World leader in the science of quality for infectious disease testing

NRL
Science of Quality

YEAR 2024 - 2025

Director's Report

NRL is an operating division of SVI, providing science as a service through a range of trusted premium solutions to improve the quality of infectious disease testing globally. As a **WHO Collaborating Centre for Diagnostics** and a **WHO IVD Pre-qualification Evaluation Laboratory**, NRL also provides GMP-licensed blood and tissue donation screening making a unique contribution to the broader SVHA family through its global reputation for technical scientific excellence and public health partnerships.

We took time out to develop a dedicated NRL Strategy 2025-29 in March this year which will drive our efforts and activities over the next three to four years. Our strategic plan focuses on four key pillars that will strengthen NRL's resilience to deliver and thrive in a volatile and changing environment:

1. Harness key **Product and Service** offerings to pivot in response to emerging opportunities

2. Optimise organisational **Efficiency** and strengthen development of our **People**

3. Strengthen NRL's **Positioning, Business Development** and leverage existing and new **Partnerships**

4. Enhance **Financial Sustainability** and viability.

Our collaborations with St Vincent's Hospital Melbourne (SVHM) have been strengthened again this year not only through the ongoing provision of our accredited SVI Biobanking services to SVHM clinical researchers on campus, but also a range of collaborative activities with the Department of Microbiology and a new joint Aikenhead Centre for Medical Discovery (ACMD) project with the Department of Biochemistry, to extend stability testing on samples collected under the National Bowel Cancer Screening Program.

A key highlight of 2024-25 has been the go-live of NRL's new **2NAT screening program** for hepatitis A and parvovirus B19, which has been a large collaborative undertaking with CSL Behring and Australian Red Cross Lifeblood with oversight from the Therapeutic Goods Administration (TGA) and the National Blood Authority. The 2NAT Program required NRL to commission a new high-throughput pathology screening laboratory with a GMP license. Taking over 12 months of careful planning and collaboration, implementation was completed in early April ensuring that Australia's plasma for fractionation into plasma products meet global regulatory standards. NRL's new laboratory is now receiving over **30,000 blood donor samples** from across Australia for testing **every week.**

In May, it was wonderful to see the launch of the **Australian Clinical Guidelines for HTLV-1** for Aboriginal Primary Care settings which are recommending antenatal screening in pregnancy and provide guidance for clinical care for those people living with HTLV-1. This is a great step forward towards the elimination of mother-to-child transmission of HTLV-1 infection.

NRL has also led the progress made by the International Retrovirology Association's Testing Working Group to share knowledge and expertise globally regarding establishing HTLV-1 proviral load (PVL) testing to countries without access to these testing services. NRL's own **HTLV-1 PVL test** is now registered as an in-house Class 3 assay in readiness for Class 4 registration that will help reduce the proportion of Indeterminate test outcomes from Confirmatory Testing. Dr Melissa John was successful in obtaining an **ACH4 grant** to extend our work to identify and develop a suitable fingerstick blood collection device that improves accessibility to HTLV-1 serology and molecular assays for people living in remote areas.

Our international capacity building activities continue to enable regional colleagues to strengthen their own systems and processes for infectious diseases testing. We completed a program of work in Indonesia under the **Australia Indonesia Health Security Partnership (AIHSP) project** and strengthened countries capacity to become proficiency testing program providers including EQAS training to the **Malaysian National Public Health Laboratory, the Sri Lankan National Blood Transfusion Service** and 1**7 scientific institutes across India.** EQAS training was also provided to the **Central Public Health Laboratory, Papua New Guinea and to the Research Institute for Tropical Medicine (RITM)** in Manila, Philippines. We were thrilled to welcome a delegation from **Papua New Guinea's National Department of Health and Health Services Sector Development Program** on their own journey to establish a National Reference Laboratory for PNG.

As a **WHO designated Performance Evaluating Laboratory (PEL)**, NRL continues to support the development of test kit evaluation protocols, perform evaluations on SARS-CoV-2 rapid antigen tests and conduct dossier assessment on behalf of WHO and the Therapeutic Goods Administration (TGA). Of particular note, the NRL team developed a **sampling and batch testing protocol** for HIV Rapid Diagnostic Test kits used in the **Democratic Republic of Congo.** The project, funded by Global Fund included the manufacture of HIV Batch testing panels, plan for sampling tests throughout the distribution channel throughout the country and the preparation of panels of well characterized sample designed to evaluate test kit performance.

The NRL quality assurance programs have gone from strength to strength. Our External Quality Assessment programs have been expanded to include programs for **vector-borne infectious diseases** including Dengue virus, Zika virus, Chikungunya virus, Japanese Encephalitis virus, West Nile virus, Murray Valley Encephalitis virus and Ross River virus. A new program has been developed for **Mpox** molecular testing and serological testing for the bacterium Burkholderia pseudomallei. The quality control services have experienced growth through our collaboration with DiaMex, Germany and its distributors, particularly in the UK (50+ labs) and Colombia (30+ labs). NRL staff have contributed to scientific literature on topics including QC for infectious diseases and quality assurance of point of care testing (PoCT).

The NRL quality assurance program for PoCT has been further developed and integrated into our normal business activities. Panels have been provided to collaborators in Scotland, Wales, Finland and South Africa. Our program also supports several Australian programs using PoCT for chlamydia, gonorrhoea, hepatitis C virus and preparations are underway for samples for group A streptococcus and HPV in almost 100 remote First Nations communities.

Contents

Quality Control Services

It has been a year of change for NRL QC Services. Late 2024 saw the acquisition of DiaMex GmbH (the manufacturer of the Optitrol range of products) by **LGC Clinical Diagnostics** (LGC CDx) which is a leading global life sciences provider that now owns three QC manufacturing stables – Technopath Clinical Diagnostics (primarily chemistry QC focused), SeraCare and now DiaMex GmbH. The latest acquisition highlights that a leading global QC product manufacturer also believes that QConnect is the future for infectious disease QC methods, with plans to apply the QConnect concept across their large and comprehensive portfolio. The acquisition creates exciting opportunities for NRL by incorporating extensive NRL scientific experience and knowledge on QC design and manufacturing with LGC manufacturing and technology expertise to allow LGC CDx to be **'QConnect-ready'** – a world-leading approach to quality improvement for quality assurance in infectious disease testing.

