

CERTIFICATE OF ANALYSIS

Product : Clauss Fibrinogen 50

Code No. : 5556H

Lot No. : 21105219

Expiry : 2014/10

Storage : As indicated on packaging.

Description : As indicated in the Instructions For Use (IFU).

Testing : PASS

Testing has shown that this material meets Quality Control specifications.

Miscellaneous: N/A

Quality Control Release Date: 19 Dec 2012

Signed: Carol J Sandercock

Date: 20 Dec 2012



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 and ISO 13485:2003.

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

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