

Certificate of Analysis

Product Name: Coagulation Control Plasma Level 3
Product Numbers: 100597 / 250597
Lot Number: 402791

Expiration Date: 2014-12
VAN Number: N/A
Storage Temperature: 2 - 8 °C

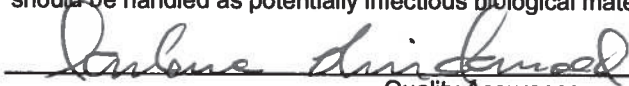
Unopened Stability: This product is stable until the expiration date indicated above when stored at 2 - 8 °C.

Reconstitution: 1.0 mL high purity water. Swirl gently and let stand undisturbed for 15 minutes at room temperature. Reconstituted control is stable for 8 hours when stored in a capped vial at 2 - 8 °C.

Test		Specification	Results		
Appearance		Buff to yellow colored solid	Complies		
Reconstituted Appearance		Straw to yellow, clear to hazy. Free of particulates (viewed against a dark background)	Complies		
Solubility		< 2 minutes	< 2 minutes		
Vial-to-Vial variability		≤ 4 %	1		
Moisture		≤ 3 %	1		
Prothrombin Time					
Reagent	Value Seconds	Mfg. Release Specifications	Confidence Interval*	Value % PT	Confidence Interval*
Thromboplastin D	30.5	25 - 34 seconds	25.9-35.1 sec	14	11-16 %
Activated Partial Thromboplastin Time					
APTT-XL	73	60 - 74 seconds	62-83 sec		
KONTACT	66	For information only.	56-76 sec		
Clauss Fibrinogen					
100 NIH U/mL Thrombin	Value mg/dL	Mfg. Release Specifications	Confidence Interval*		
	333	150 - 450 mg/dL	283-383 mg/dL		

*Calculated from recovered values. Actual values recovered in the user laboratory will depend on reagent lot number, instrument and technique in use. Each laboratory should establish control ranges using instrument, reagent & technique in place.

All individual donor units comprising this lot of Coagulation Control Plasma have been tested and found nonreactive for HBsAG and negative for antibodies to HIV and HCV. As with all blood products, this product should be handled as potentially infectious biological material.


10/16/13
 Quality Assurance Date