The past year has also seen NRL continue our commitment to improve the quality of tests and testing globally, by sharing our expertise in quality assurance whilst on the road. Dr Wayne Dimech and Joe Vincini – both separately and together - visited many laboratories, conferences, manufacturing sites and global organisations in Europe, Asia, North and South America: presenting on QC in the setting of infectious disease testing and fostering relationships with QC and assay manufacturers and distributors, laboratory scientists and key scientific opinion leaders. Yet it was not all about travelling overseas. NRL conducted the first (of many we hope), **Australian Roadshows on Quality Control** in the Infectious Disease Testing Laboratory. The sessions encouraged core laboratory scientists to come and listen to why NRL feels strongly that traditional QC methods are not appropriate for all types of testing, and an alternative Meaningful QC method is more appropriate and will generate real savings in time, resources and money.

Early 2025 saw NRL engaging in a series of discussions with Sten Westgard, from Westgard QC. Over the last few years, NRL has demonstrated thought leadership through publication of original papers, letters to editors, and rebuttals to counter publications related to QC for infectious disease testing, co-authored by Sten Westgard himself, that could lead laboratories to problematic practices such as Six-Sigma metrics and continuation of frustrations observed through the use of inappropriate QC practices in infectious disease testing. In response to NRL activities, Sten Westgard wished to explore the scientific thinking and logic behind NRL's approach, culminating in a interview that was critical in helping scientists understand the science behind QConnect.

The discussion was published on the Westgard QC website in their newsletter and has sparked some thoughtful debate and dialogue on how laboratory scientists and managers can better understand whether their QC systems are appropriate and meaningful. Much of the feedback was in support of alternative approaches to QC for infectious disease testing, and NRL works to improve scientific practice and reduce unnecessary cost for managers frustrated by the status of QC, particularly serology testing for infectious diseases, in the core laboratory.

"The growing global adoption of QConnect reinforces NRL's role in redefining quality control for infectious disease testing."

Highlights

1 Extensive improvements within the EDCNet software platform to enhance our user experience, both NRL customers and NRL QC Services staff alike, including:

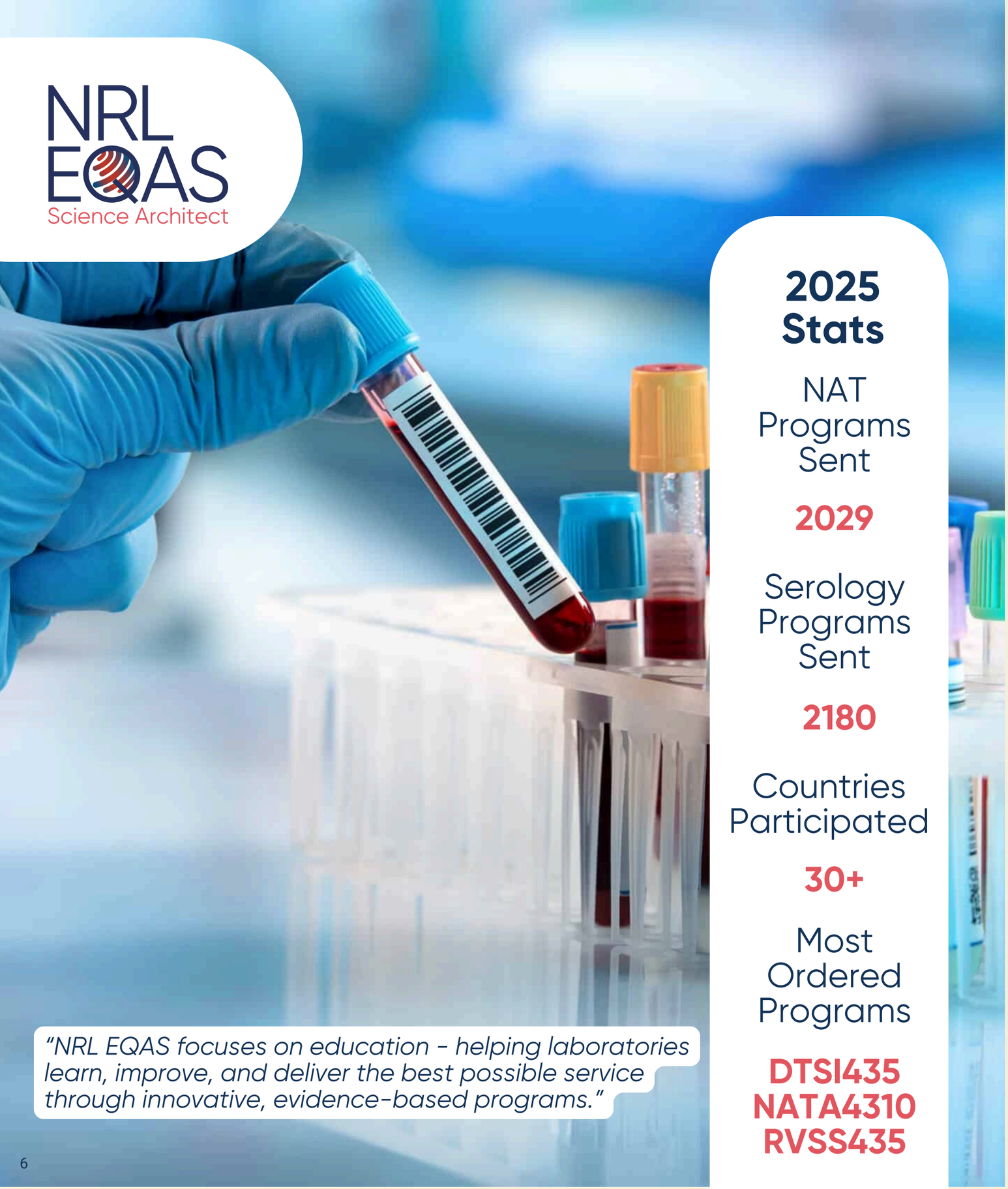
- **Improved search functionality**
- **Various background access upgrades to improve NRL investigation efforts**
- **The ability to apply QConnect Limits across multiple QC lots**

2 Publication detailed a cost-benefit analysis of different QC practices used in an Australian laboratory has estimated the true cost of inappropriate QC system practices.

3 Publication conducted an evidence-based assessment of recent publications trying to incorporate six-sigma metrics methods into infectious disease testing settings.

