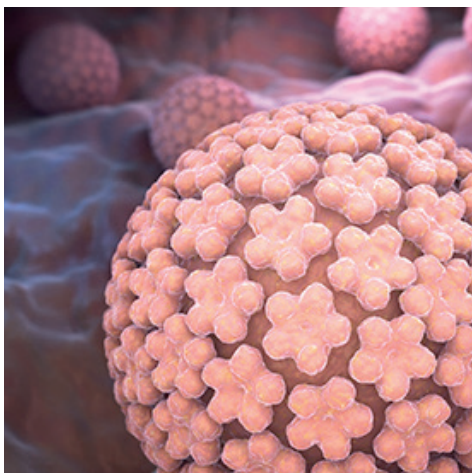
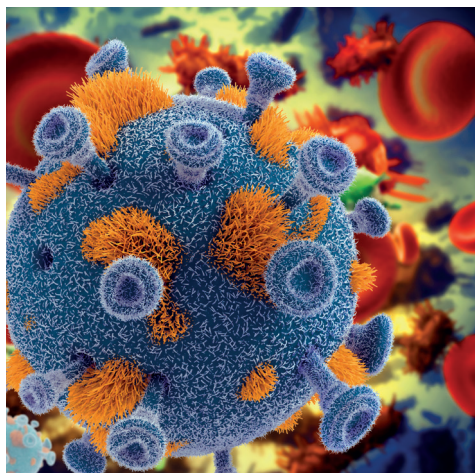
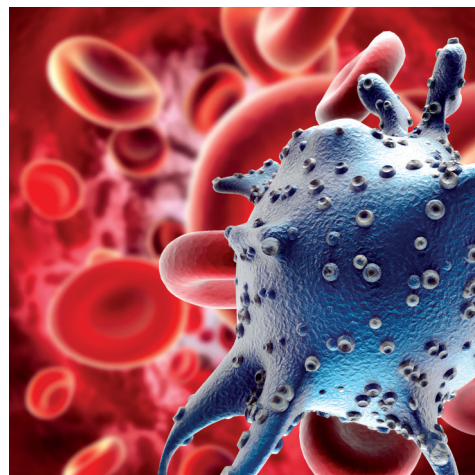
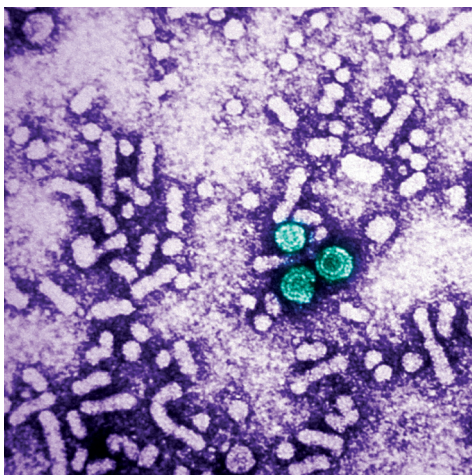
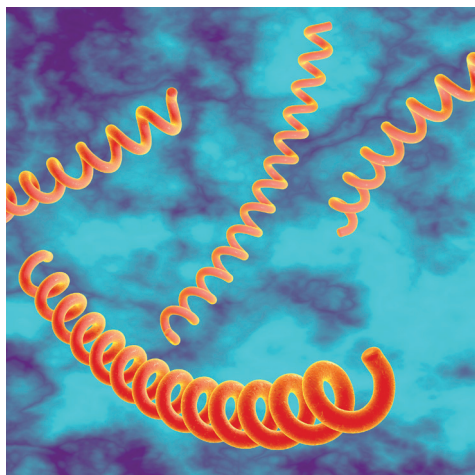
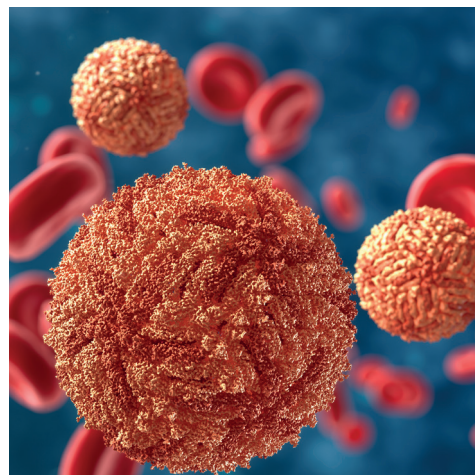
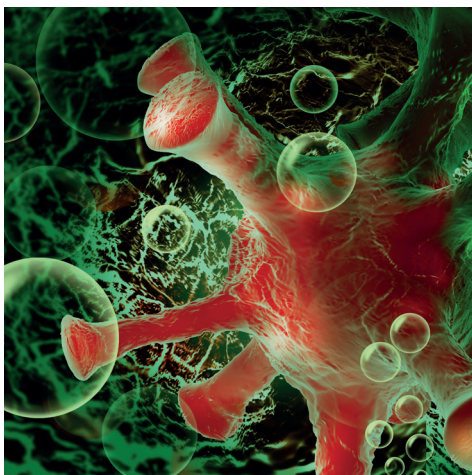
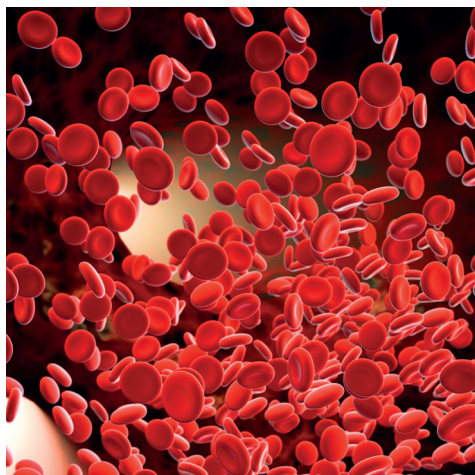


