

Certificate of Analysis

Product Name: Fibrinogen Assay Set - Orig:USA
Product Number: 100600
Lot Number: 423506

Expiration Date: 04/30/2016
Storage: 2 - 8°C

Description	Lot Number	Expiration Date
Bovine Thrombin [BT] (2)	423509	2016-06-30
Imidazole Buffered Saline [IBS]	423508	2016-04-30
Fibrinogen Reference Plasma [FRP] (3)	423511	2016-04-30

Specification	Specification Limit	Result
BT Appearance Cake	White solid	Complies
BT Appearance Reconstituted	Clear, colorless with no particulates	Complies
BT pH	7.3 - 7.8	7.7
BT Moisture (Karl Fischer)	<= 3 %	0
BT Vial-to-Vial	<= 4 %	1
BT Assigned Value	100 NIH U/mL	100 NIH U/mL
IBS Appearance	Clear, colorless with no particulates	Complies
IBS pH	7.2 - 7.6	7.4
FRP Appearance Cake	Yellow to buff colored solid	Complies
FRP Appearance Reconstituted	Yellow to straw colored, clear to hazy, free of particulates when viewed against dark background	Complies
FRP Solubility	Less than 2 minutes	Complies
FRP Moisture (Karl Fischer)	<= 3 %	1
FRP Vial-to-Vial	<= 1.5 %	0.6
FRP Assigned Value	200 - 400 mg/dL	312
r-squared (photo-optical)	>= 0.96	1.00
Low Control	Assigned Value (4)	105 mg/dL
Low Control	Recovered Value (5)	95 mg/dL
Low Control (% of assigned)	-15 - 15 %	-9
Normal Control	Assigned Value (4)	303 mg/dL
Normal Control	Recovered Value (5)	299 mg/dL
Normal Control (% of assigned)	-15 - 15 %	-1
High Control	Assigned Value (4)	595 mg/dL
High Control	Recovered Value (5)	530 mg/dL
High Control (% of assigned)	-15 - 15 %	-11

For in-vitro diagnostic use.

1. All clot-based testing was performed on a photo-optical instrument.
2. The bovine based material used in this product is from farms certified to be free of transmissible spongiform encephalitis (TSE).

3. Each unit of source material used in the preparation of this product has been tested by an FDA licensed method and found non-reactive for HBsAg and negative for antibodies to HIV and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit hepatitis, AIDS, or other infectious diseases. This product, like all materials of human origin, should be handled as potentially infectious biological material.

4. The assigned value is lot dependent and may change when the lot number of control is changed.

5. Recovered value is based on ten replicates and is dependent on the reagent, the control, and the instrument used for testing.



Quality Representative

Date: 2013-12-19