

Certificate of Analysis

Product Name: APTT-XL Reagent mL
Product Numbers: 100402 / 250402
 100403 / 250403
Lot Number: 212710
Expiration Date: 2014-06

VAN Number: 204842

Storage Temperature: 2 - 8 °C

Handling: Unopened vials are stable until the expiration date indicated above when stored at 2 - 8° C.
 Once opened, vials are stable for 30 days when stored at 2 - 8 °C. Do not freeze.

Test	Specification (all CT specs are for photo-optical instruments)	Results
Appearance	Clear yellow solution free of particulates	Complies
Vial-to-vial variability	≤ 1.5% CV	0.9%
Level 1 Master Lot# V33072	27-34 seconds*	29
Level 2 Master Lot# V39124	42-56 seconds*	52
Level 3 Master Lot# V39684	64-81 seconds*	77
Heparin Level 2 Lot# V41730	50-64 seconds*	54
Normal Donors (mean of 3)	For information only	26
20% Factor VIII	20% VIII CT ÷ Level 1 CT = ≥ 1.10	<u>20 % VIII CT</u> 40.4 <u>CT ÷ Level 1 CT</u> 1.22
20% Factor IX	20% IX CT ÷ Level 1 CT = ≥ 1.07	<u>20 % IX CT</u> 36.35 <u>CT ÷ Level 1 CT</u> 1.09
20% Factor XI	20% XI CT ÷ Level 1 CT = ≥ 1.21	<u>20 % XI CT</u> 44.8 <u>CT ÷ Level 1 CT</u> 1.35

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


 Quality Assurance

7-20-12
 Date