4 Thought leadership from Dr Wayne Dimech, Joe Vincini (NRL) and Sten Westgard (Westgard QC) on QC in the serology laboratory, titled "Where traditional rules cannot tread: an interview with NRL scientists about Serology Testing QC."

https://westgard.com/interviews/interview-dimech-vincini.html



"NRL EQAS focuses on education - helping laboratories learn, improve, and deliver the best possible service through innovative, evidence-based programs."

2025 Stats

NAT Programs Sent

2029

Serology Programs Sent

2180

Countries Participated

30+

Most Ordered Programs

DTSI435
NATA4310
RVSS435

EQAS

NRL has advocated that medical testing laboratories need more than a punitive measure of their laboratory testing from our very inception in 1985. Laboratories must strive to deliver a service that learns from its mistakes and shortfalls, and improves to be the best they can be, rather than be fearful that a failure means a loss of license or hefty financial punishment. With this, NRL EQAS continues to be focused on the educational aspects that other proficiency testing programs do not offer.

NRL strives to provide EQA programs that are **evidence-based** and **supportive** of the laboratory needs. Programs that are:

- **Innovative and adaptable to modern testing requirements**
- **Challenging yet achievable**
- **Able to support laboratory quality and give insight to areas needing improvement**
- **Conducted in collaboration with scientific partners and associations**
- **Affordable and sustainable for regions that struggle to gain access to such programs, such as in LMIC settings**

With this approach, NRL EQAS strives to develop new programs identified as critical to participant service improvement, collaborate with associations such as **WHO** and the **Asian Association of Transfusion Medicine (AATM)** to promote participation in programs, and provide in-country support to develop their own EQA schemes to achieve sustainability, better serve their laboratory base though expanded capacity, whilst providing direct traceability to NRL EQA scheme excellence.

Introduction of New EQA Programs

Vector-Borne Infectious Diseases **(VECT435)** EQAS was designed for laboratories that perform molecular surveillance testing of vector-borne emerging infectious diseases, including Dengue virus, Zika virus, Chikungunya virus, Japanese Encephalitis virus, West Nile virus, Murray Valley Encephalitis virus and Ross River virus.

Mpox Molecular **(MPOX423)** is a specialised EQAS for laboratories that perform molecular surveillance testing of Mpox virus.

Melioidosis Serology **(MLIO423)** is a specialised EQAS for laboratories that perform serological surveillance testing of the bacteria *Burkholderia pseudomallei* that causes Melioidosis.

Expansion of current EQA Programs

HIV-2 RNA detection was incorporated in Multimarker Blood Screening Molecular **(NATA4310)** and HIV Molecular **(HIVL435)** EQAS.

Treponema pallidum DNA detection was incorporated in Viral Exanthems Molecular **(RASH435)** EQAS.

New Ordering Process

A new online portal was introduced to provide a more interactive experience and to facilitate easier access to pricing, order processes and faster customer service.

Quality Assurance for Point of Care Testing

NRL's Commitment to Point of Care Testing Quality

Over the years, NRL has demonstrated our commitment to improving the quality of point of care testing (PoCT), as a service to the Australian and global community, and in the quality assurance (QA) of the testing offered and test devices used. A significant investment of resources and time have been made in program design and testing, as evident in previous NRL Annual Reports.

From Research to Business as Usual (BAU)

Behind the scenes, NRL has developed many schemes, samples and services in delivery of PoCT QA, however, this has primarily been for short term projects or pilot programs with limited resourcing and a 'just in time' approach. It is clear to us that to expand and contribute more meaningfully to PoCT QA with accredited and certified programs, our offering needs to be fully integrated as a routine activity of NRL Quality Assurance.

In 2024-25 we successfully completed the full integration of the service which was transitioned from our R&D team into our routine Quality Assurance (QA) Services with the products and services now offered under the **RapidQ** name.

Introducing RapidQ

RapidQ encompasses all things **PoCT QA.** Samples, software, ease of use, affordability for limited resources, ease of transportation and adoption by our in-country partners around the World.

RapidQ embraces and expands on concepts already in place, such as accredited and qualified **EQA** and **competency panels** to help educate and transform personnel delivering PoCT services outside the laboratory setting. The software is simple to use with QR Code functionality designed for mobile phone technology and sample types make it easier to move around the globe with minimal necessity for expensive logistics. All the things that are important to LMIC where participation in quality assurance is often impossible.

Engagement and Global Impact

In support of our commitment to addressing shortfalls in the quality of point of care testing which is used extensively across South East Asia and the Western Pacific regions, NRL staff attended the second Asia Pacific Conference on Point of Care Testing for Infectious Diseases (POC25) in Bangkok, Thailand in June. The conference sessions included community impact, accessibility, and innovation in the PoCT landscape.

Senior Scientist Liza Cabuang presented a poster outlining further findings of NRL's Quality Assurance Program for PoCT which involved more than **100 near-patient** and PoCT sites from **eight countries** in Africa, Asia and the Pacific Region.

NRL also provided scholarship support to presenters in key population groups (such as First Nations people) to attend POC25, demonstrating NRL's commitment to quality in infectious disease testing, globally.

Testing Services

Specialised Donor Screening Services

NRL offers a comprehensive range of specialised testing services, including TGA-licensed screening of blood and tissue donors for HAV, HIV, HCV, HBV, HTLV, parvovirus B19 and syphilis on specimens collected from both living and cadaver donors.

Expansion of High-Throughput Screening Capability

Our service expansion to provide donor screening for HAV and parvovirus B19 followed a major collaborative project with **CSL Behring** to add these viruses to the existing screening program performed by Australian **Red Cross Lifeblood (Lifeblood)** of plasma for fractionation. In preparation for the new service, NRL commissioned a new high-throughput pathology GMP licensed screening laboratory which is now receiving and testing over **32,000 samples per week.** This was a complex project with NRL staff working closely alongside CSL Behring, Lifeblood, TGA, the National Blood Authority and Roche Diagnostics. The provision of this service now positions NRL to be part of the critical infrastructure ensuring the safety of Australia's blood and blood product supply.

Reference and Authorised Prescriber Testing

In addition to donor screening, NRL Testing serves as a reference laboratory for complex HIV and HTLV specimens that cannot be resolved through routine screening by other diagnostic laboratories. These cases are managed using validated and specialised testing algorithms.

Another key service includes TGA-licenced testing of specimens under the Authorised Prescriber Scheme, particularly in cases where IVDs are not validated for alternative specimen types. This enables the use of specific serological and molecular IVDs with otherwise unvalidated specimens, such as cord blood samples.

