

Certificate of Analysis

Product Name: Coag Control Level 2 (Abnormal)-Orig:USA
Product Number: 100596
Lot Number: 795164

Expiration Date: 06/30/2018
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	<= 2 %	1
Thromboplastin DS	Report	41.6 S
Thromboplastin DS	Confidence Interval*	35.4-47.8 S
Thromboplastin DS	Value % PT	20 %
Thromboplastin DS	Confidence Interval*	16-24 %
Thromboplastin D	Lower Limit	18 S
Thromboplastin D	Upper Limit	24 S
Thromboplastin D	Result	21 S
Thromboplastin D	Confidence Interval*	17.9-24.2 S
Thromboplastin D	Value % PT	19 %
Thromboplastin D	Confidence Interval*	15-23 %
APTT-XL	Lower Limit	41 S
APTT-XL	Upper Limit	61 S
APTT-XL	Result	53 S
APTT-XL	Confidence Interval*	44.8-60.6 S
Kontakt	Report	40 S
Kontakt	Confidence Interval*	34.3-46.3 S
Fibrinogen**	150 - 450 mg/dL	288
Fibrinogen**	Confidence Interval*	245-331 mg/dL

For in-vitro diagnostic use. ** Clauss fibrinogen

* 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: 2016-01-27