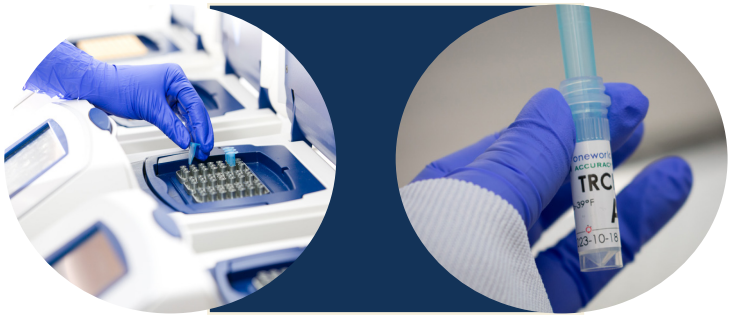
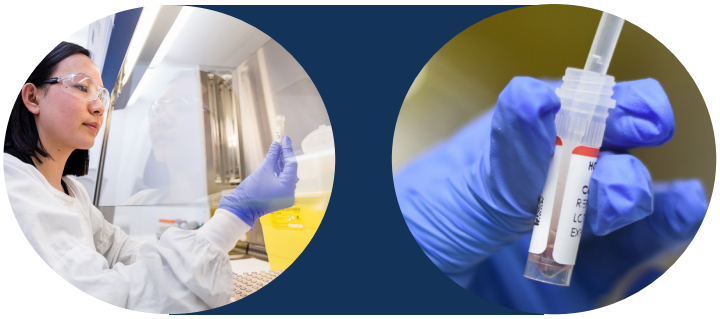
NRL YEAR

2022-2023





ANNUAL REPORT

NRL
Science of Quality

ABOUT US

Every day around the world, millions of people are tested for infectious diseases – including influenza, Hepatitis, HIV and COVID-19.

Keeping us all safe and connected relies on the accuracy of this testing.

NRL is a global leader in the science of quality for infectious disease testing. We support laboratories in more than 70 countries to ensure that their results are accurate, consistent and reliable.

From a new laboratory in London, to a point-of-care test in Mongolia, from a blood bank in Manila to a public laboratory in Melbourne – NRL's mission is to create healthy communities across the globe, through supporting **accurate, high-quality infectious disease testing.**

CONTENTS

DIRECTORS REPORT

As the 2022 year progressed and the COVID-19 pandemic waned, we welcomed a slow return to normality enabling staff travel including to support capacity building projects, international customers and conferences. **The South-East Asian Laboratory Strengthening (SEALAB) Project** in Cambodia and Laos, undertaken in collaboration with The Mérieux Foundation and Integrated Quality Laboratory Services, had largely been undertaken virtually until this point. The ability to visit in-person gave us a far deeper understanding and appreciation of the unique contexts within which each of the laboratories operate and enabled the further customisation of training and mentoring to suit the individual needs of each laboratory.

The SEALAB Project concluded in early 2023 and the improvements and knowledge gained as a result of the initiative were highly commendable.

While COVID-19 ifections dropped, the importance of accurate testing for **SARS-CoV-2** did not diminish. Our collaboration with the **Doherty Institute** to conduct post-market sensitivity evaluations on COVID-19 Rapid Antigen Test kits being used in Australia on behalf of the **Therapeutic Goods Administration (TGA)** was recognition of this fact. All of this work was conducted at NRL using our quality management systems and facilities with NRL, Doherty and TGA staff in attendance.

Dr Philippa Hetzel

Similarly, the project commissioned in 2022 by the **Foundation for Innovative and New Diagnostics (FIND)** to deliver quality assurance programs for COVID-19 Rapid Antigen Tests in a community setting in 10 countries across Africa, Pacific Islands and South-East Asia, identified that some countries had purchased test kits that were not fit for use. This has led to a review of selection processes by those Ministries of Health. NRL's quality assurance programs for POCT in a community setting are now being transitioned into routine services and made available across more analytes and in more countries.

In recognition of NRL's continued support for **WHO** and countries across the Western Pacific and South-East Asian regions, NRL was re-designated in November 2022 for another 4 years as a WHO Collaborating Centre for Diagnostics & Laboratory Support for HIV/AIDS and other blood-borne infections. Our role in global health reports into Geneva, and includes our designation as a Pre-Qualification Evaluation Laboratory. However, we also provide extensive expertise and support across all WHO regions. As part of St. Vincent's Institute's new Strategic Plan 2023-25, an External Review of NRL was undertaken which highlighted NRL as a **Centre of Scientific Excellence** generating significant social value. Our capabilities and range of service offerings are quite unique globally, and we continue to collaborate and partner with a broad range of stakeholders.

In 2023, we executed a Memorandum of Understanding with **Asian Association of Transfusion Medicine (AATM)** and were delighted to be granted an **Excellence Award** for 2023 in recognition of our 'highly valuable work for blood safety in various countries across the globe and significant assistance in initiating a number of training, quality, research and development programs for AATM member countries.'

Our Research and Development Team continued to support a series of collaborative projects including the **HTLV-I Longitudinal Study** led by the **Baker Institute.** NRL staff provided support to the National Aboriginal Controlled Congress of Health Services program of work to improve the health response to HTLV-1 in central Australia. We contributed globally by helping to establish an international Testing Working Group on behalf of the **International Retrovirology Association,** to provide expertise and support for countries developing their own molecular test methods - as there is no commercial test available.

We were delighted that **Dr Wayne Dimech** was conferred with his Doctor of Philosophy (PhD) from Flinders University in April titled "The Standardisation and Control of Infectious Disease Testing". The thesis was developed by prior publication in peer reviewed journals and is well deserved recognition for his thought leadership and pioneering concepts in quality control.

Finally, I would like to acknowledge the scientific excellence, commitment and resilience demonstrated by NRL staff throughout the year and thank them.

Our work throughout 2022-23 highlights the many successes and contributions we have made.