2019 | **NRL** YEAR

SCIENCE OF QUALITY





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ABOUT NRL

As a division of St Vincent's Institute of Medical Research, NRL specialises in monitoring and enhancing the quality of testing for infectious diseases.

As a designated World Health Organization (WHO) Collaborating Centre for Diagnostics and Laboratory Support for HIV/AIDs and other Blood-borne Infections, NRL supports collaborative scientific partners worldwide in the provision of accurate diagnosis and management of human communicable diseases. NRL is supported by the Australian Government Department of Health in assuring high quality testing in Australian laboratories.

NRL's mission is to promote the quality of tests and testing of infectious diseases globally

Accredited to ISO 15189 as a Medical Testing Laboratory, ISO 17043 as a Proficiency Test Scheme Provider, and licensed by the Therapeutic Goods Administration (TGA) as compliant with the Australian Code of Good Manufacturing Practice, NRL's scope includes the following integrated services that underpin its mission:

- Comprehensive quality assurance (QA) programs including External Quality Assessment Schemes (EQAS) and Quality Control (QC) that support global laboratory networks in over 70 countries;
- Training and mentorship in laboratory systems with sustainable, self-sufficient outcomes;
- Consultancy and advisory services to ministries of health (MOH), WHO and national public health laboratories;
- Pre- and post-market evaluation of *in-vitro* diagnostic medical devices (IVDs);
- Patient sample reference testing for HIV, HCV and HTLV;
- TGA-licensed screening of samples collected from blood and tissue donors.



DIRECTOR'S REPORT

2019 was a year of new partnerships and collaborations for NRL as we continued to strengthen our relationships with customers and stakeholders; and our contributions continued to improve the accuracy and quality of testing for infectious diseases globally.

In collaboration with the WHO Western Pacific Regional Office (WPRO) and the Victorian Infectious Diseases Reference Laboratory (VIDRL), NRL conducted a satellite meeting in Vietnam for laboratories that perform reference testing for hepatitis in the WHO WPRO and South-East Asia regions. We also undertook a number of capacity building and training initiatives internationally. NRL joined as a member organisation of the Global Health Alliance Australia in Melbourne (GLHAAM) and the WHO Collaborating Network in Australia; and renewed our professional affiliations with ASHM and BAA locally.

Following a review of our QC manufacturing relationships, we renewed our partnership with DiaMex GmbH who will be manufacturing molecular controls in addition to serology QC products and



who will be relaunching their Optitrol brand during 2020. In July, we entered a new partnership with Technopath Clinical Diagnostics who are known for their high quality Multichem clinical chemistry controls. We are proud to be working with both of these companies because they share our commitment for high quality and scientific excellence and we are delighted to be endorsing their products with the QConnect Trademark.

Our educational workshops were held in Hanoi and Gold Coast and both events were very well attended and highly successful. We introduced an award for New Scientists at the 36th Annual NRL Symposium on Infectious Diseases Testing in Australia and were delighted with the very high quality and diversity of applications. We look forward to continuing this award at future Symposia to support and encourage young scientists in the field of infectious diseases testing.

As part of our ongoing renewal of products and services and in response to customer feedback, two new proficiency programs were introduced – one for molecular *Mycobacterium tuberculosis* and the other an STI & Bacterial Vaginosis molecular EQAS containing multiple analytes. We also

undertook a complete review of all proficiency testing panels in preparation for a reformulation of NRL's EQAS for 2021.

