

Certificate of Analysis

Product Name: APTT-XL - Orig:USA
Product Number: 100402
Lot Number: 438100

Expiration Date: 11/30/2015
Storage: 2 - 8°C

Specification	Specification Limit	Result
Appearance	Clear, yellow solution free of particulate matter.	Complies
Vial-to-vial Variability (CV)	$\leq 1.5 \%$	0.6
Level 1 Master Lot*	26 - 34 S	33
Level 1 Master Lot	Lot Number	147251
Level 2 Master Lot*	42 - 56 S	55
Level 2 Master Lot	Lot Number	251055
Level 3 Master Lot*	62 - 79 S	75
Level 3 Master Lot	Lot Number	210194
Heparin Level 2*	63 - 77 S	77
Heparin Level 2	Lot Number	234521
Normal Donors (Mean of 3)	Report	30 S
20% Factor VIII / Level 1 Control	≥ 1.10	1.35
20% Factor IX / Level 1 Control	≥ 1.07	1.19
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: 2014-02-03