As demonstrated in this report, NRL is a global leader in the science of testing for infectious diseases and we strive to ensure the highest standards in every aspect of our work.

> ***Thank you to our funders, supporters, collaborators, partners and customers. We sincerely appreciate the support we've received from you all!***

QUALITY CONTROL

Significant change is on the horizon in the serology QC world

Laboratories from around the world participate in NRL's QC program - **QConnect** – to support their ongoing quality of laboratory testing processes. This year was a breakout year in quality control for infectious disease testing serology, with a global acknowledgement that better understanding of the implications of applying traditional QC methods (as used in the clinical chemistry laboratory) to infectious diseases testing, where testing is typically qualitative in nature.

NRL QC Services was invited to contribute to the UK Standard Microbiology Investigations document UK SMI Q2 **"Quality assurance in the diagnostic infection sciences laboratory"**, which has resulted in movement away from its mandatory requirement for all UK laboratories to always use traditional QC methods available to UK laboratories. This was a significant step towards helping laboratories apply evidence-based science and to support the development of their own best quality practices. EDCNet and QConnect continue to be an Australian success story as they have been implemented extensively in laboratories across the United Kingdom.

> ***The NRL QConnect approach is the only scientifically validated way to monitor infectious disease testing QC results.***

IMPACT

In 2022, NRL staff collaborated with key opinion leaders in Europe and the USA to release an important publication on the need to separate and distinguish QC usage in infectious diseases serology testing from the traditional methods for QC used in clinical chemistry and the core laboratories that are becoming the 'new norm' for global laboratory setup and resource rationalisation. The paper highlights the key features distinguishing serology testing and explains why there is a need for scientists, managers and laboratorians to better understand the reasons for a different approach to QC in the serology laboratory and how to approach it.

The QC Services team, in particular, **Dr Wayne Dimech** and **Joe Vincini,** have continued to demonstrate thought leadership throughout 2022/23 by expanding the movement towards **"Meaningful QC."** Including a letter to the Clinical Chemistry and Laboratory Medicine editor, which was sent to address the significant complexity in the nature of testing when using multimarker QC samples for an assay that detects multiple analytes.

HIGHLIGHTS

In 2022/23, NRL introduced a range of changes and new products to support our customers:

Expansion of the suite of molecular Optitrol™ QC samples first launched in 2021 such as Optitrol NAT HIV2, Optitrol NAT CTNG and Optitrol NAT CMV – all following the **QConnect concept.**

The NRL catlogue of products continued to expand, due to a complex program of development work underway with our manufacturer **DiaMex GmbH** (Heidelberg, Germany).

Better collaboration between NRL, DiaMex and our international QC distribution partners.

More than 400,000 data points entered across 200+ labs in 25+ countries

In 2022, we saw the logistics and supply problems of 2021 start to improve, with good supply chain performance overall. Better planning and forecasting helped in overall service improvement.

EXTERNAL QUALITY ASSESSMENT SCHEMES

Proficiency programs designed to assess the integrity of tests and testing processes.

NRL External Quality Assessment Schemes (EQAS) are designed to assess the integrity of the entire laboratory testing process for infectious disease markers from sample receipt through to reporting of patient test results. The design and analysis of NRL's EQAS draws upon NRL's extensive experience and scientific methods to ensure maximum scope for error detection.

NRL EQAS proficiency panels consist of a combination of positive and negative samples representative of those typically received by a testing laboratory. NRL analyses and reports participants' results online via OASYS - an internet-based application owned and managed by our partner **Oneworld Accuracy** (Vancouver, Canada).

NRL is a fully accredited **ISO 17043** provider and our EQAS features include:

SYNDROMIC PANELS
Provide programs including a range of analytes associated with a clinical syndrome.

MULTI ANALYTE PROGRAMS
NRL's 3 clinical serology programs (HEPM, RVSS and TORCH) cover over 28 different analytes.

EASY MANAGEMENT
NRL EQAS streamlined all molecular frozen pro-grams in the same time frames (3 Test Events), and all serology and Point-of-Care programs in the same time frames (3 Test Events) as well.

COST EFFECTIVE
Syndromic and multi-analyte programs save the costs of programs, reagents and time.

INFORMATICS
NRL EQAS has person-alised comments, graphical results and an international peer group, driven by OASYS.

SCIENTIFIC EXCELLENCE
NRL only uses only true and undiluted patient samples for serology pro-grams. All NRL EQAS samples have known reference results with full algorithm.

1ST
TEST EVENT 2023
1491
Panels Sent

2ND
TEST EVENT 2023
1566
Panels Sent
(Serology Only)

3RD
TEST EVENT 2023
837
Panels Sent
(Serology Only)

HIGHLIGHTS

Expanded the Respiratory Molecular offering and launched two new programs for 2023: Extended Viral Respiratory Molecular Program (RESV435) and Bacterial Plus Respiratory Molecular Program (RESB435).

These three programs cover most analytes for respiratory molecular testing.

Re-introduced CMV Molecular Program (CMVN435) in 2023. The program is designed for laboratories which perform viral load and/or qualitative CMV molecular testing on plasma samples.

Developed our own SARS-CoV-2 Antibodies Program (COVS435/432) for 2023 with two panel sizes (2-sample and 5-sample panels).