An important review was undertaken of the NRL workforce in order to ensure that we are well positioned and enabled for our future. As an outcome of the review, we have established an R&D stream under Dr Rosemary Ffrench, our Principal Scientist. Rose was successful in receiving funding approval from ACH² for several collaborative projects with the Burnet, Baker and Doherty Institutes relating to testing for HTLV1 in remote indigenous communities and we look forward to further expanding our capacity in this area.

Finally, I would like to thank the Australian Government for its funding support, our customers for their loyalty, our partners, collaborators and all stakeholders for your support of our work and mission. Together we have made a very significant contribution to improving the quality and accuracy of testing globally.

Dr Philippa AS Hetzel

QUALITY CONTROL

“QConnect is an independent and integrated QC program developed by NRL, designed to monitor the precision & accuracy of infectious disease test results.”

Laboratories from around the world participate in NRL's QC program QConnect to support the ongoing quality of laboratory testing processes and IVDs in use.

QConnect is an independent and integrated QC program developed by NRL, designed to monitor the precision and accuracy of infectious disease test results. QConnect incorporates the following features:

- Serology and NAT QC samples that are optimised for specific IVDs;
- EDCNet, an internet-based application designed for monitoring infectious disease testing in real-time;
- Robust control limits for each QC/IVD combination;
- Constant monitoring and investigations of unexpected QC results;
- Uncertainty of Measurement (MU) reports for laboratory regulatory requirements.

NRL QConnect Serology QCs are registered IVDs and manufactured in an ISO 13485 facility in partnership with DiaMEX, Germany and NRL QConnect NAT QC samples are manufactured in partnership with Exact Diagnostics, USA. In July 2019, NRL entered into a new partnership with Technopath Clinical Diagnostics for the provision of a new serology and molecular range of quality controls for infectious

disease testing. In October, we also revised our partnership with DiaMEX GmbH who will also produce molecular controls for infectious diseases in addition to the serology quality controls they manufacture.

In Australia, use of QC for HIV and HCV serology and molecular testing; and HTLV serology testing is supported by the Australian Government Department of Health.

Specificity Monitoring

Specificity Monitoring is a specialist service performed by NRL for Australian and overseas blood banks to identify rates of false positive reactivity that can be attributed to different IVD lots or laboratory practices. Specificity Monitoring ensures false positive reactivity is minimised and unnecessary

wastage of blood and blood products are reduced which is essential for blood transfusion services.

HIGHLIGHTS

- One hundred requests from Australian and overseas laboratories seeking support to evaluate unusual QC performance leading to twelve investigations identifying sources of error potentially preventing inaccuracy of patient test results being reported
- Enhancing EDCNet by providing this software in four additional languages- Polish, Italian, French and German



OUR IMPACT Preventing the Misdiagnosis of Hepatitis C in Patients through the use of NRL's QConnect Program

In February 2019, a manufacturer of a commercial anti-HCV IVD released new reagent lots for use in laboratories which were associated with a decrease in QConnect Blue reactivity (NRL's QC sample designed to monitor the performance of this assay). This decrease in reactivity was much greater than that previously experienced with other reagent lot numbers for this assay and therefore was detected by NRL's QConnect limits, triggering an investigation.

QConnect Blue was tested on forty-five anti-HCV assay reagent lots that were released between February 2018-February 2019 (from the same manufacturer) and six reagent lots were found to be effected. This led to further investigation to determine the impact the change may have had on patient/donor sample results,

in particular on seroconversion samples; and to determine if there was an increased likelihood of a false negative test result being reported.

The reactivity of the early seroconversion samples was compared using the non-effected and effected reagent lots. Of 25 seroconversion samples tested, four samples were found to be below the cut-off on the effected lot and would have otherwise been reported as per the manufacturer's *Instruction for Use* as non-reactive. However, results in unaffected batches for all four samples were very close to the cut-off and rarely encountered in a clinical setting.

NRL's QConnect program was able to identify the analytical performance issue associated with this reagent lot and worked collaboratively with the manufacturer. Without the QConnect program functioning as an international, integrated system, this issue may not have been detected and could have potentially resulted in the mis-diagnosis of patients if not rectified.

Through collaboration with the manufacturer, the root cause of the issue was rapidly identified and resolved which limited the potential impact on patient care.

