

Certificate of Analysis

Product Name: FDP Assay Kit - Orig:USA
Product Number: 100650
Lot Number: 746414

Expiration Date: 11/30/2016
Storage: 2 - 8°C

Description	Lot Number	Expiration Date
Latex Reagent	745389	2017-10-31
Positive Control	603376	2016-11-30
Negative Control	728030	2017-03-31
Sample Collection Tubes	718094	2017-01-31
Glycine Buffered Saline	740013	2017-03-31

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: 2015-11-30