Detections of genotypes and drug resistant strains are introduced in multiple molecular programs, including Viral Respiratory Molecular Program (RESP435), Sexually-Transmitted Infections Molecular Program (STIC435) and HPV Molecular (HPVN435)

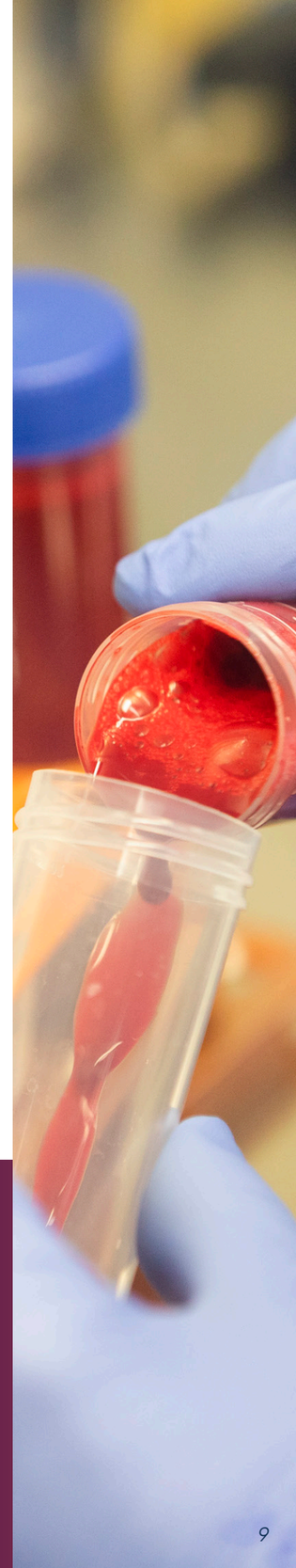
Participation in EQAS is compulsory in many jurisdictions and is vital in assessing the integrity of the entire infectious disease testing process.

> ***NRL is the leader in EQAS programs for infectious disease, with syndromic programs which typically reflect a range of analytes as requested by physicians.***

QUALITY PROGRAMS FOR QUALITY SCIENCE

Delve deeper into the world of NRL, with our EQAS scientists Bernadette Portelli and Kirsten Muscat. This video, 'Quality Programs for Quality Science' highlights the strengths and unqiue offering of NRL EQAS.

Scan QR code for video



EVALUATIONS

Independent assessment of in vitro diagnostic devices (IVDs) and provision of customised validation and verification panels, data analysis and reporting

Pre-market and post-market evaluation of in-vitro diagnostic devices (IVDs) are critical to ensure that new and existing diagnostic products are safe, high quality and fit for use, with patient lives depending on the accuracy of test results.

NRL Evaluations conducts assessments of IVDs that test for infectious diseases ensuring the associated evidence is scientifically robust and key performance, quality and safety criteria are met.

NRL is 1 of 14 World Health Organisation (WHO) designated Prequalification Evaluating Laboratories globally.

The WHO Prequalification of Diagnostics Program aims to increase the accessibility to affordable and high-quality diagnostics technology for use in resource limited settings.

NRL is one of only two laboratories globally that is authorised to perform Prequalification Assessment of IVDs to detect bloodborne infections. NRL also conducts IVD evaluations on behalf of stakeholders such as the Australian Therapeutic Goods Administration (TGA), commercial manufacturers and other regulatory and non-governmental agencies.

In 2022, in collaboration with the **Doherty Institute,** NRL undertook a post-market analytical sensitivity evaluation for **85 SARS-CoV-2 Rapid Antigen Tests (RATs)** on behalf of the TGA.

2023 SERVICES DELIVERED

SARS-COV-2 RAT KITS EVALUATED ON BEHALF OF THE TGA

85

LABORATORY PERFORMANCE EVALUATION OF AN HCV RDT FOR WHO PREQUALIFICATION

1

LABORATORY VERIFICATION OF A SARS-COV-2 RAT KIT FOR AN INTERNATIONAL DOH

1

Estimation of the Limit of Detection for SARS-CoV-2 Rapid Antigen Tests for on behalf of the Therapeutic Goods Administration

All SARS-CoV-2 (COVID-19) laboratory antigen tests and rapid antigen tests (RATs), including point-of-care and self-tests for use in Australia must be included in the Australian **Register of Therapeutic Goods (ARTG).** The TGA oversees the regulation and release of such products pre- and post-market.

Once released to market, manufacturers are expected to undertake ongoing analysis to verify that their tests continue to perform as intended particularly for emerging variants of concern (VOC), identifying any adverse impacts and communicating this to users and regulatory authorities.

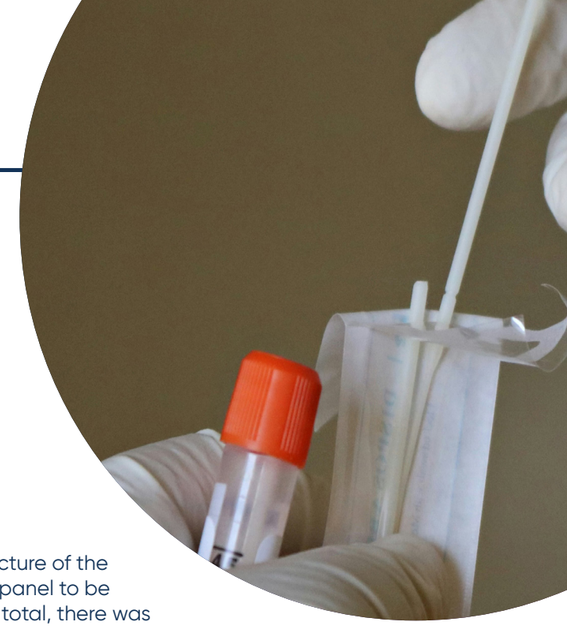
As an additional measure, the TGA commissioned the **Peter Doherty Institute for Infection and Immunity (the Doherty Institute)**, in collaboration with the National (Serology) Reference Laboratory (NRL) to determine if the ARTG listed COVID-19 RAT kits were able to detect the emerging SARS-CoV-2 Delta and Omicron variants.

The primary aim of the evaluation was to verify the manufactures' claims regarding the test kit analytical sensitivity - Limit of Detection (LOD) for SARS-CoV-2 Wild-type, Delta and Omicron variants. The test kits were required to meet the sensitivity recommendations as prescribed by the WHO which was that the LOD be no higher than 1,000 TCID50/mL (tissue culture infectious dose – TCID).

In conjunction with the TGA and the Doherty Institute, NRL developed a standardised protocol to assess the performance of each RAT which included the composition and manufacture of the sample panel to be used. In total, there was an estimate of up to **100 COVID-19 RAT kits** to be assessed. NRL acquired viral stock material of the three SARS-CoV-2 variants from the Doherty Institute and manufactured more than 100 panels that comprised 210 sample members. In addition, NRL produced **100 competency panels** (comprising five and seven sample members) for quality assurance purposes.

> ***NRL is one of only 2 laboratories globally who are authorised to perform pre-qualification assessment of IVDs that detect bloodborne infections.***

The practical laboratory evaluation, led by NRL and held on-site at NRL, included staff from all three stakeholders- NRL, The Doherty Institute and TGA which at any one time involved ten individuals. Testing was conducted on over 80 SARS-CoV-2 RAT kits in a 12-month period and NRL, in conjunction with the Doherty Institute reviewed and analysed all the data generated, providing individual reports to the TGA for each RAT assessed.



In total, **79 RATs** were found to be compliant with TGA's requirements, as they had acceptable product quality (the number of invalid results being less than 5%, appropriate labelling and instructions for testing) and met the requirements for analytical sensitivity (less than 1000 TCID50/mL) for Wild-type, Delta, and Omicron variants. **8 RATs** were unable to be evaluated as they showed reactivity to the panel sample diluent that was used. **6 RATs** were found to be non-compliant and were cancelled from the ARTG, initiated either by the sponsor or the TGA, and are no longer supplied in Australia.

It is evident, given 6 SARS-CoV-2 RATs were non-compliant, that post-market IVD assessment and monitoring, is vital in ensuring public health safety.

TESTING SERVICES

TGA licensed screening of blood and tissue donors, reference testing, and contract testing for projects

NRL Testing offers a range of specialised testing services including **TGA-licensed blood and tissue donor screening** for HIV, HCV, HBV, HTLV and Syphilis for specimens collected from both living and cadaver donors. NRL Testing also operates as a **reference laboratory** for testing HIV and HTLV specimens whose status cannot be resolved via routine screening by other diagnostic laboratories using validated testing algorithms.

NRL's specialised testing services include where IVDs are not validated for alternative specimen types, TGA-licenced testing of specimens for use in certain serology and molecular IVDs under the TGA-Authorised Prescriber. In addition, NRL Testing provides **batch-release testing** of HIV and Syphilis rapid IVDs for Victorian point-of-care testing sites. Batch release testing involves testing of new batches of IVDs to confirm that their performance is consistent from batch to batch.

NRL Testing is also able to provide **contract testing** for scientific projects in collaboration with other organisations for a range of services that include but are not limited to: Validation of testing algorithms, epidemiological studies, stability studies (accelerated and long-term stability) and testing for clinical trials.

HIGHLIGHTS

Professor Deborah Williamson, Director of VIDRL joined NRL as our Supervising Pathologist in March 2022 and in September, Drs Chuan Lim and Eloise Williams were appointed, also from VIDRL.

In 2022, despite staff changes, the Testing team at NRL continued to support services and companies involved in cell and tissue banking for transplantation and cell therapies in Australia. Infection status of the blood product or tissue sample is confirmed via multiple assays (Serology, NAT) prior to release for transfusion, transplantation and cell and tissue banking. NRL is licensed by the TGA under the cGMP to perform this testing.

In collaboration with NRL's Research & Development team, Testing supported the ongoing **HTLV Longitudinal study** led by the **Baker Heart and Diabetes Institute**, to investigate the relationship between HTLV-1 infection and disease among indigenous Australian residents in central Australia as part of a **National Health and Medical Research (NHMRC)** grant.

NRL Testing was also involved in the stability study to determine the stability of SARS-CoV-2 RNA in **Viral Transport Media (VTM)** under real time and accelerated periods of up to 18 months.

> ***We are proud of our reputation as a screening and confirmatory laboratory for infectious disease testing, including services such as reference testing, screening of blood and tissue donors, and contract testing.***

Our Stakeholders

Australian Government Department of Health
Australian Red Cross Lifeblood
Becton Dickinson
Bio-Rad Laboratories Pty Ltd
Burnet Institute
CSL Behring Australia
Department of Health and Human Services, Victoria
IVD Manufacturers
Kirby Institute
MP Biomedicals Australasia Pty Ltd
Peter Doherty Institute for Infection and Immunity
PRONTO!
Roche Diagnostics Australia
DiaSorin Australia Pty Ltd
St Vincent's Hospital Melbourne
Therapeutic Goods Administration
Victorian Infectious Diseases Reference Laboratory (VIDRL)

RESEARCH & DEVELOPMENT

Organisations enabling research translation are uncommon in academia because we focus on the "Development" aspects of R&D rather than breakthrough or discovery research. NRL's development work has the potential to affect lives today, rather than some potential future date.

The NRL's ability to focus on the Development aspects of translational research arises from our mature Quality Management System and our considerable expertise in regulatory affairs from many years of collaboration with Australia's Therapeutic Goods Administration and other regulatory bodies. Our R&D team can assist in the formal design of new IVDs and expedite the translation of existing design concepts into commercially ready products and services. This can include external support in the verification and validation of new IVDs as well as laboratory support for clinical trials.

NRL's R&D team is a stand-alone department that also supports research and development activities across NRL's various departments. We actively perform novel development work on IVDs to improve their quality and accessibility for regional, rural and remote areas.

IMPACT

Using the grant awarded by the **Foundation for Innovative New Diagnostics** (FIND, Geneva) and The Global Fund under the ACT-A project **(https://www.act-a.org/)**, NRL was commissioned to design, deliver and manage a SARS-CoV-2 Antigen Rapid Diagnostic Test Quality Assurance (QA) program. This included the development of stable, highly characterised samples and the provision of Competency and External Quality Assessment Panels and the development of smartphone data entry for QA results.

The QA program was delivered to **131 sites** in **eight** countries, including across Africa, Pacific Islands and South-East Asia. For the Competency Panels, **3714 results** were received and at least **81 test sites** submitted results for the External Quality Assessment Panels.

