

## *Certificate of Analysis*

Product Name: APTT-XL - Orig:USA  
Product Number: 100402  
Lot Number: 464221

Expiration Date: 03/31/2016  
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                                          | 56       |
| Level 2 Master Lot                | Lot Number                                         | 251055   |
| Level 3 Master Lot*               | 62 - 79 S                                          | 77       |
| Level 3 Master Lot                | Lot Number                                         | 210194   |
| Heparin Level 2*                  | 63 - 77 S                                          | 76       |
| Heparin Level 2                   | Lot Number                                         | 234521   |
| Normal Donors (Mean of 3)         | Report                                             | 30 S     |
| 20% Factor VIII / Level 1 Control | $\geq 1.10$                                        | 1.32     |
| 20% Factor IX / Level 1 Control   | $\geq 1.07$                                        | 1.15     |
| 20% Factor XI / Level 1 Control   | $\geq 1.21$                                        | 1.44     |

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.

*Connie Carroll*

Quality Representative

Date: 2014-04-01