Contract, Research and Quality Assurance Testing

NRL Testing provides contract testing in collaboration with external organisations for a range of scientific and research projects. These services include, but not limited to:

- **Specialised testing services**
- **Validation of specialised testing algorithms**
- **Clinical trial testing support**
- **Stability studies (both accelerated and long-term)**
- **Prevalence studies testing support**
- **BioSpec testing support**
- **EQAS testing support**

Point of Care IVD Batch-Release Testing

Furthermore, NRL Testing conducts batch-release testing of HIV and syphilis for designated point of care testing sites, ensuring that new batches of IVDs perform consistently and reliably before release for use.

Major Milestone
2NAT Program

The 2024-2025 year saw a significant milestone achieved by the NRL Testing Services team, with the commencement of a **blood screening service for hepatitis A virus and human parvovirus B19** at a newly commissioned site in Melbourne suburb of Notting Hill in Victoria. This service (known as the 2NAT Program) is performed on blood samples received from **Australian Red Cross Lifeblood** on behalf of **CSL Behring** who offer plasma-derived therapies to treat rare and serious conditions as well as support transplantation and critical care.

This large project commenced testing activities in April 2025 following an extended period of planning and commissioning activities led by Shannon Curley and Tamara McDonald, that included all facility, equipment and process validation activities required to obtain a TGA license for this screening program.

Since going live, the team at Notting Hill led by Tony Field and Alice Chynoweth have worked closely with staff at NRL Fitzroy to expertly oversee the testing of approximately **150,000 samples each month**, with plans to further streamline this process. The successful execution of this activity represents a significant step forward towards expanding the scientific services offered by NRL/SVI to the Australian community.

Stakeholders

CSL Behring
Australian Red Cross Lifeblood
NATIONAL BLOOD AUTHORITY AUSTRALIA
Roche
Australian Government
Department of Health
Therapeutic Goods Administration

Highlights

1. Go live of our new 2NAT blood donor screening program in early April

2. Clinical trial testing support for SVHM

Provision of testing support for identifying potential tissue donors in compliance with regulatory requirements and medical evaluations. In this study, donors selected to undergo liposuction for the collection of human adipose tissue are screened for blood-borne infectious diseases. The harvested tissue is used for the isolation and expansion of adipose-derived mesenchymal stem cells (MSCs), intended for allogeneic applications in research, clinical development, and potentially commercial use.

2. Development of the 4th WHO International Standard for HBsAg

Currently contributing testing support to the World Health Organization (WHO) international collaborative study aimed at establishing the 4th WHO International Standard for hepatitis B surface antigen (HBsAg).

3. Implementation of NewBio TPHA Syphilis Assay

Completion of the evaluation of the NewBio TPHA Syphilis assay, which will be implemented as a replacement to Serodia TPPA assay for syphilis confirmation.

4. Clinical Validation of the Roche cobas HPV Test on the cobas 6800 System for Cervical Screening and Qualification as a second-generation comparator test

NRL Testing contributed to the MaRVE study by providing testing support to evaluate the performance of the cobas HPV test on the Roche cobas 6800 system. To assess inter-laboratory reproducibility, 550 cervical samples were tested at NRL using the cobas 6800 platform. Published Paper: Journal of Virological Methods Volume 335, June 2025, 115145

5. Change of supervising pathologist at NRL

Dr Amy Crowe, Director of Microbiology, and Dr Victoria Madigan, Clinical Microbiologist, at the St. Vincent's Hospital, Melbourne (SVHM) have been appointed as Honorary Consultants at NRL, responsible for providing oversight of pathology services, supervision, and clinical governance for testing services.

Research & Devlopment

HTLV-1 Proviral Load Assay Accreditation

In February 2025, the NRL **HTLV Proviral Load (PVL) assay** was formally added to our NATA scope of accreditation under **ISO 15189** as a **Class 3 in-house assay.** This assay assesses how many cells in an infected individual carry HTLV-1 virus (the proviral load) with the result being used by clinicians, and ultimately, patients to manage the significant risk of mother-to-child transmission of this virus through breast feeding. Of note, this NRL assay has also been used in the large (1200 participant) **National HTLV-1 Longitudinal Study** led by the **Kirby and Baker Institutes** which aims to more clearly define the prevalence and disease-association of HTLV-1 over time in Aboriginal people living in Central Australia.

Strengthening National HTLV-1 Diagnostic Capability

This marks a significant milestone for NRL, providing a fully accredited assay to quantify HTLV-1 PVL and providing this as service to HTLV-1 patients. The availability of this assay strengthens NRL's diagnostic capabilities and supports the implementation of the Australian HTLV-1 Clinical Guidelines for use in Primary care in Central Australia.

Improving HTLV-1 Testing in Remote Communities

The Australian Centre for HIV and Hepatitis Virology Research **(ACH4)** grant was awarded for the 2024–2025 period to support investigations towards improving the diagnosis and monitoring of HTLV-1 in Australia. NRL acknowledges and thanks the Australian Government Department of Health, Disability and Ageing as the source of these funds.

In this study, three fingerstick blood collection devices were assessed to identify an easy, minimally invasive, and stable way of collecting blood for HTLV testing from patients living in remote settings like Central Australian Aboriginal communities. One device was **successfully identified** as providing suitable material for both serology and molecular testing at a cost-effective price **($1 AUD per device)** and it is hoped they can be used to dramatically improve diagnostic turnaround times as well as rates of confirmed diagnosis when used with NRL tests.

Leadership and Collaboration in HTLV-1 Research

This and other work were presented at the **Third NACCHO HTLV-1 Workshop** held on 4 June 2025 in Alice Springs by Dr Nick Vandegraaff, Executive Manager - Clinical & Research Services: who outlined the current hurdles and key developments towards improving HTLV testing outcomes in Australia. His talk covered aspects of assay innovation, improved test accessibility, and the creation of reference materials and quality assurance programs to help address both National and global gaps in testing capability and services. Nick also reflected the extensive work NRL staff are delivering as part of the International Retrovirology Association **(IRVA)** Testing Working Party of which NRL Director, Dr Philippa Hetzel is co-chair. It was a privilege to share the progress we've made in this critical area, with further exciting developments currently underway at NRL.

