

Certificate of Analysis

Product Name: Coag Control Level 1 (Normal) - Orig:USA
Product Number: 100595
Lot Number: 423512

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

Specification	Specification Limit	Result
Appearance	Yellow to buff colored solid	Complies
Appearance Reconstituted	Yellow to straw colored, clear to hazy, free of particulates when viewed against dark background	Complies
Solubility	Less than 2 minutes	Complies
Vial-to-Vial Variability	<= 1.8 %	0.6
Moisture	<= 3 %	1
Thromboplastin DS	Report	13.5 S
Thromboplastin DS	Confidence Interval*	11.4-15.5 s
Thromboplastin DS	Value % PT	87 %
Thromboplastin DS	Confidence Interval*	70-104 %
Thromboplastin D	10.1 - 11.8 S	11.1
Thromboplastin D	Confidence Interval*	9.4-12.8 s
Thromboplastin D	Value % PT	105 %
Thromboplastin D	Confidence Interval*	84-126 %
APTT-XL	26 - 33 S	29
APTT-XL	Confidence Interval*	25-34 s
Kontakt	Report	28 S
Kontakt	Confidence Interval*	24-33 s
Thrombin Time Rgt	Report	13.8 S
Thrombin Time Rgt	Confidence Interval*	11.0-16.5 s
100 NIH U/mL Throm.	200 - 400 mg/dL	312
100 NIH U/mL Throm.	Confidence Interval*	265-359

For in-vitro diagnostic use.

* 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 ranges using instrument, reagent and 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 Representative

Date: 2013-12-05