Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2024-LI-09712-1

Granted to:

St Vincent's Institute of Medical Research
T/A National Serology Reference Laboratory Australia
ABN: 52 004 705 640

Manufacturing Site Address:

12 Ferntree Place
NOTTING HILL VIC 3168

The manufacturer above is hereby authorised under Section 38 of the *Therapeutic Goods Act 1989* to carry out the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Manufacturing Step
Testing Laboratory - Blood Tissue Cellular	NAT testing for HAV NAT testing for Parvovirus B19

This licence is subject to the requirements of the *Therapeutic Goods Act 1989,* and its Regulations.

Section 40(4) of the *Therapeutic Goods Act 1989* and Regulation 19, 20, 21 and 22 of the Therapeutic Goods Regulations 1990 impose various statutory conditions on all licences to manufacture therapeutic goods.

In addition to that, the specific conditions mentioned in Part 2 of this licence have been imposed under Section 40(1) or 40(2) of the *Therapeutic Goods Act 1989*.

Originally Granted: **17 March 2025** **Date Revised:** **10 November 2025**

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

TGA Health Safety Regulation

Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 2: Schedule of Conditions

Licence Number:

MI-2024-LI-09712-1

Granted to:

St Vincent's Institute of Medical Research
T/A National Serology Reference Laboratory Australia
ABN: 52 004 705 640

Manufacturing Site Address:

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In addition to the statutory conditions that have been imposed on all licences to manufacture therapeutic goods under Section 40(4) of the *Therapeutic Goods Act 1989* and Regulations 19, 20 and 21 of the Therapeutic Goods Regulations 1990, the conditions specified below have been imposed on this licence under Section/s 40(1) and/or 40(2) of the *Therapeutic Goods Act 1989*:

The following limitations are applicable to these manufacturing operations:

Testing should exclusively utilise the Cobas ® DPX, Duplex HAV and parvovirus B19 nucleic acid test for use on the Cobas 5800 or 6800 systems.

Originally Granted: **17 March 2025** **Date Revised:** **10 November 2025**

This licence is the property of the Therapeutic Goods Administration and must be returned or destroyed upon demand.
This licence remains valid until otherwise suspended or revoked by the Therapeutic Goods Administration.
The status of an Australian licence may be viewed at https://www.ebs.tga.gov.au/

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