

## *Certificate of Analysis*

Product Name: APTT-XL - Orig:USA  
Product Number: 100402  
Lot Number: 127911

Expiration Date: 03/31/2019  
Storage: 2 - 8°C

| Specification                     | Specification Limit                                | Result   |
|-----------------------------------|----------------------------------------------------|----------|
| Appearance                        | Clear, yellow solution free of particulate matter. | Complies |
| Vial-to-vial Variability (CV)     | $\leq 1.5 \%$                                      | 0.5      |
| Level 1 Master Lot*               | Lower Limit                                        | 31 S     |
| Level 1 Master Lot*               | Upper Limit                                        | 35 S     |
| Level 1 Master Lot                | Result                                             | 31 S     |
| Level 1 Master Lot                | Lot Number                                         | 601316   |
| Level 2 Master Lot*               | Lower Limit                                        | 46 S     |
| Level 2 Master Lot*               | Upper Limit                                        | 58 S     |
| Level 2 Master Lot                | Result                                             | 55 S     |
| Level 2 Master Lot                | Lot Number                                         | 636284   |
| Level 3 Master Lot*               | Lower Limit                                        | 65 S     |
| Level 3 Master Lot*               | Upper Limit                                        | 80 S     |
| Level 3 Master Lot                | Result                                             | 75 S     |
| Level 3 Master Lot                | Lot Number                                         | 636283   |
| Heparin Level 2*                  | Lower Limit                                        | 57 S     |
| Heparin Level 2*                  | Upper Limit                                        | 69 S     |
| Heparin Level 2                   | Result                                             | 66 S     |
| Heparin Level 2                   | Lot Number                                         | 585181   |
| Normal Donors (Mean of 3)         | Report                                             | 29 S     |
| 20% Factor VIII / Level 1 Control | $\geq 1.10$                                        | 1.44     |
| 20% Factor IX / Level 1 Control   | $\geq 1.07$                                        | 1.24     |
| 20% Factor XI / Level 1 Control   | $\geq 1.21$                                        | 1.43     |

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: 2017-04-19