Fourteen different COVID-19 RDTs were used and known positive sample in the competency panel was correctly identified only **34%** of the time, while the known negative sample was correctly identified **97%** of the time. These results were both surprising and alarming, and have emphasised the importance of applying quality assurance processes to this kind of testing. As a result of this project, a number of Ministries of Health have reviewed their practices for selection of Rapid Diagnostic Tests (RDTs).

NRL were awarded a grant through the Australian Centre for Hepatitis B, C, HIV and HTLV (ACH4) to prototype a new assay able to distinguish between strains of Human T -Lymphotropic Virus (HTLV) found in Australia and other strains of HTLV found globally. Since only HTLV-1c is typically detected in Australia, it is intended that such an assay will provide a valuable surveillance tool to rapidly identify new strains of this life-threatening virus that may have been introduced into Australia through migration or other means.

HIGHLIGHTS

NRL continues to support the National HCV POCT project. The R&D team are developing QA material that can be used for RDTs, which will lead to cost savings by testing for HCV antibodies first, with HCV antibody-positive patients then being tested on an HCV Molecular test.

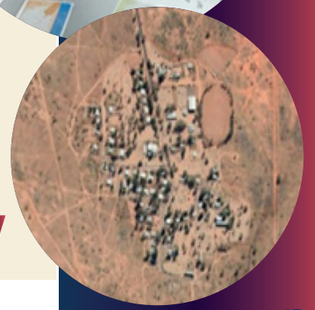
The **ACT-A** project was successfully completed, and on review of the report, FIND allocated further funding to allow NRL to perform troubleshooting work. This allowed NRL to continue to aid the various in-country partners and to provide guidance to various Ministries of Health.

Together with the NRL Testing team, the NRL R&D team have also continued to provide HTLV testing services for the **5-year Longitudinal Study** led by the Baker Institute, aimed at investigating associations of HTLV-1 infection with disease among aboriginal people living in central Australia.
Due to issues around blood sample stability over the extended periods of time spent consenting participants, collecting blood and transporting samples from remote communities (up to a week), it was necessary to validate a novel blood collection tube known as the **Cell Preparation Tube** (CPT) for use in the study.

This was achieved in May, 2023, when members of the NRL R&D Team travelled to the Amoonguna community near Alice Springs to help conduct a small Sample Validation study. Together with data obtained in the laboratory setting, this sub-study was able to clearly show that the CPT was compatible with all HTLV-1 tests used in the study (both serology and molecular tests) over the extended timeframes, as well as the conditions likelyto be encountered in central Australia.

In 2023, the R&D team in collaboration with **Roche Australia** also extended previous work to identify a low-cost, fingerstick blood collection device able to provide material for the molecular testing for HTLV. Such a collection device would be expected to improve accessibility to HTLV testing in LMIC and remote/very remote settings. This will enable widescale testing for HTLV that can be used to improve our understanding of HTLV prevalence globally. Studies aimed at clinically validating the use of this fingerstick collection device and obtaining HTLV prevalence data across the South Asia region are expected to commence in early 2024.

Participants & communities in the Baker Institute led HTLV-1 Longitudinal Study, which NRL are providing study planning, sample validation and testing services.



"Our expert knowledge in diagnostics and laboratory medicine enables us to assist in the formal design of new IVDs and to expedite the translation of existing design concepts into commercially ready products and services."

SCIENTIFIC CONSULTING & TRAINING

Customised and sustainable programs to enhance quality of infectious disease testing through education, advocacy and mentorship.

IMPACT

In recognition of NRL's continued support for WHO and countries across the Western Pacific and South-East Asian regions, NRL was re-designated in November 2022 as a **WHO Collaborating Centre** for Diagnostics & Laboratory Support for HIV/AIDS and other blood-borne infections, for another **4 years.**

The lifting of COVID-19 travel restrictions enabled NRL staff to travel to Cambodia and Laos in 2022 to perform in-person laboratory assessments and on-site training, in addition to conducting virtual training workshops and one-on-one mentoring sessions. The opportunity to visit the laboratories in person provided NRL's trainers with a deeper understanding and appreciation of the unique contexts within which each of the labs operate, and enabled the further customisation of training and mentoring to suit the individual needs of each laboratory.

NRL works in collaboration with Ministries of Health, non-government agencies, laboratories and in-country development partners to ensure that our international capacity-building activities remain relevant and support appropriate, sustainable and effective outcomes.
As a WHO Collaborating Centre, our staff have significant expertise and are highly regarded as consultants and technical experts. We support the development of technical guidance and make recommendations in line with national and i nternational strategies and standards.

WHO SEARO SRI LANKA

In early 2023, the **WHO South East Asia Regional Office** (WHO SEARO) contracted NRL Australia to provide capacity building support for the National Blood Transfusion Service (NBTS) in Sri Lanka to comply with the principles of **ISO/IEC 17043:2010** Conformity assessment – General requirements for the competence of proficiency testing providers and conduct a regional EQAS program.

The project is to be carried out over **three phases.** The first phase was completed in May 2023 when NRL visited the Sri Lanka NBTS to perform a baseline capacity assessment against ISO 17043. The assessment report also included a proposed workplan with prioritised actions to address identified gaps over the subsequent two phases.

INDIAN COUNCIL OF MEDICAL RESEARCH (ICMR) AND WHO SEARO INDIA

The NRL, supported by WHO SEARO, has developed a capacity building program to train and mentor **15** selected institutes in India to become providers of serology and molecular biology External Quality Assurance Schemes (EQAS). The customised program was initiated at the request of the **Indian Council of Medical Research (ICMR)** and will be delivered in **three phases.**

The first phase was the delivery of a series of virtual training sessions held between April and June 2023, designed to provide participants with the theoretical knowledge of production of EQAS panels in preparation for an onsite practical training workshop to be held as Phase 2 in late 2023

YAYASAN KNCV INDONESIA (YKI)

The NRL, in collaboration with **Yayasan KNCV Indonesia (YKI),** has supported the National AIDS Program (NAP) in Indonesia through capacity strengthening of four nominated laboratories for the development and delivery of an HIV viral load external quality assurance program (HIV VL EQA).

