

Certificate of Analysis

Product Name: Coag Control Level 2 (Abnormal)-Orig:USA
Product Number: 100596
Lot Number: 142323

Expiration Date: 04/30/2020
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	50.2 S
Thromboplastin DS	Confidence Interval*	42.7-57.8 S
Thromboplastin DS	Value % PT	17 %
Thromboplastin DS	Confidence Interval*	13-20 %
Thromboplastin D	Lower Limit	19 S
Thromboplastin D	Upper Limit	25 S
Thromboplastin D	Result	24 S
Thromboplastin D	Confidence Interval*	20.1-27.3 S
Thromboplastin D	Value % PT	14 %
Thromboplastin D	Confidence Interval*	11-17 %
APTT-XL	Lower Limit	40 S
APTT-XL	Upper Limit	60 S
APTT-XL	Result	53 S
APTT-XL	Confidence Interval*	44.7-60.5 S
Kontakt	Report	46 S
Kontakt	Confidence Interval*	38.8-52.4 S
Fibrinogen**	150 - 450 mg/dL	287
Fibrinogen**	Confidence Interval*	244-330 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: 2017-06-28