

## *Certificate of Analysis*

Product Name: Thromboplastin-DS - Orig:USA  
Product Number: 100354  
Lot Number: 195216

Expiration Date: 07/31/2020  
Storage: 2 - 8°C

| Specification                           | Specification Limit                                       | Result   |
|-----------------------------------------|-----------------------------------------------------------|----------|
| Appearance                              | White to buff-colored solid                               | Complies |
| Appearance Reconstituted                | Straw-colored to grey liquid, cloudy with no particulates | Complies |
| Lot Variability                         | $\leq 5\%$                                                | 3        |
| Coag Level 1*                           | Lower Limit                                               | 11.4 S   |
| Coag Level 1*                           | Upper Limit                                               | 14.0 S   |
| Coag Level 1*                           | Result                                                    | 12.6 S   |
| Coag Level 1                            | Lot Number                                                | 601316   |
| Coag Level 2*                           | Lower Limit                                               | 33 S     |
| Coag Level 2*                           | Upper Limit                                               | 43 S     |
| Coag Level 2*                           | Result                                                    | 36 S     |
| Coag Level 2                            | Lot Number                                                | 636284   |
| Destiny (Photo-optical) ISI             | Report                                                    | 0.95     |
| Sysmex (Photo-optical) ISI**            | 0.85 - 1.07                                               | 0.91     |
| ACL (Nephelometric) ISI                 | Report                                                    | 0.93     |
| Destiny (Mechanical) ISI                | Report                                                    | 0.97     |
| Recon Stability, capped, 7 day @ 2-8 °C | $\leq 10\%$                                               | -1       |

For in-vitro diagnostic use.

\* Sysmex clot times, specifications are specific for the master control used for the manufacture of the lot.

\*\* This product is manufactured using the Sysmex as the reference instrument; therefore, only a Sysmex specification is reported.

Traceability Statement: The rabbit-based material used in this product is from farms certified to be free of transmissible spongiform encephalitis (TSE).

Warning: Thromboplastin-DS contains sodium azide. Sodium azide under acidic conditions yields hydrazoic acid, an extremely toxic compound. Dilute with running water before discarding, and then flush with large volumes of water. These precautions are recommended to avoid deposits in metal piping where explosive conditions may develop.



Quality Representative

Date: 2017-10-19