

Certificate of Analysis

Product Name: APTT-XL - Orig:USA
Product Number: 100403
Lot Number: 736819

Expiration Date: 03/31/2017
Storage: 2 - 8°C

Specification	Specification Limit	Result
Appearance	Clear, yellow solution free of particulate matter.	Complies
Vial-to-vial Variability (CV)	$\leq 1.5 \%$	1.3
Level 1 Master Lot*	Lower Limit	29 S
Level 1 Master Lot*	Upper Limit	36 S
Level 1 Master Lot	Result	30 S
Level 1 Master Lot	Lot Number	601316
Level 2 Master Lot*	Lower Limit	42 S
Level 2 Master Lot*	Upper Limit	56 S
Level 2 Master Lot	Result	48 S
Level 2 Master Lot	Lot Number	251055
Level 3 Master Lot*	Lower Limit	62 S
Level 3 Master Lot*	Upper Limit	79 S
Level 3 Master Lot	Result	69 S
Level 3 Master Lot	Lot Number	210194
Heparin Level 2*	Lower Limit	76 S
Heparin Level 2*	Upper Limit	90 S
Heparin Level 2	Result	90 S
Heparin Level 2	Lot Number	406500
Normal Donors (Mean of 3)	Report	30 S
20% Factor VIII / Level 1 Control	≥ 1.10	1.48
20% Factor IX / Level 1 Control	≥ 1.07	1.21
20% Factor XI / Level 1 Control	≥ 1.21	1.42

For in-vitro diagnostic use.

All clot time specifications are for the Sysmex CA1500. They may be different for other photo-optical instruments.

* Control specifications are lot-specific. Before the stated control lots expire or are depleted, new ranges will be established for the replacement lots.



Quality Representative

Date: 2015-09-28