The collaboration has involved three key activities, including the delivery of customised virtual training, onsite practical training and assessments of the capacity at each of the four laboratories and provision of advice to NAP for the selection of a National HIV VL provider. The first activity was delivered in June 2023 with a 1.5 day virtual workshop.

HIGHLIGHTS

Yayasan KNCV Indonesia on the provision of capacity building support for the selection of the National HIV VL EQAS Provider for Indonesia.

TECHNICAL ADVISORY

Development of HIV testing algorithm with WHO Laos, in view of procurement of HIV/ Syphilis test kids and HBsAg for use on the Elimination of Mother to Child Transmission (EMTCT).

Laboratory capacity building: supported technical meetings with WHO Philippines, with particular focus on HIV-related topics

Rapid HIV diagnostic algorithm (rHIVda) validation, whole genome sequencing (WGS), laboratory network, and quality management systems (QMS).

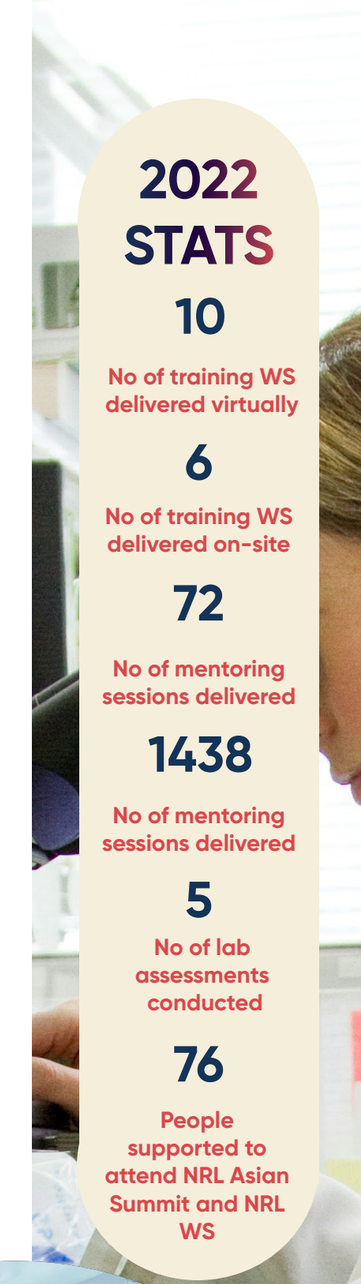
PROJECT UPDATES

SEALAB

NRL completed its collaboration with The Mérieux Foundation and Integrated Quality Laboratory Services (IQLS) on the South East Asia Laboratory Strengthening (SEALAB) project in March 2023.

Commissioned and funded by the Indo-Pacific Centre for Health Security at the Australian Department of Foreign Affairs and Trade, SEALAB delivered training to both improve laboratory quality management systems and expand the knowledge of quality control and quality assurance in human and animal testing laboratories in Cambodia and Laos. In Cambodia, the training was also enhanced by onsite assessments of laboratory quality management systems against the requirements of ISO 15189:2012 Medical Laboratories – Requirements for quality and competence in preparation for two of the laboratories to seek accreditation.

At the conclusion of the SEALAB project, the human and animal laboratories' capacity to detect and respond to emerging infectious disease outbreaks was significantly strengthened, and two human laboratories in Cambodia were prepared for accreditation.



2022 STATS

10

No of training WS delivered virtually

6

No of training WS delivered on-site

72

No of mentoring sessions delivered

1438

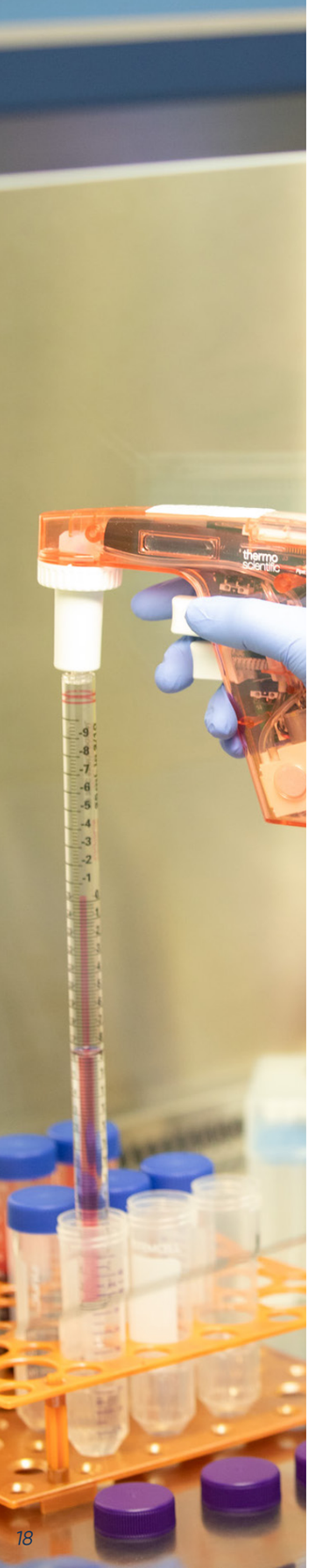
No of mentoring sessions delivered

5

No of lab assessments conducted

76

People supported to attend NRL Asian Summit and NRL WS



SVI BIOBANK

Storage resource and repository for research groups, clinical trials organisations and others requiring contract storage of biological samples.

The SVI Biobank is managed by and housed at NRL's primary laboratory facility. Founded in 2015, our Biobank continues to grow, with the commencement of support for 5 new studies. Further details of some of these projects can be found below. ~70% of the studies Biobank supports are based on the St Vincent's Hospital Melbourne campus, but we also assist with sample processing and storage for multi-site clinical trials and provide a sample storage-only service.

