

Certificate of Analysis

Product Name: APTT-XL - Orig:USA
Product Number: 100402
Lot Number: 960561

Expiration Date: 08/31/2018
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	31 S
Level 1 Master Lot	Lot Number	601316
Level 2 Master Lot*	Lower Limit	45 S
Level 2 Master Lot*	Upper Limit	59 S
Level 2 Master Lot	Result	55 S
Level 2 Master Lot	Lot Number	636284
Level 3 Master Lot*	Lower Limit	64 S
Level 3 Master Lot*	Upper Limit	81 S
Level 3 Master Lot	Result	78 S
Level 3 Master Lot	Lot Number	636283
Heparin Level 2*	Lower Limit	56 S
Heparin Level 2*	Upper Limit	70 S
Heparin Level 2	Result	59 S
Heparin Level 2	Lot Number	585181
Normal Donors (Mean of 3)	Report	32 S
20% Factor VIII / Level 1 Control	≥ 1.10	1.44
20% Factor IX / Level 1 Control	≥ 1.07	1.29
20% Factor XI / Level 1 Control	≥ 1.21	1.45

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: 2016-11-21