

CERTIFICATE OF ANALYSIS

Product : Manual D-Dimer

Code No. : 5250

Lot No. : 21451319

Expiry : 2018-11

Storage : As indicated on packaging.

Testing : PASS

Testing has shown that this material meets Quality Control specifications.

Quality Control Release Date: 17 May 2017

Signed: Carol J Sandercock

Date: 17 May 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.

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom