

# HEALTH-CHEM DIAGNOSTICS, LLC

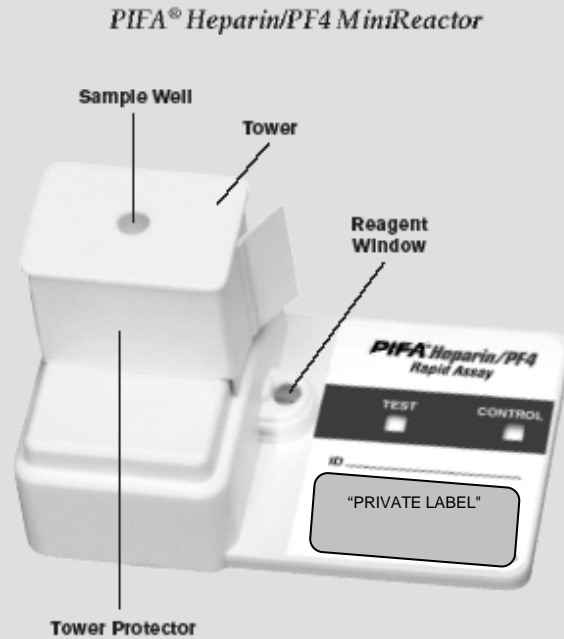
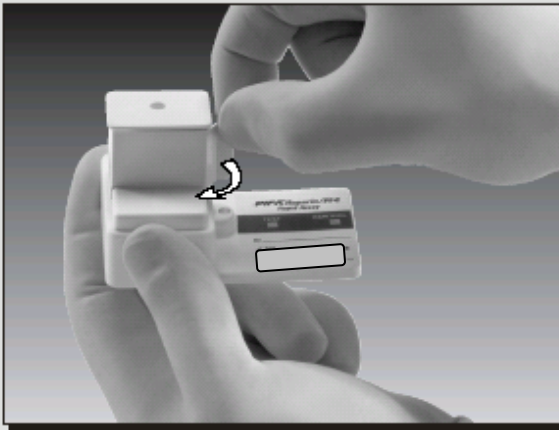
3341 S.W. 15<sup>th</sup> Street – Pompano Beach, FL 33069 - USA – Phone: (954) 979-3845 – Fax: (954) 979-7997 – www.healthchemdiagnostics.com

## HealthTEST - HEPARIN/PF4 ANTIBODY ASSAY

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

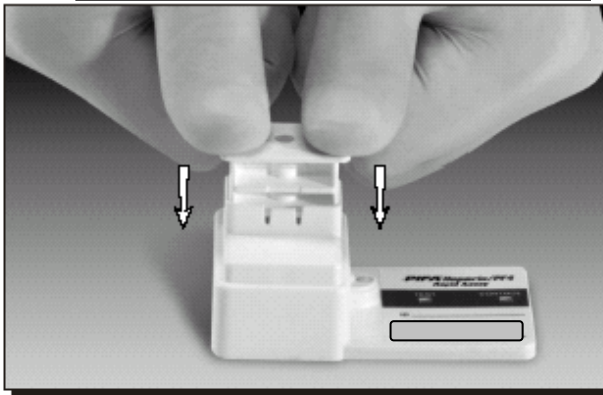
Before beginning the test procedure:

1. Remove the PIFA Heparin/PF4 MiniReactor from refrigeration and allow to sit at an ambient temperature (18-27°C; 64-81°F) 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.

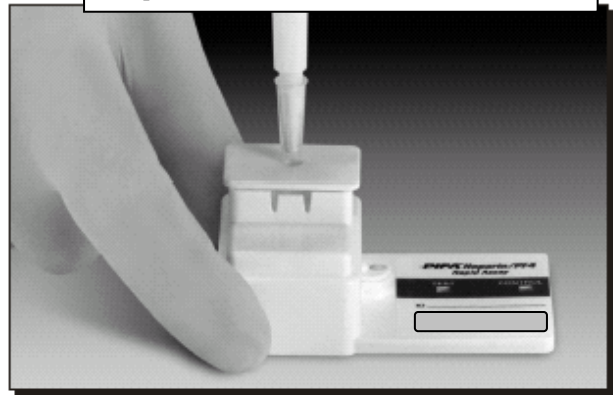


### Simple Test Procedure

- 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.

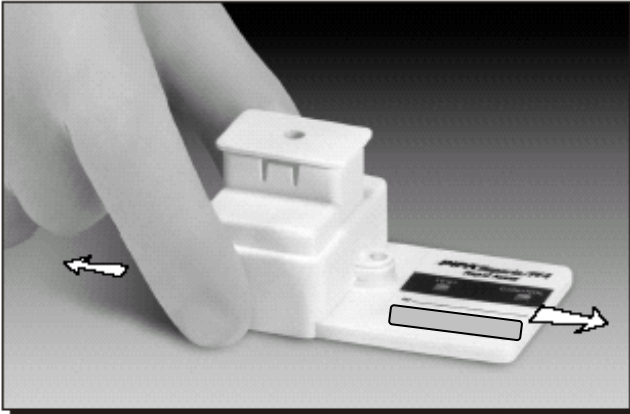


## HealthTEST - HEPARIN/PF4 ANTIBODY ASSAY

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

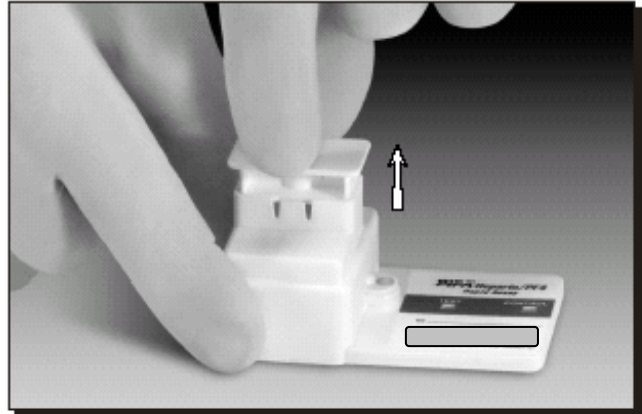
**3**

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



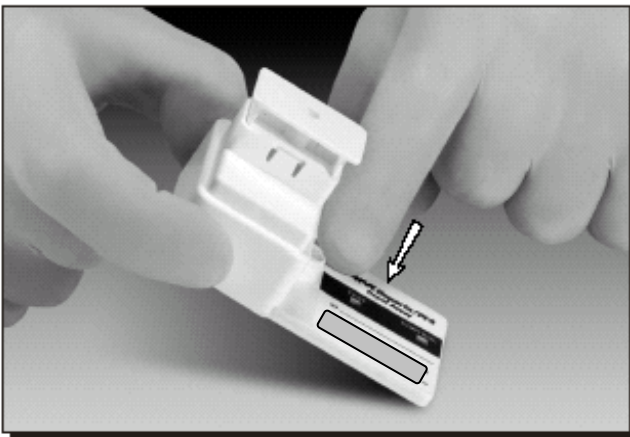
**4a**

Pull the Tower up to the stop position



**4b**

Tilt the miniReactor 45° 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 by: HEALTH-CHEM DIAGNOSTICS LLC**  
**US FDA & ISO CERTIFIED FACILITY**



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