Development of Novel HTLV Molecular Assays

Dr Melissa John, NRL R&D Senior Scientist presented at the **ACH4 2025 Conference** in Sydney where she showcased NRL's new molecular HTLV test currently in development, which distinguishes the HTLV-1 subtype C, endemic in Central Australian Aboriginal communities, from other HTLV-1 subtypes and from the HTLV-2 virus found elsewhere in the world. This test is being developed for use with fingerstick devices that allow easy sample collection in remote areas, and it is hoped that this assay will further improve rates of confirmed diagnosis of HTLV, as well as provide important surveillance information regarding the incidence of endemic virus versus virus introduced into Australia via migration and/or returned travellers.

Expanding Quality Assurance for Point-of-Care Testing

The R&D team continues to support NRL PoCT QA through the development of new swab samples for a growing number of infectious pathogens. Once validated, these products will be incorporated into BAU activities via the NRL RapidQ, EQAS and QC Services catalogues, expanding the range of quality assurance materials available to laboratories and remote testing sites. The development work enables efforts to improve the quality of diagnostic testing to at-risk populations such as First Nation communities in Australia's regional and remote areas.

Supporting PoCT Product Development

As part of NRL's support of point-of-care testing (PoCT) manufacturers by assisting with the design and optimisation of their diagnostic products, the R&D team evaluated numerous hepatitis B virus PoCT prototype devices on behalf of an international client to determine the most suitable example to advance through the formal product development pipeline.

Highlights

- **ISO 15189 accreditation achieved** for NRL HTLV-1 PVL Class 3 in-house assay
- **Clinical impact:** supports management of mother-to-child HTLV-1 transmission risk
- **Used in national study** of 1,200 participants in Central Australia
- **ACH4-funded innovation:** $1 fingerstick device identified for remote HTLV testing
- **New molecular HTLV assay** in development to distinguish subtype C and HTLV-2
- **National & global leadership** through support of and contributions to NACCHO, ACH4, WHO and IRVA
- **Expanded PoCT QA** materials to support high-quality testing in remote communities
- **PoCT device evaluation** for hepatitis B to support diagnostic innovation

Consulting & Training

NRL's experience and activities in supporting sustainable capacity building across the Western Pacific **(WPRO)** and Southeast Asian **(SEARO)** regions makes a critical contribution to regional health security. Our approach is collaborative and customised to the needs of each laboratory and country. We invest in the transfer of knowledge which enables independence and the will to continuously improve the quality of testing for infectious diseases.

WHO Projects

NRL continued its support for WHO and Ministries of Health across the WPRO and SEARO regions by undertaking several projects funded through WHO regional and country offices.

India

NRL completed delivery of a customised training program in November 2024, delivered in three phases and supported by WHO SEARO. Originally starting in May 2023, the program comprised of virtual training workshops **(Phase 1)**, a practical in-country training workshop **(Phase 2)** and virtual mentoring sessions which provided technical support during EQAS implementation **(Phase 3).**
NRL developed and delivered the capacity building program to train and mentor **seventeen selected institutes** under the Indian Council of Medical Research **(ICMR)**, to become providers of serology and molecular biology External Quality Assurance Schemes (EQAS). The purpose of the program was to support ICMR and its selected institutes to design and produce their first EQAS panel, by improving their knowledge and understanding of:

- **The production of EQAS panels from sourcing plasma and storage, through production, validation and packing to dispatch**
- **Analysis of EQAS participant results and troubleshooting**
- **Preparation and issue of preliminary (interim) reports, followed by final reporting.**

The NRL, ICMR and WHO partnership was instrumental in supporting sustainable, high-quality diagnostic testing nationwide, by building local expertise and equipping participating institutes with the skills to implement their own EQAS programs.

Malaysia

In November 2024, NRL provided training on the production and delivery of syphilis serology External Quality Assessment Schemes (EQAS) to a staff member from the National Public Health Laboratory **(NPHL)** in Malaysia. Held on-site at NRL and supported by the WHO Malaysia Country Office, the purpose of the training was for the NPHL staff member to on-share the new knowledge with the Bacteriology Department at NPHL and facilitate the implementation of improvements to their existing EQAS.

Sri Lanka

In 2023, NRL commenced the provision of capacity building support for the National Blood Transfusion Service **(NBTS)** in Sri Lanka, to expand its current production of National External Quality Assessment Schemes.

With support from the WHO SEARO the first phase of the program involved an onsite capacity assessment of NBTS' existing EQAS program.

NRL commenced the second phase of the program, the delivery of theory and practical training and mentoring to support a pilot EQAS, in the second half of 2024. The virtual theory training covered all EQAS production activities, from the sourcing of samples to issuing the final report to participants. The practical training element of the program is currently in progress, with NRL supporting NBTS with the practical aspects of producing a pilot EQAS.

Philippines

In January 2025, with support from the WHO Country Office in the Philippines, NRL provided training to the Research Institute for Tropical Medicine **(RITM)** on the theoretical fundamentals of EQAS. The purpose of the training was to support RITM in the development of a plan to implement their new EQAS in 2025.

Overall, the workshop met its objectives as confirmed by the measurable results from both a training knowledge quiz and a training evaluation and saw excellent engagement from participants.

Global Fund Project in the Democratic Republic of Congo

From 2024 to 2025, NRL supported the Global Fund and the Democratic Republic of Congo **(DRC)** to **Fight AIDS, Tuberculosis and Malaria.** Evaluations of the performance of HIV rapid test kits used in the country were conducted by sampling test kits at certain geographical sites along the supply chain; and assessments ensuring expected results were conducted on those test kits at a central laboratory, using a standard set of positive and negative samples. As a WHO Prequalification Evaluation Laboratory that is accredited to a range of international quality standards, and licensed to the Code of Good Manufacturing Practice, NRL is ideally suited to provide this service.

In addition to the above, NRL also supported **Global Fund** with a virtual assessment of the National Reference Laboratory for AIDS & STIs in DRC's **(LNRS)** capacity to expand its current production of EQA and proficiency testing programs that are provided to laboratories in surrounding regions within the DRC. A proof-of-concept protocol was developed to identify the best sample type and delivery method required to provide quality assurance samples for use in Malaria Lateral Flow Rapid Diagnostic Tests and verification of LNRS' HIV serology dried tube sample protocol was also conducted.

AIHSP

In late 2023, NRL had commenced a capacity strengthening project in Indonesia through the Department of Foreign Affairs and Trade **(DFAT)** funded Australia Indonesia Health Security Partnership **(AIHSP).** The project was focused on laboratories from five Provinces, selected from the three lower primary healthcare Tiers 1 to 3 which traditionally receive little if any international support. The objective was to support and strengthen the public health system at the primary healthcare level and improve the quality of laboratory-based disease surveillance in Indonesia.

