Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

of ingredients and/or components for blood derived medicinal products

Certificate Number:

MI-2019-CE-12002-1

Issued to:

National Genetics Institute (NGI)

Manufacturing Site Address:

Suite 135 / 2440 S Sepulveda Boulevard
Los Angeles CA 90064
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.

This certificate is issued based on a remote inspection of GMP compliance during COVID-19 travel restrictions. From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 21 to 24 March 2022, 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.

Issue Date: 07 November 2022 **Expiry Date: 24 March 2024**

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: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

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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	NAT Testing for HIV and HCV
Testing Laboratory	NAT Testing for HBV, HAV and B19

The testing is restricted to the testing of plasma and plasma Pools for fractionation.

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