HIGHLIGHTS

New study: IMPACT clinical trial

In early 2022, Biobank commenced support of an International Phase IIa, multi-centre clinical trial in patients with a recent onset Type 1 diabetes – the IMPACT clinical trial. SVI Biobank is providing Biobanking services to all 5 of the Australian sites running this clinical trial. A total of 84 participants are to be recruited over the course of the trial, with samples for Biobanking collected at 11 different timepoints.

New study: HCC sample collection

In collaboration with the St Vincent's Hospital Department of Gastroenterology, Biobank began collecting samples from HepatoCellular Carcinoma (HCC) patients in mid-2022.

Biobanking is offered as an add-on to treatment for patients who have provided informed consent. The ultimate aim is to build a strong resource of biological specimens to facilitate research into this disease. Repeat sample collections over time throughout the patient's treatment period are common.

> ***Biobank has grown to a collection of more than 22,000 specimens from over 600 participants. Primarily a bank of blood products (including plasma, serum, PBMC, and whole blood), the Biobank also houses a growing collection of tissue samples.***

Membership of MACH, ABNA, ISBER

Biobank has expanded its networks and interactions with other Biobankers. Within Victoria we participate in the **Melbourne Academic Centre for Health (MACH)** Biobank registry.

Nationally, we are members of the **Australasian Biospecimen Network Association (ABNA),** including participating in the specimen locator tool. Internationally, we are members of the **International Society for Biological and Environmental Repositories (ISBER),** with NRL staff attending the 2022 AGM virtually.

2022 STATS

8672

Vials of biological speciemens stored

625

Participant samples collected

468

Vials of biological specimens stored

363

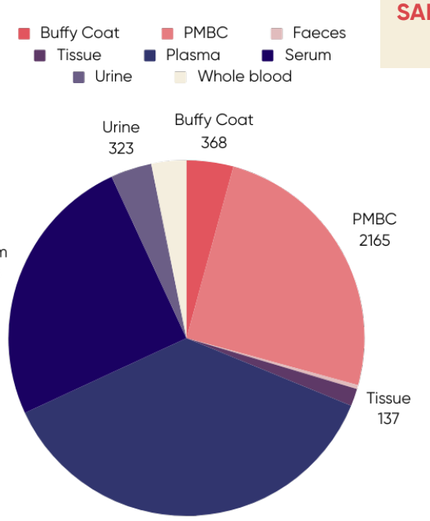
New Biobank participants

QUALITY FOCUS

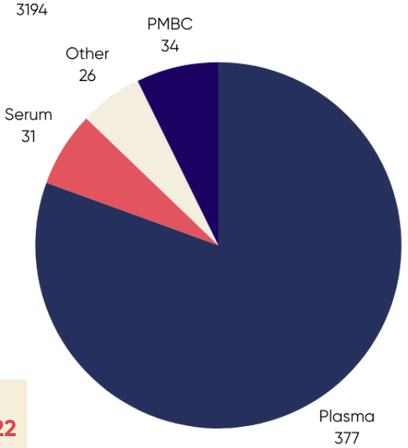
Along with the rest of NRL, Biobank maintains a strong quality focus. We are working towards attaining NATA accreditation to the relatively new quality standard for Biobanking - **ISO 20387.**

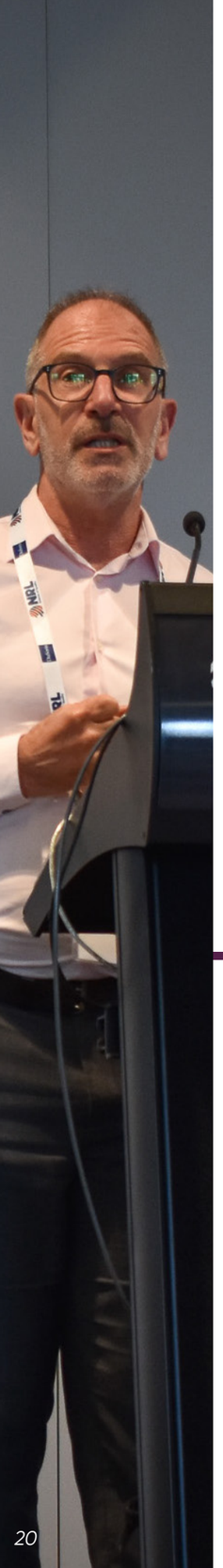
We participate in a proficiency testing program offered by the ImmunoVirology Research Network (IVRN) up to three times a year, and are certified as competent in PBMC processing by this group.

SAMPLES STORED 2022



SAMPLES RETRIEVED 2022





EVENTS

2022 NRL WORKSHOP
LANGHAM, MELBOURNE

97% Expectations Met

76% Prefer Face to face

1st **Face-to-face** Workshop since Covid

36% Heard about the NRL Workshop through **word of mouth**

67% Were **regular** attendees

33% Were **first time** attendees

55% Attended the NRL Workshop to **broaden their knowledge**

68% Of attendance was **delegates**

A BIG THANK YOU TO

Abbott
Abacus dx
AusDiagnostics
BD (Becton Dickinson)
Cepheid
DiaSorin
Genetic Signatures
Hologic
Integrated Sciences
Roche
SpeeDx
TaG Diagnostics
Technopath

Jim Huggett, LGC Group

HIGHEST RATED SESSIONS

DAY 1	Emerging Infection Preparedness	90%
DAY 2	Antimicrobial Resistance	91%
DAY 3	point of care Testing	91%

Rated as **Very Good** or **Excellent**

> Overall it was a wonderful workshop, everyone did an amazing job. I enjoyed all 3 days and thought the workshop content was excellent.

2023 ASIAN SUMMIT
VIRTUAL

100% Expectations Met

86% Prefer Face to face

72% Attended **virtual** events before

43% Attended the NRL Workshop to **broaden their knowledge**

86% Rated the content, themes and topics as **Very Good** or **Excellent**

100% Will be returning to the next event

HIGHEST RATED SESSIONS

DAY 1	External Quality Assessment	86%
DAY 2	Point of Care Testing and Sequencing and New technologies	72%

Rated as **Excellent**

PUBLICATIONS & PRESENTATIONS

PRESENTATIONS/POSTERS

Title: The St Vincent's Biobank – Biobanking in the Hospital Setting.