More than **50 participants** from the laboratories (70% female and 30% male, reflecting the gender distribution of the Indonesian health sector workforce) attended the training program which ran over **10 months.** During this time several activities were conducted including: three capacity assessment visits, three training workshops and 15 mentoring sessions.

The project concluded in November 2024 with a successful on-site assessment of the effectiveness of the training program, conducted across two provinces at each of six selected laboratories representing the three tiers.

"NRL delivers collaborative, tailored capacity building that strengthens laboratory independence and regional health security across WPRO and SEARO."

SVI Biobank

Introduction

The SVI Biobank is managed by and housed at NRL's primary laboratory facility. Founded in 2015, Biobank has maintained its consistent growth, with **2 new studies** recruited over the **past 12 months**. Further details of some of these projects can be found below. Approximately **70%** of the studies Biobank supports are based on the SVHM campus in collaboration with several departments, but we also assist with sample processing and storage for multi-site clinical trials, and provide a sample storage-only service.

New study: Dermatological Autoimmune Diseases

Biobank has skin in the game! In early 2025, we commenced a collaboration with the SVHM Department of Dermatology. In fortnightly clinics patients with autoimmune diseases of the skin are seen, and these individuals are asked if they would also like to participate in Biobank. To date we have **18 participants** who have provided around **100 samples** and are continuing to grow this interesting cohort.

New study: International Diabetes Clinical trial

The **T1D-PLUS study** is a clinical trial in adults with newly diagnosed Type-1 Diabetes. Globally, it is run by the **INNODIA** group. In Australia, St Vincent's Institute are the local sponsor. The T1D-Plus trial is designed to screen combination therapies for potential benefits to participants, with the aim of protecting the insulin-producing beta cells which are destroyed in Diabetes. The study will be undertaken at **40 sites globally,** and up to **10 in Australia.** For Australian sites, Biobank commenced provision of services for processing, storage, distribution, and management of samples in April 2025.

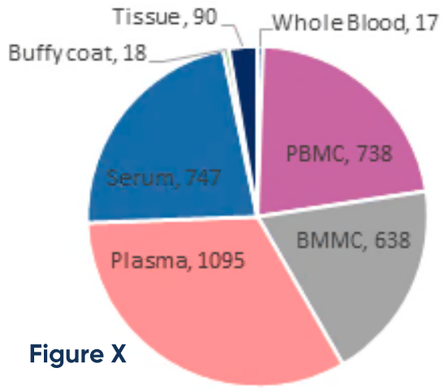
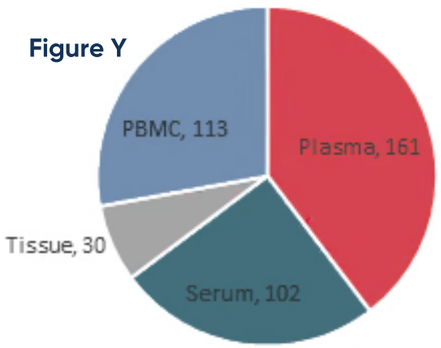


Figure X

Samples Stored

In the past year, **146** new participants were recruited to the Biobank. Taking into account repeat visits from previously registered participants, Biobank acquired a total of **329 participant samples** over the year. From these, a total of **8,254 vials** of biological specimens were stored, consisting of the biospecimen types shown in Figure X.

Figure Y



Samples Retrieved

Over the same period, a record annual total of **408 vials** of specimens from multiple different Biobank studies were retrieved from the Biobank and sent for use in scientific research projects. An overview of these sample types is shown in Figure Y

ACMD

The **Aikenhead Centre for Medical Discovery** is new purpose-built facility, just next door to Biobank. Researchers are currently moving into to the building, and the SVI Biobank will be responsible for providing Biobanking services onsite. To this end, we delivered a presentation to interested parties in mid-2024, see https://www.acmd.org.au/events/acmd-link-biobanking for a recording. We have also obtained a liquid nitrogen tank for use onsite at the ACMD and will be moving it into the centre over the course of 2026.

Quality focus

Along with the rest of NRL, Biobank maintains a strong quality focus and over the last 12 months, we have finalised our preparations to attain **NATA accreditation** to the quality standard for Biobanking - **ISO 20387.** Towards this goal, NATA auditors conducted an initial assessment in June 2025. Their report highlighted some areas, and Biobank is in the process of addressing these improvement opportunities. We hope to receive accreditation in September 2025, which would make us just the **second Biobank in Australasia to achieve this milestone.**

We participate in a proficiency testing program run by the ImmunoVirology Research Network **(IVRN)** up to three times a year and are certified as competent in PBMC processing by this group.

Biobank Networks

Biobank maintains strong networks and interactions with other Biobankers both within Australia, and globally. We are members of the Melbourne Academic Centre for Health **(MACH)** biobank registry, the Australasian Biobank Network Association **(ABNA),** and the International Society for Biological and Environmental Repositories **(ISBER).**

Our Impact

- Over the past year, Biobank has contributed to an **MRFF research grant** application, bringing together the clinicians who are involved in participant recruitment and sample collection, and the researchers who use the samples in their study programs.
- At Biobank we are always thrilled to see samples used for innovative ground-breaking projects. The samples in Biobank have supported a funding application to MRFF Genomics Health Futures on a project in **Breast Cancer.**
- Previous research work done using Biobank samples has led to the following publication in the last year: ***Preservation of functionality, immunophenotype, and recovery of HIV RNA from PBMCs cryopreserved for more than 20 years.***

"Our evaluations combine scientific rigour with real-world relevance, ensuring IVD performance is assessed using evidence and samples representative of local populations."

Highlights

- Laboratory Performance Evaluations of **SARS-CoV-2 Rapid Antigen Tests (RAT's**) kits for WHO Prequalification
- Protocol development for sampling and batch testing of **HIV Rapid Diagnostic Test Kits (RDT)** and the manufacture of **HIV Batch testing panels** for **Global Fund** in the Democratic Republic of Congo
- Dossier assessments conducted for **WHO** and **TGA**
- Ongoing advice provided for **WHO Prequalifications** in developing and updating existing evaluation protocols.

Evaluations

NRL specialises in assessing the analytical and clinical performance of *in vitro* diagnostic devices **(IVDs)** that detect infectious diseases to ensure they meet their stated intended use and conform to key performance, quality and safety criteria. A well-designed, laboratory-based assessment of IVD performance can provide a realistic expectation of how the IVD will perform relevant to local conditions using samples representative of the local population.

