

Certificate of Analysis

Product Name: Coagulation Control Plasma Level 3
Product Numbers: 100597 / 250597
Lot Number: 170842

Expiration Date: 2015-03
VAN Number: N/A
Storage Temperature: 2 - 8 °C

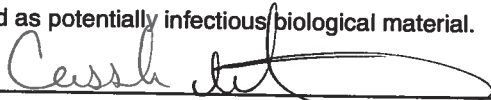
Unopened Stability: This product is stable until the expiration date indicated above when stored at 2 - 8 °C.

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	Complies
Vial-to-Vial variability	≤ 4 %	2
Moisture	≤ 3 %	1
Prothrombin Time		
Reagent	Value Seconds	Mfg. Release Specifications
Thromboplastin D	29.7	25 - 34 seconds
Activated Partial Thromboplastin Time		
APTT-XL	68	60 - 74 seconds
KONTACT	62	For information only.
Clauss Fibrinogen		
	Value mg/dL	Mfg. Release Specifications
100 NIH U/mL Thrombin	293	150 - 450 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.


 Quality Assurance

04/13/12
 Date