Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

of ingredients and/or components for blood derived medicinal products

Certificate Number:

MI-2014-CE-05650-1

Issued to:

National Genetics Institute (NGI)

Manufacturing Site Address:

2440 S Sepulveda Boulevard Suite 135, Los Angeles CA 90064
Los Angeles, CA United States Of America

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer of ingredients and/or components for blood derived medicinal products has been inspected following section 25(1)(g) of the *Therapeutic Goods Act 1989* in connection with marketing authorisation/s listing ingredients and/or components manufacturers located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2 to 5 February 2016, it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the Australian Code of Good Manufacturing Practice for human blood and blood components, human tissues and human cellular therapy products (2013).

This certificate reflects the status of the manufacturing site at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

EXPIRY DATE: 5 February 2018

ISSUE DATE: 26 August 2016

Name and signature of an authorised person of the Competent Authority of Australia:

Signed: .....

Matt Davis, Senior Inspector
Manufacturing Quality Branch

This certificate is valid only if the security provisions (blue and grey curved dotted lines on the bottom half of each page) are visible.
This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

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MANUFACTURING OPERATIONS

This certificate covers the following steps in the manufacture of ingredients and/or components for therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Manufacturing Step
Testing Laboratory - Blood Tissue Cellular	NAT Testing for HIV and HCV
Testing Laboratory - Blood Tissue Cellular	NAT Testing for HBV, HAV and B19

The following limitations are applicable to these manufacturing operations:

Testing is restricted to the testing of plasma and plasma pools for fractionation.

HIV testing is restricted to NAT testing for HIV-1.

Name and signature of an authorised person of the Competent Authority of Australia:

Signed: .....

Matt Davis, Senior Inspector
Manufacturing Quality Branch

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