

Certificate of Analysis

Fibrinogen Assay Set: p/n 100600

Lot #: 233073

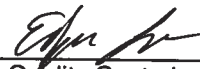
Expire: 2015-04

Kit Components ¹

Lot number Exp date	Bovine Thrombin ²		Imidazole Buffered Saline		Fibrinogen Reference Plasma ³	
	Specification	Result	Specification	Result	Specification	Result
	233072 2015-06		233075 2015-04		233074 2015-04	
Cake Appearance	white, solid	Complies	NA		Buff to yellow colored, solid	Complies
Reconstituted Appearance	clear, colorless, with no particulates	Complies	clear, colorless, with no particulates	Complies	Straw to yellow, clear to hazy, free of particulates when viewed against dark background	Complies
pH	7.3 - 7.8	7.8	7.2 - 7.6	7.4	NA	
Solubility	NA		NA		less than 2 min	Complies
Moisture (Karl Fisher)	≤ 3%	0.2 %	NA		≤ 3%	0.6 %
Vial-to-Vial	≤ 4%	0 %	NA		≤ 1.5%	1 %
Assigned Value	(100 NIH u/mL)	(100 NIH u/mL)	NA		200 - 400 mg/dL	327

Kit Performance ¹

	Assigned Value ⁴	Recovered Value ⁵	Specification	Result
r-value (photo-optical)			≥ 0.98	0.99
Recovery of a low control	104	112	±15% of assigned	7
Recovery of a normal control	303	281	±15% of assigned	-7
Recovery of a high control	592	599	±15% of assigned	1


Quality Control

9/27/12
Date

- All clot-based testing was performed on a photo-optical instrument.
- 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.
- The bovine-sourced material used in this product is from farms certified to be free of transmissible spongiform encephalitis (TSE).
- The assigned value is lot dependent and may change when the lot number of control is changed.
- Precision is based on 10 replicates and is dependent on the reagent, the control, and the instrument used for testing.