

CERTIFICATE OF ANALYSIS

Product: DRVVT Confirm

Code No. : 5485

Lot No. : 21092602

Expiry : 2014/08

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: 07 September 2012

Signed: Mick Henderson Date: 10 September 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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