

## **CERTIFICATE OF ANALYSIS**

**Product**: Thromboplastin L

**Code No.** : 5265L

**Lot No.** : 21385704

**Expiry** : 2017-03

**Storage**: As indicated on packaging.

Testing : PASS

Testing has shown that this material meets Quality Control specifications.

Quality Control Release Date: 21 Apr 2016

Signed: Carol J Sandercock Date: 22 Apr 2016

Regulatory Affairs & Quality Assurance Officer

Note: N/A = Not Applicable

## Declaration

This product was manufactured and tested in compliance with the directives of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, ISO 13485:2003 and EN ISO 13485:2012.

Helena Biosciences are accredited to ISO 13485:2003 and EN ISO 13485:2012 for the manufacture of medical devices. Copies of this certification are available upon request.