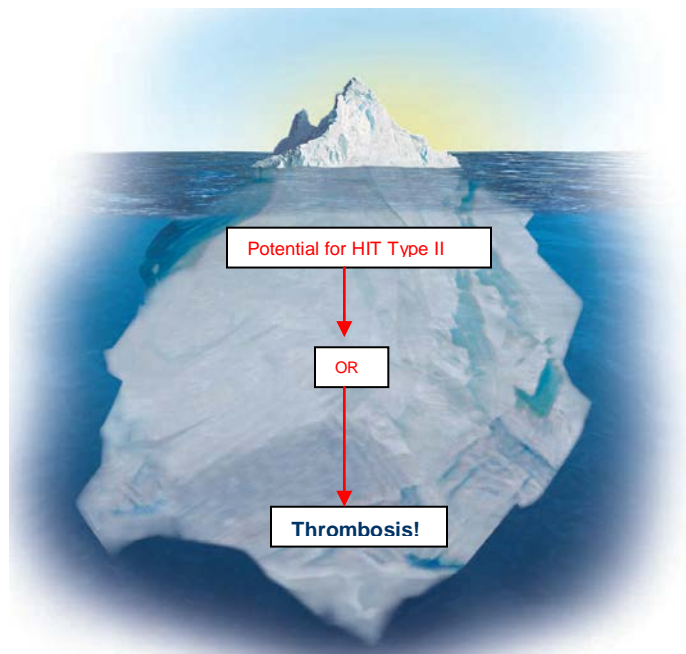


PIFA HEPARIN / PF4 *Rapid assay*

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 15th Street, Pompano Beach, FL 33069 – USA
Tel: (954) 979-3845 – Fax: (954) 979-7997 –
www.healthchemdiagnostics.com

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

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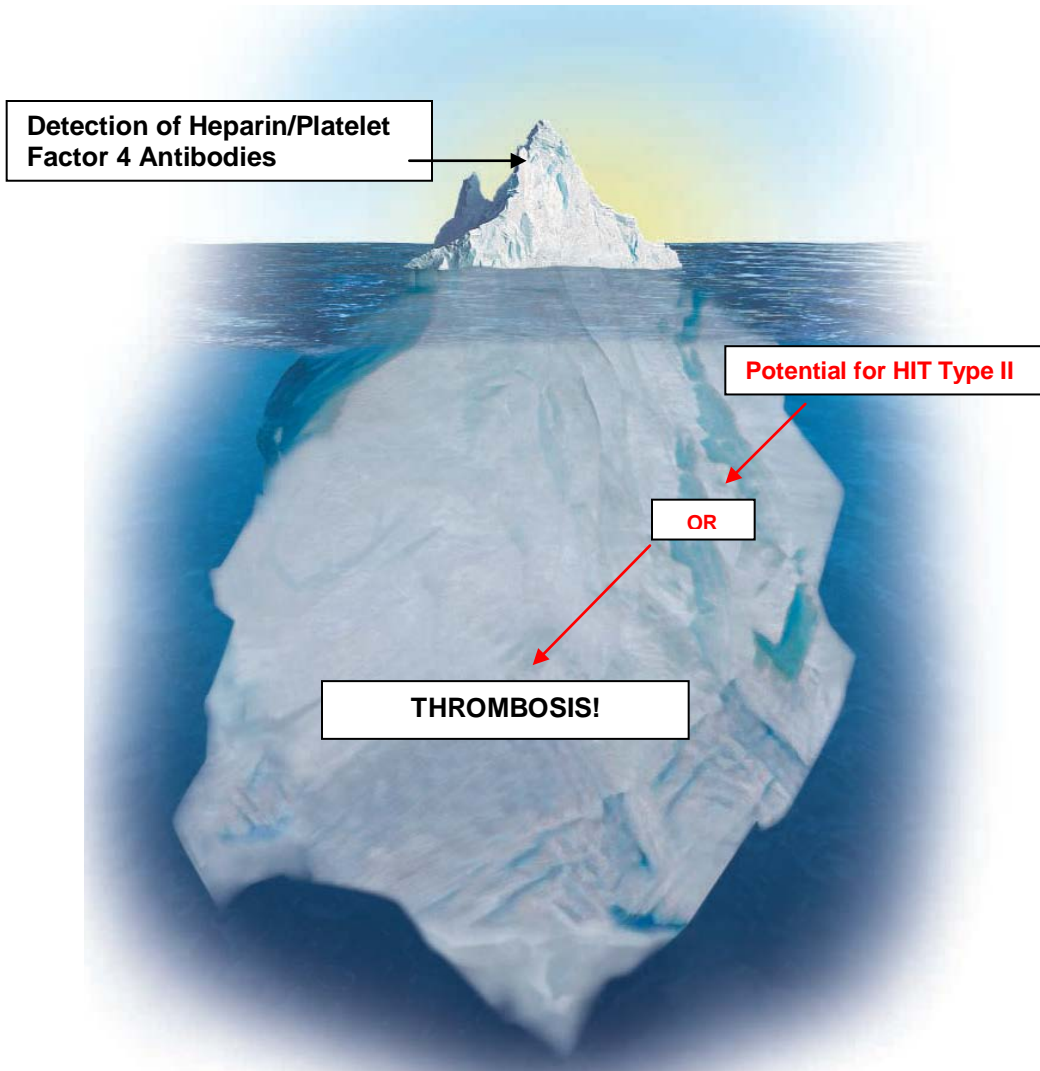
Health-Chem Diagnostics LLC has been, for many years, developing proprietary, *in vitro* diagnostic technology that accelerates the rate at which clinicians can obtain single patient test results, with the same level of accuracy as traditional, often time-consuming testing methods.

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 ^{1,2,3}

- **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%.**^{4,5}
- **Subsequent risks of HIT with Thrombosis (HITT)** ^{6,7}
 - **Mortality: 30%**
 - **Limb Amputation: 20%**
- **HIT-associated thromboembolic events may increase hospital stays at a cost of at least \$8,000.**⁸

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 circulating⁹
- ✚ 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 II⁴

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:⁴

- ✚ 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.