

Certificate of Analysis

Product Name: Thromboplastin-DS 4 mL
Product Numbers: 100354

Storage Temperature: 2 - 8°C

Lot Number: 192132A
Expiration Date: 2015-03

Handling: Reconstitute with 4 mL high purity water.

Stability: Unopened vials are stable until the expiration date indicated above when stored at 2 - 8°C. Do not freeze.

Test	Specification	Results
Appearance	white to buff colored solid	Complies
Reconstituted Appearance	straw to grey colored liquid, cloudy with no particulates	Complies
Functional Testing		
Lot Variability	≤ 5%	2
Control values	Sysmex Clot time (seconds)	Sysmex Clot time (seconds)
Coag Level 1 lot #: V33072	*11.3 - 13.9	13.1
Coag Level 2 lot #: V39124	*31 - 42	36
ISI values		
Destiny (photo-optical)	Report	1.12
Sysmex (photo-optical)	0.85 - 1.07	1.04
ACL (nephelometric)	Report	1.12
Destiny (mechanical)	Report	1.04
Reconstituted stability, capped 7 day change at 2-8°C	≤ 10%	-10

*specifications are specific for the master control

For *In Vitro* Diagnostic use only

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 acid 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 in which explosive conditions may develop.

Quality Assurance

Date