

CERTIFICATE OF ANALYSIS

Product : Thrombin Time

Code No. : 5392

Lot No. : 21412721

Expiry : 2018-09

Storage : As indicated on packaging.

Testing : PASS

Testing has shown that this material meets Quality Control specifications.

Quality Control Release Date: 21 Sep 2016

Signed: Carol J Sandercock

Date: 21 Sep 2016

A handwritten signature in black ink, appearing to read "C Sandercock", written over a light grey circular background.

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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