Authors: Katherine Woods, Madeleine Doyle, Michaela Waibel, Fabian Busby, Philippa Hetzel, Thomas Kay.

Conference: 24th Annual Australasian Biobanking Network Association AGM. 19th-21st Oct 2022

Pandemic Sciences Conference poster

Global Hepatitis Summit 2023 - A NATIONAL PROGRAM TO SCALE-UP DECENTRALIZED HEPATITIS C VIRUS POINT-OF-CARE TESTING AND TREATMENT IN AUSTRALIA

PUBLICATIONS

Byrne JA, Banaszak AT, Carpenter JE, Carroll SL, Castelhano MG, Espinal PS, Henderson MK, Hettiaratchi A, Maseme M, Ng W, Patel K.... & Woods, K. *Priorities in Biobanking Research: A Report on the 2021 ISBER Round Table. Biopreservation and Biobanking*. 2023 Feb 1;21(1):111-3.

Faridi P, Woods K, Viviane J, Rossjohn J, Schittenhelm R, Behren A, Croft N, Purcell A. Spliced HLA p*eptides, a novel source for melanoma immunotherapy.* Molecular Immunology. 2022 Oct 1;150:11-2.

Giuseppe A. Vincini and Wayne J. Dimech. *What is the best external quality control sample for your laboratory? Clinical Chemistry and Laboratory Medicine.* 30-0ct-2022.

A-361 Implementation of a Fit-for-purpose Point of Care Quality Assurance Program. W J Dimech, L Cabuang, G Vincini. Clinical Chemistry, Volume 69, Issue Supplement_1, October 2023, hvad097.319, https://doi.org/10.1093/clinchem/hvad097.319

A-245 Reagent Lot Variation—When should I be Concerned? G Vincini, Wayne Dimech. Clinical Chemistry, Volume 69, Issue Supplement_1, October 2023, hvad097.217, https://doi.org/10.1093/clinchem/hvad097.217

GLOBAL REACH

WE ACKNOWLEDGE AND THANK OUR STAKEHOLDERS

- Asian Association of Transfusion Medicine (AATM)
- Abacus dx
- Abbott Diagnostics
- Aikenhead Centre for Medical Discovery
- Alice Springs Hospital
- African Society for Laboratory Medicine (ASLM)
- American Society for Microbiology (ASM)
- AusDiagnostics
- Australian Centre for HIV and Hepatitis Virology Research (ACH4)
- Australian Global Health Alliance
- Australian Government Department of Health
- Australian Indonesia Health Security Partnership (AIHSP)
- Australian Institute for Medical and Clinical Scientists
- Australian Network of WHO Collaborating Centres
- Australian Red Cross Lifeblood
- Australasian Society for HIV, Hepatitis & Sexual Health Medicine
- Australian WHO Collaborating Centre Network
- Austin Health
- AIHSP - Australian-Indonesian Health Security Partnership
- American Society for Clinical Pathology (ASCP)
- Baker Institute
- Becton Dickinson
- Biomerieux
- Bio-Rad Laboratories Pty Ltd
- BD Life Sciences Blood and Tissue Donation Services
- Bunsiness Events Adelaide
- Burnet Institute
- Bureau of Medical Laboratory Services (BMLS), Ministry of Health, Cambodia
- Cepheid
- Central Public Heath Laboratory (CPHL)
- Clinical Diagnostics division of LGC
- CSIRO
- CSL Behring Australia
- Department of Health and Human Services, Victoria
- DiaMex GmbH
- DiaSorin Australia Pty Ltd
- Diagnostic Technology
- Flinders University International Centre for Point-of-Care Testing
- Fleming Fund
- Foundation for Innovative New Diagnostics
- Genetic Signatures
- Global Fund
- Hologic
- ICAP at Columbia University
- Indian Council of Medical Research
- Immuno-Virology Research Network (IVRN)
- Indonesia One Health University Network (INDOHUN)
- Indo-Pacific Centre for Health Security
- Integrated Quality Laboratory Services (IQLS)
- Integrated Sciences
- Infectious diseases testing laboratories
- International Retrovirology Association (IRVA)
- Institutions providing samples for NRL programs
- International Plasma and Fractionation Association
- Irish Blood Transfusion Service
- IVD Manufacturers
- Kirby Institute
- LGC
- MNX Global Logistics
- MP Biomedicals Australasia Pty Ltd
- National Association of Testing Authorities, Australia
- National Centre for Laboratory and Epidemiology (NCLE)
- National Institute of Biological Standards and Controls (NIBSC)
- National Measurement Institute
- National Reference Laboratory/ San Lazaro Hospital STD AIDS Cooperative Central Laboratory, Philippines
- New South Wales Ministry of Health
- New Zealand Blood Service
- NACCHO - National Aboriginal Controlled Congress of Health Organisations
- Oneworld Accuracy, Canada
- Ortho-Clinical Diagnostics
- Pathology Technology Australia
- Peter Doherty Institute for Infection and Immunity
- PRONTO!
- QIAGEN
- Research Institute for Tropical Medicine, Philippines
- Roche Diagnostics Australia
- Royal College of Pathologists of Australasia (RCPA)
- Shanghai Blood Centre
- Siemens Healthineers
- South African National Blood Service
- SoGAT
- SpeeDx
- St Vincent's Hospital Melbourne
- St Vincent's Hospital Sydney
- Sysmex
- The Mérieux Foundation (FM)
- Therapeutic Goods Administration
- US Centres for Disease Control and Prevention
- Victorian Infectious Diseases Reference Laboratory
- Vircell
- WHO Collaborating Centres
- World Health Organization Headquarters and Regional Offices
- World Health Organization Member States
- Yayasan KNCV Indonesia