# HEALTH-CHEM DIAGNOSTICS, LLC

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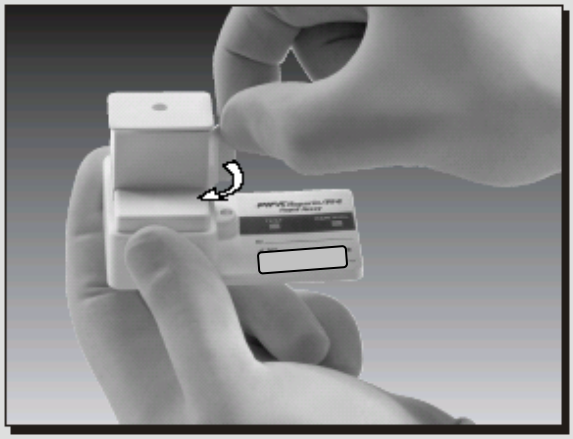
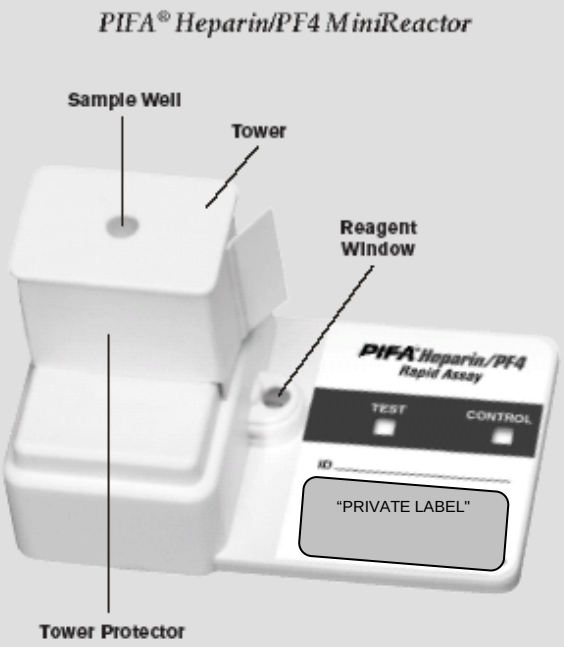
## HealthTEST - HEPARIN/PF4 ANTIBODY ASSAY

For *In Vitro* Diagnostic Use
Review Package Insert before initiating test.

Before beginning the test procedure:

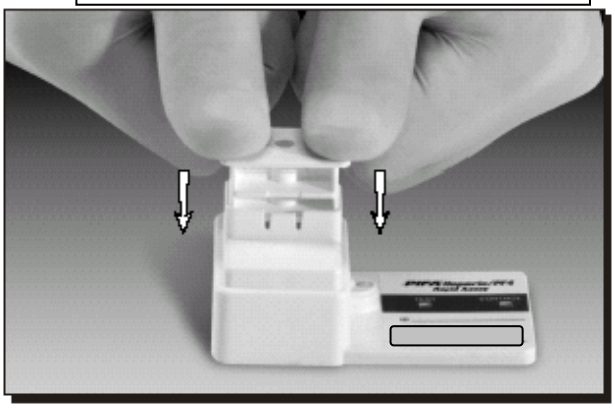
1. Remove the PIFA Heparin/PF4 MiniReactor from refrigeration and allow to sit at an ambient temperature (18-27ºC; 64-81ºF) for a minimum of 30 minutes.
2. Visually inspect device to confirm date of use is prior to expiration date
3. Label the device with the patient's identification and place on a level surface
4. Remove the Tower Protector.



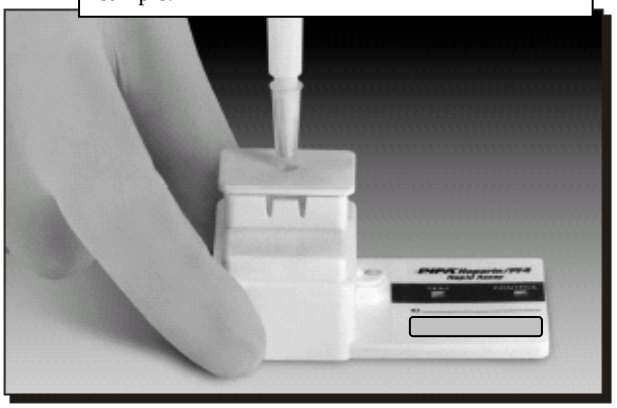



**Simple Test Procedure**

**1** Push the Tower down completely to release the reagents into the Reaction Chamber.



**2** Pipet 20µL of the patient's FRESH serum into the Sample Well on the top of the Tower. When the pipettor tip makes contact with the bottom of the Well, pull up slightly and dispense the sample.



