

Certificate of Analysis

Product Name: FDP Assay Kit - Orig:USA
Product Number: 100650
Lot Number: 148977

Expiration Date: 11/30/2017
Storage: 2 - 8°C

Description	Lot Number	Expiration Date
Latex Reagent	956519	2018-09-30
Positive Control	994973	2017-11-30
Negative Control	933540	2018-07-31
Sample Collection Tubes	101742	2018-10-31
Glycine Buffered Saline	933803	2018-09-30

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+	2+

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: 2017-05-23