SERVICES DELIVERED

- 144 Sites utilised EDCNet
- 1094 Registered QConnect members
- 28 QConnect QCs available
- 211,252 Serology and 82,589 NAT QC data points entered into EDCNet
- 14 Countries used QConnect QCs
- 12 QConnect QC investigations undertaken

“QConnect Blue was tested on forty-five anti-HCV assay reagent lots ... six reagent lots were found to be effected.”

“NRL EQAS incorporates scientifically designed panels comprised of positive and negative samples of known analyte.”

Proficiency programs are vital in assessing the integrity of the entire infectious diseases testing process by identifying and resolving any potential sources of error, ultimately preventing misdiagnosis of infection.

As part of the comprehensive suite of quality assurance services that NRL provide, NRL EQAS incorporates scientifically designed panels comprised of positive and negative samples of known analyte. Assessment begins from sample receipt through to the final reporting and interpretation of the test result. EQAS participants submit testing results online via an internet-based application known as OASYS (developed by Oneworld Accuracy, Vancouver, Canada) and all results are assessed by NRL which is reported in a final summary incorporating peer comparison and recommendations where required.

NRL EQAS is accredited to ISO 17043 and includes specifically designed single and multi-analyte programs for Blood Screening, Clinical NAT, Clinical Serology and Point-of-Care (POC) testing. Panels are comprised of sample types that are representative of specimens normally received by the laboratory such as plasma, as



well as alternatives like dried tube samples for use by those working in remote communities or under-resourced regions. NRL is able to provide genuine and diverse samples through

material transfer agreements (MTAs) with collaborating blood transfusion services under which plasma packs identified for discard are provided for use in NRL's QA programs.

In Australia, HIV, HCV and HTLV EQAS provided to laboratories are supported by the Australian Government Department of Health.

HIGHLIGHTS

- The introduction of a new molecular EQAS for the detection of *Mycobacterium tuberculosis* completed by nine participants
- A new STI and Bacterial Vaginosis molecular EQAS containing multiple analytes that include *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, *Mycoplasma* and *Ureaplasma* species completed by seven participants
- Supporting the Human Reproductive Program (HRP) project, “Advancing STI control and prevention through new innovations for STI testing technology: Integrated Point-Of-Care Testing (POCT)” by providing dry swab-based EQAS



OUR IMPACT

Assuring Accuracy of Testing for *Mycobacterium tuberculosis* Globally

Mycobacterium tuberculosis (TB) is one of the top 10 causes of death globally with 1.5 million people reported as having died from TB in 2018¹. Whilst TB is a treatable and curable disease, there are strains that have become resistant to one or more of anti-TB drugs commonly utilised and multidrug-resistant TB (MDR-TB) has become a public health crisis. The WHO estimates that there were 484,000 new TB cases with resistance to rifampicin – the most effective first-line drug for treatment, diagnosed in 2018¹.

In September 2018, the United Nations met to address the status of the TB epidemic and how to reduce its spread¹. Agreement on Sustainable Development Goals and WHO's End TB Strategy were affirmed and included targets to end the TB epidemic by 2030¹. This included strategies for the early diagnosis of tuberculosis including universal drug-susceptibility testing, and systematic screening of contacts and susceptible groups.

In line with this important initiative and to aid in assuring diagnostics for TB,

NRL developed an EQAS that is compatible with qualitative molecular TB tests, used in both the laboratory and community-based testing environments and for institutions that perform antibiotic resistance typing using molecular methods.

NRL Contributes to the WHO Global Health Sector Strategy on STIs 2016-2021

Sexually Transmitted Infections (STIs) are a highly endemic public health challenge worldwide and globally it is estimated that each year there are 357 million new cases of the four major curable STIs among people aged 15–49 years: chlamydia infection (131 million), gonorrhoea (78 million), syphilis (6 million) and trichomoniasis (142 million)². In order to respond to this high burden of disease and in line with the 2030 Agenda for Sustainable Development, the WHO has developed a global health sector strategy on STIs 2016–2021, which focuses on prioritizing surveillance and prevention, expansion of testing; and treatment through innovative service delivery models².

To support and facilitate universal access to high-quality STI testing, the

development and implementation of appropriate, reliable and low-cost POCT have been identified as an important objective³. Supported by the Human Reproductive Program (HRP) the project, “Advancing STI control and prevention through new innovations for STI testing technology: Integrated Point-Of-Care Testing (POCT)” was implemented.

As part of this initiative, NRL provided dry swab-based EQAS and QC material for use in both primary care and laboratory settings in China, Italy, Malta, Morocco, Guatemala, Peru, Australia and South Africa. This study was designed to review the feasibility of near-patient POCT instruments by comparing performance of POC NAT assays with “laboratory gold standard NAT” assays in each region. This study was also used to assess the training of POC community/peer testers given such staff are generally not qualified medical scientists.