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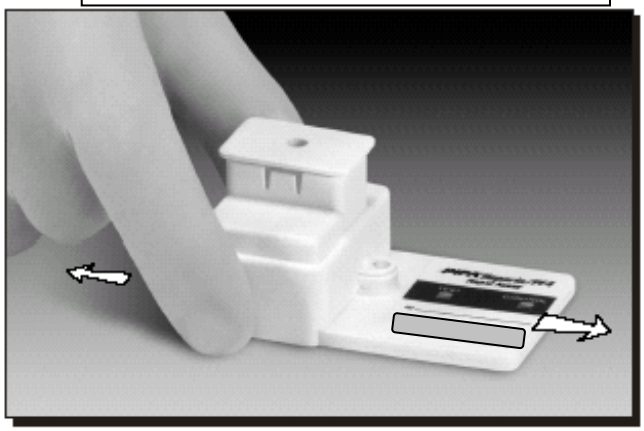
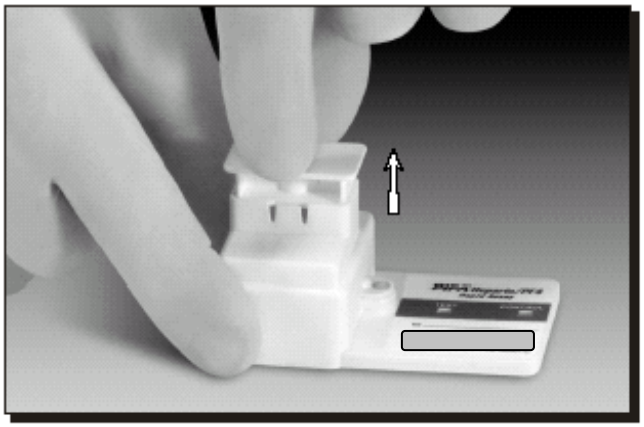
***The rapid manual assay that delivers accurate results in minutes!***

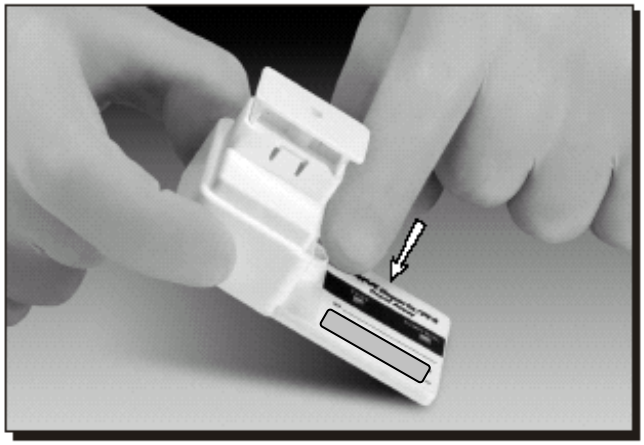
**3** Slide the device from side to side for 5 seconds, then keep it stationary for 1 minute.



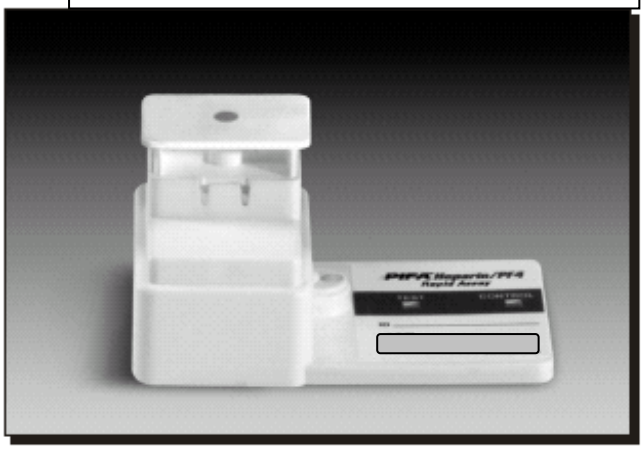
**4a** Pull the Tower up to the stop position



**4b** Tilt the miniReactor 45º so that the Tower portion is elevated and tap the device with finger until a blue color appears in the Reagent window.



**5** Lay unit on a level surface in well-lit conditions, but NOT in direct sunlight. Wait approximately 10 minutes or until a RED color appears in the CONTROL Window. Read the record result in the TEST Window. The test result will be stable for one (1) hour.



## RESULTS - INTERPRETATION GUIDE

| TEST WINDOW | CONTROL WINDOW | RESULT |
|---|---|---|
| NO BLUE | ANY RED | Reactive / Positive |
| ANY BLUE | ANY RED | Non-Reactive / Negative |
| NO BLUE | NO RED | Invalid |
| ANY BLUE | NO RED | Invalid |

Please note: Intensity of colors in test window may vary.


Manufactured in the USA by:

**HEALTH-CHEM DIAGNOSTICS LLC,**
**POMPANO BEACH, FLORIDA**
**Website: www.healthchemdiagnostics.com**

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