



**Australian Government**

**Department of Health and Aged Care**  
Therapeutic Goods Administration

## **Licence to Manufacture Therapeutic Goods – Part 1**

**Licence Number:**

MI-23022005-LI-000452-2

**Granted to:**

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

**Manufacturing Site Address:**

4th Floor Healy Wing, 41 Victoria Parade  
FITZROY VIC 3065

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	Virology Screening Syphilis Testing NAT Testing for HIV, HCV and HBV 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:** 15 July 1999

**Date Revised:** 17 March 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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## **Licence to Manufacture Therapeutic Goods – Part 2: Schedule of Conditions**

**Licence Number:**

MI-23022005-LI-000452-2

**Granted to:**

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

**Manufacturing Site Address:**

4th Floor Healy Wing, 41 Victoria Parade  
FITZROY VIC 3065

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:

The NAT (Nucleic Acid Testing) for HIV encompasses both HIV -1 and HIV-2.

The licence also covers the receipt and testing of plasma samples for NAT testing for HAV and Parvovirus B19.

**Originally Granted: 15 July 1999**

**Date Revised: 17 March 2025**

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