

**PIFA® Heparin/Platelet Factor 4
Rapid Assay
For In Vitro Diagnostic Use**

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Rapid Assay**

Product #: 4036025
Sleeve of 6 devices

- **Manual, single test device**
- **Convenient and cost effective**
- **Easily performed in minutes**
- **For the specific determination of antibodies to Platelet Factor 4 (PF4)**

Background

Heparin Induced Thrombocytopenia (HIT) is often caused by platelet-activating antibodies that recognize complexes of Heparin/PF4. Currently available laboratory tests for HIT are highly complex, take many hours to perform, and often provide confirmation of HIT or HIT and thrombosis (HITT) after symptoms are seen in a patient. As a result, there is a need for an easily performed rapid test that helps clinicians identify and treat patients at risk for HIT or thrombosis.

Principle

The PIFA® Heparin/PF4 Rapid Assay is based upon principles of the Particulate ImmunoFiltration Assay (PIFA). Dyed microparticles coated with purified PF4 protein derived from platelet-rich plasma bind to antibodies present in patient serum. 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.

Procedure

1. Push the MiniReactor Tower down completely to release the reagents in the Reaction Well.
2. Pipet 20 µl of FRESH Serum into the sample well on top of the Mini Reactor Tower.
3. Slide the device from side-to-side for 5 seconds, then keep it stationary for 1 minute.
4. Pull the MiniReactor Tower up to the stop position. Tilt the MiniReactor 45° so that the Tower portion is elevated. Tap the Results Flange with finger until a blue color appears in the Reagent Window.
5. Lay unit on the table and wait approximately 10 minutes or until a RED color appears in the CONTROL window. Read and record result in the TEST window.

Interpretation of Results

Test Window	Control Window	Result
Wet/glossy or the color of serum. No blue color	RED	Reactive/ Positive
Blue (any intensity)	RED	Non-Reactive/ Negative
White	White	Invalid
Blue (any intensity)	White	Invalid

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