

CERTIFICATE OF ANALYSIS

Product : Thrombin Time

Code No. : 5392

Lot No. : 21491123

Expiry : 2019-09

Storage : As indicated on packaging.

Testing : PASS

Testing has shown that this material meets Quality Control specifications.

Quality Control Release Date: 27 Oct 2017

Signed: Carol J Sandercock

Date: 31 Oct 2017



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.

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