We are **one of 14 Performance Evaluating Laboratories (PEL)** designated by WHO for conducting performance evaluation for one or several types of IVDs. WHO Pre-qualification aims to ensure IVDs for supply to low-income countries are quality-assured, safe, effective and accessible. NRL also conducts IVD evaluations on behalf of other regulatory bodies, IVD manufacturers, and non-government agencies.

NRL Evaluations conduct assessments of IVD's by reviewing manufacturers evidence to ensure the key performance, quality and safety criteria are met and the evidence presented is scientifically sound.

What We Do

1 of 14
WHO-designated Performance Evaluating Laboratories (PEL) globally

WHO Prequalification evaluations conducted across multiple IVD categories

Regulatory support for WHO, TGA, manufacturers and NGOs

Independent, evidence-based assessments of manufacturer data and dossiers

The 40th Annual NRL Workshop on Infectious Disease Testing

NRL's 40th Annual Workshop on Infectious Disease Testing delivered three days packed with scientific insights, innovation, and strong collaboration across laboratory medicine and public health. **Celebrating four decades of leadership in diagnostics**, this milestone event brought together medical scientists, clinicians, public health experts, and industry partners from across the region.

Day One opened with a Welcome to Country and reflections from NRL Director Dr Philippa Hetzel on NRL's enduring role in strengthening diagnostic capacity. The agenda kicked off to a strong start with HIV and HTLV advances, WHO elimination goals, and evaluation of emerging assays. Rapid molecular testing took centre stage, highlighting new point-of-care solutions and self-testing for hepatitis C and syphilis. The day concluded with impactful talks on hepatitis epidemiology, antenatal HBV testing from Vanuatu, and practical quality control strategies.

Day Two spanned microbiology, virology, and One Health with presenters exploring GI syndromic panels, parasitology expertise, fungal biomarkers, and enhanced national response to Japanese encephalitis virus. A biospecimen repository update showcased NRL BioSpec's growing capability. Syphilis and sexual health sessions spotlighted improved pathways for the investigation of congenital syphilis, multiplex PCR solutions, and streamlined STI diagnostics.

The final day shifted to quality and preparedness. A proficiency testing panel challenged laboratories to drive performance improvement. Experts shared lessons on rapid PCR in emergency care, cervical screening in the Pacific, and readiness for emerging threats. Automation, artificial intelligence, and respiratory diagnostics rounded out the program with a forward-looking lens.

Delegates enjoyed valuable opportunities to connect with peers and industry partners throughout the Workshop. NRL proudly acknowledges **DiaSorin (Platinum Sponsor)** and **Roche** and **Abbott (Gold Sponsors)** for their continued support and contribution to the success of this event.

This **40th anniversary** event showcased what collaboration in infectious disease testing can achieve. Thank you to every presenter, attendee, and partner for contributing to a standout year. We look forward to seeing you at future NRL events.

94%

RATED THE PROGRAM AS "EXCELLENT" OR "VERY GOOD"

91%

RATED PRESENTATION QUALITY & RELEVANCE AS "EXCELLENT" OR "VERY GOOD"

203

2024 ATTENDEES

*"**Brilliant event** that offers both **relevant scientific updates** and **networking** with peers in the infectious diseases laboratory and diagnostic community."*

*"...**Great venue, great food, excellent quality** of presentations and **great attendance**."*

Celebrating 40 Years of Innovation

MAJOR ORGINISATIONS ATTENDEED

Australian Red Cross Lifeblood · Sullivan Nicolaides Pathology · VIDRL · Melbourne Pathology · Austin Health | Pathology

KEY SPONSORS

Diasorin The Diagnostic Specialist · Roche · Abbott · Cepheid A better way. · AusDiagnostics · Hologic The Science of Sure · QIAGEN · Genetic Signatures

"Key peer-reviewed publications demonstrating our expertise in immunology, long-term sample preservation, and infectious disease quality control."

Publications

1 Preservation of functionality, immunophenotype, and recovery of HIV RNA from PBMCs cryopreserved for more than 20 years - PubMed - Dyer et al, Frontiers in Immunology, Aug 2024. Preservation of functionality, immunophenotype, and recovery of HIV RNA from PBMCs cryopreserved for more than 20 years. DOI 10.3389/fimmu.2024.1382711

2 Published Paper: Journal of Virological Methods Volume 335, June 2025, 115145

3 Cost-benefit analysis of two quality control approaches for infectious disease testing - Pathology - Publication detailed a cost-benefit analysis of different QC practices used in an Australian laboratory has estimated the true cost of inappropriate QC system practices.

4 Evidence-based assessment of the application of Six Sigma to infectious disease serology quality control - PubMed - Publication conducted an evidence-based assessment of recent publications trying to incorporate six-sigma metrics methods into infectious disease testing settings.

5 https://westgard.com/interviews/interview-dimech-vincini.html - "Where traditional rules cannot tread: an interview with NRL scientists about Serology Testing QC"

6 Dyer et al, Frontiers in Immunology, Aug 2024. Preservation of functionality, immunophenotype, and recovery of HIV RNA from PBMCs cryopreserved for more than 20 years. DOI 10.3389/fimmu.2024.1382711

OUR GLOBAL REACH

WE ACKNOWLEDGE AND THANK OUR STAKEHOLDERS

Abacus Dx
Abbott Diagnostics
ACH4 – Australian Centre for HIV, HTLV and Hepatitis Virology Research
ACMD – Aikenhead Centre for Medical Discovery
African Society for Laboratory Medicine (ASLM)
Alice Springs Hospital
American Society for Clinical Pathology (ASCP)
American Society for Microbiology (ASM)
Asian Association of Transfusion Medicine (AATM)
Association of Public Health Laboratories (APHL)
Australian Global Health Alliance

Australian Government Department of Health and Ageing
Australian Indonesia Health Security Partnership (AIHSP)
Australian Institute for Medical and Clinical Scientists
Australian Network of WHO Collaborating Centres
Australian Red Cross Lifeblood
Australian WHO Collaborating Centre Network
Austin Health
Baker Institute
Becton Dickinson (BD)
Bio-Rad Laboratories Pty Ltd
Biomerieux

