

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

St Vincent's Institute of Medical
Research
4th Floor, Healy Building, 41 Victoria Parade
Fitzroy VIC 3065

Holds Certificate Number:

FS 605059

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Please see scope page.

For and on behalf of BSI:

Marc Barnes, Managing Director, BSI Group ANZ

Original Registration Date: 1998-02-25

Latest Revision Date: 2020-06-24

Effective Date: 2020-06-11

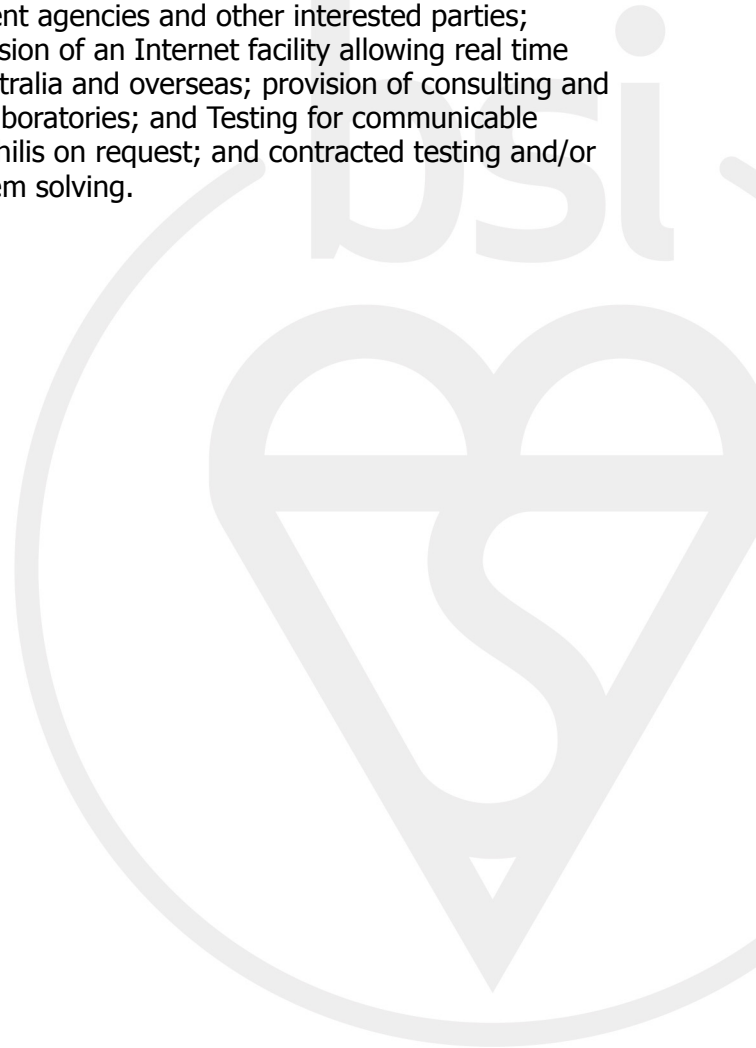
Expiry Date: 2023-06-30



Certificate No: **FS 605059**

Registered Scope:

Delivery of a multifaceted National Quality Assurance Program for qualitative and quantitative serology (includes assays using nucleic acid amplification techniques (NAT)) within terms of reference devised under the National HIV AIDS and Communicable Diseases Strategies of the Commonwealth of Australia, including: evaluation of in-vitro test kits prior to approval for registration by Therapeutic Goods Administration; maintenance of a sample repository used for evaluation and ongoing performance monitoring of test kits; provision of quality control samples and laboratory panels for quality assessment programs (proficiency testing) for various analytes; monitoring of ongoing performance of test kits and provision of statistics to Australian laboratories, Government agencies and other interested parties; provision of premarket kit batch-testing as required; provision of an Internet facility allowing real time monitoring of quality control results by laboratories in Australia and overseas; provision of consulting and training services in serology for Australian and overseas laboratories; and Testing for communicable diseases especially for HIV, HTLV, HCV, HBV, CMV and syphilis on request; and contracted testing and/or research for specific projects, clinical trials or assay problem solving.



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Page: 2 of 2

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