

Certificate of Analysis

Product Name: Thromboplastin-DS - Orig:USA
Product Number: 100362
Lot Number: 894375

Expiration Date: 08/31/2018
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	<= 5 %	2
Coag Level 1*	Lower Limit	12.4 S
Coag Level 1*	Upper Limit	15.0 S
Coag Level 1*	Result	12.6 S
Coag Level 1	Lot Number	601316
Coag Level 2*	Lower Limit	35 S
Coag Level 2*	Upper Limit	46 S
Coag Level 2*	Result	38 S
Coag Level 2	Lot Number	251055
Destiny (Photo-optical) ISI	Report	1.00
Sysmex (Photo-optical) ISI**	0.85 - 1.07	0.90
ACL (Nephelometric) ISI	Report	0.97
Destiny (Mechanical) ISI	Report	1.01
Recon Stability, capped, 7 day @ 2-8 °C	<= 10 %	8

For in-vitro diagnostic use.

* Sysmex clot times, specifications are specific for the master control used for the manufacture for 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: 2016-07-27