

## *Certificate of Analysis*

Product Name: FDP Assay Kit - Orig:USA  
Product Number: 100650  
Lot Number: 319758

Expiration Date: 06/30/2014  
Storage: 2 - 8°C

| Description             | Lot Number | Expiration Date |
|-------------------------|------------|-----------------|
| Latex Reagent           | 263425     | 2014-08-31      |
| Positive Control        | 227368     | 2014-08-31      |
| Negative Control        | 273026     | 2014-12-31      |
| Sample Collection Tubes | 275173     | 2014-06-30      |
| Glycine Buffered Saline | 292649     | 2015-01-31      |

| Specification                      | Specification Limit | Result   |
|------------------------------------|---------------------|----------|
| Positive Control **(using dropper) | 3+ to 4+            | 4+       |
| Negative Control**(using dropper)  | Negative            | Negative |
| 1 µg/mL Fibrinogen                 | 1+ to 3+            | 1+       |

For in-vitro diagnostic use.

\*\* Effective concentration decreases from 40 µg/mL due to approximate dropper delivery volume.

Latex Reagent: 1 x 5 mL  
Positive Control: 1 x 2 mL  
Negative Control: 1 x 2 mL  
Sample Collection Tubes: 30 Tubes  
Glycine Buffered Saline: 1 x 100 mL  
Slides: 10  
Stir Sticks: 100  
Plastic Pipettes: 30

This kit contains bovine-sourced material.

Each unit of source material used in the preparation of the Positive Control has been tested by an FDA approved method and found nonreactive for the presence of Hepatitis B surface antigen (HBsAg) and negative for antibodies to HIV and HCV. However, no known test can offer assurance that products derived from human blood will not transmit hepatitis or other infectious disease. This product, like all materials of human origin, should be handled as potentially infectious biological material.



Quality Representative

Date: 2013-04-25