

Certificate of Analysis

Product Name: FDP Assay Kit - Orig:USA
Product Number: 100650
Lot Number: 299871

Expiration Date: 10/31/2018
Storage: 2 - 8°C

Description	Lot Number	Expiration Date
Latex Reagent	280277	2020-01-31
Positive Control	122887	2019-04-30
Negative Control	179330	2019-06-30
Sample Collection Tubes	214254	2018-10-31
Glycine Buffered Saline	232628	2019-10-31

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+	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: 2018-06-26