Blood and Tissue Donation Services
Burnet Institute
Bureau of Medical Laboratory Services (BMLS), Ministry of Health, Cambodia
Business Events Adelaide
Central Public Health Laboratory (CPHL), Papua New Guinea
Cepheid
Clinical Diagnostics division of LGC
Cordaid International
CSIRO
CSL Behring Australia
DT Global
Department of Health and Human Services, Victoria
DiaMex GmbH

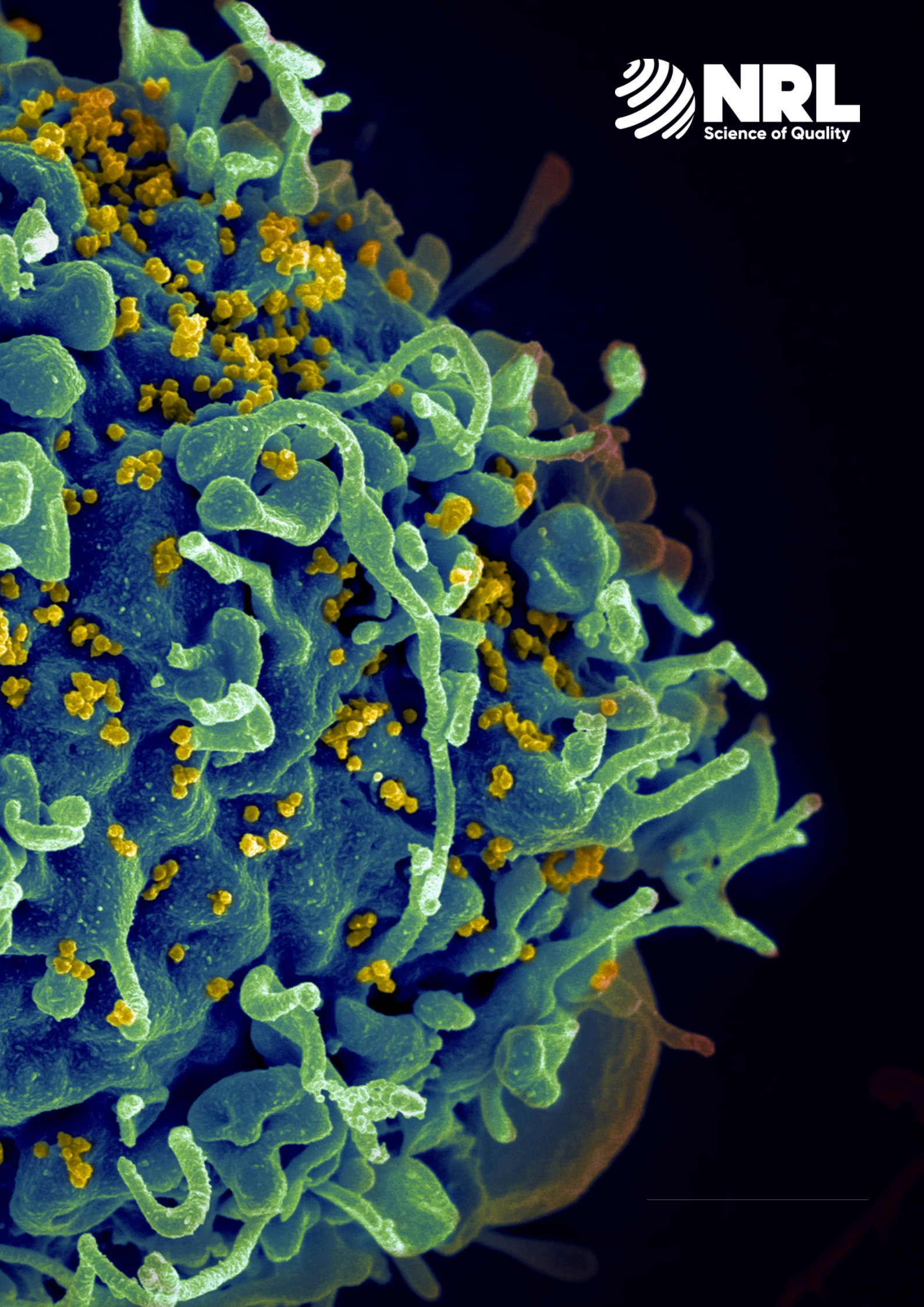
DiaSorin Australia Pty Ltd
Diagnostic Technology
Fleming Fund
Flinders University International Centre for Point-of-Care Testing
Foundation for Innovative New Diagnostics
Genetic Signatures
Global Fund
Hologic
ICAP at Columbia University
Immuno-Virology Research Network (IVRN)
Indian Council of Medical Research
Indo-Pacific Centre for Health Security

Indonesia One Health University Network (INDOHUN)
Infectious diseases testing laboratories
Integrated Quality Laboratory Services (IQLS)
Integrated Sciences
Institutions providing samples for NRL programs
International Plasma and Fractionation Association
International Retrovirology Association (IRVA)
Irish Blood Transfusion Service
IVD Manufacturers
Kirby Institute
LGC
Melbourne University

MNX Global Logistics
MP Biomedicals Australasia Pty Ltd
NACCHO – National Aboriginal Controlled Congress of Health Organisations
National Association of Testing Authorities, Australia
National Centre for Laboratory and Epidemiology (NCLE)
National Institute of Biological Standards and Controls (NIBSC)
National Measurement Institute, Australia
National Reference Laboratory/San Lazaro Hospital, Philippines
New South Wales Ministry of Health
New Zealand Blood Service
Oneworld Accuracy, Canada
Ortho-Clinical Diagnostics

Pathology Technology Australia
Peter Doherty Institute for Infection and Immunity
PNG Australia Transition To Health (PATH)
PRONTO!
QIAGEN
Roche Diagnostics Australia
Royal College of Pathologists of Australasia (RCPA)
Royal Darwin Hospital
SANRU ASBL
Siemens Healthineers
SoGAT
South African National Blood Service
SpeeDx
St Vincent's Hospital Melbourne
St Vincent's Hospital Sydney

Southern Cross Diagnostics Pty Ltd
Sysmex
Thai Red Cross Society
The Mérieux Foundation (FM)
Therapeutic Goods Administration
US Centres for Disease Control and Prevention
VCS Pathology Services, Cervical Cancer Prevention Australia
Victorian Infectious Diseases Reference Laboratory (VIDRL)
Vircell
WHO Collaborating Centres
World Health Organization Headquarters and Regional Offices
World Health Organization Member States
Yayasan KNCV Indonesia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Science of Quality