SERVICES DELIVERED

- 6106 EQAS subscriptions provided to 80 countries
- 1097 EQAS enrolled participants
- 26 different EQA schemes

TRAINING AND SCIENTIFIC CONSULTING SERVICES

“NRL staff are highly regarded consultants and technical experts sought by MOH, non-government organisations and the WHO”

High quality testing is vital to ensure accurate diagnosis and appropriate management of patients.

NRL provides advocacy, scientific consultancies, customised training programs and mentorship to laboratories, particularly in resource limited settings to enhance the quality of testing for infectious diseases. NRL's Training and Consulting Services is culturally sensitive and customised based on locally identified needs. As a WHO Collaborating Centre, NRL staff are highly regarded consultants and technical experts sought by MOH, non-government organisations and the WHO to participate in reviewing countries' capacity building programs and in the development of technical recommendations aligned with national and international strategies.



HIGHLIGHTS

- In partnership with Roche Vietnam, training on IVD evaluations, provision of proficiency testing, validation of data management systems, diagnostic tests and testing algorithms; sample characterisation and QC were delivered to the National Institute of Haematology and Blood Transfusion in Vietnam
- On behalf of the WHO, NRL provided technical assistance in the validation of two HIV testing algorithms, one for use in POCT settings and one for laboratory reference testing in PNG
- NRL delivered IVD evaluations and Sample Bank development training to the Myanmar National Health Laboratory supported by the Asian Development Bank as part of the Greater Mekong Subregion Health Security Project in enhancing responses to emerging infections
- Roche Vietnam continued its collaboration with NRL in jointly conducting an annual infectious diseases Workshop focusing on QC and EQAS for all laboratories in Vietnam who participated in NRL EQA programs
- Funded by the WHO Eastern Mediterranean Regional Office (EMRO) NRL delivered training to support the provision of EQAS by the Central Public Health Laboratory in Jordan
- On behalf of Foundation for Innovative New Diagnostics, NRL conducted a Training Workshop on EQA for Hepatitis C Viral Load Testing using the GeneXpert in Myanmar
- Requested by the Research Institute for Tropical Medicine, Department of Health, Philippines, NRL provided training to the Molecular Biology Laboratory on laboratory assessments and EQA for molecular testing
- Staff from the Public Health Laboratory Services Branch of the Hong Kong Department of Health attended the office of NRL to receive training on IVD implementation, testing algorithms and QC monitoring



OUR IMPACT

NRL Contributes to the Management of HIV in the Western Pacific Region

HIV is a major global health issue. By the end of 2018, there were 1.9 million people in the Western Pacific region living with HIV⁴. Testing is vital in the prevention, treatment, care and other support services for the management of HIV infections. The Joint United Nations Programme on HIV/AIDS most recent epidemiological data, estimates the prevalence of HIV in Papua New Guinea (PNG) to be approximately 0.8% (0.7% – 0.9%) which is considered to be a low prevalence setting. The WHO recommend that in a low HIV prevalence setting (<5%), a three test, HIV confirmatory testing algorithm should be implemented. This recommendation is intended to reduce the likelihood of false positive results and inform accuracy of testing.

PNG has historically been using a two-test algorithm for the detection of HIV and supported by the WHO, NRL provided technical assistance to aid in the validation of two additional HIV testing algorithms, both of which will use three tests for the confirmation of HIV antibody status. One algorithm was for use in POCT settings and the other for use in laboratory-based reference testing. Once the validation process has been completed for both algorithms, the next planned phase is the implementation of a pilot study to assess the performance of these algorithms ahead of a proposed national roll out.

SERVICES DELIVERED

- 8 Countries received NRL Training services
- 8 New training projects undertaken
- 1 Consultancy delivered
- 3 Training projects continued

“Testing is vital in the prevention, treatment, care and other support services for the management of HIV infections.”

EVALUATIONS

“Understanding the analytical performance of an IVD is an essential part of an effective testing strategy”

NRL has highly specialised expertise in the pre and post market assessment of the analytical performance of IVDs used to diagnose and manage infectious diseases.

A formal well-designed, laboratory-based assessment of IVD performance will provide a scientifically sound understanding of how the IVD will perform. Understanding the analytical performance of an IVD is an essential part of an effective testing strategy as a means to ensure high quality test results and the assessment must represent local conditions by using a large range of relevant samples.

NRL provides three major Evaluation services:

1. Assessments of IVDs by reviewing manufacturer's evidence to ensure the key

performance, quality and safety criteria are met and the evidence presented is scientifically sound.

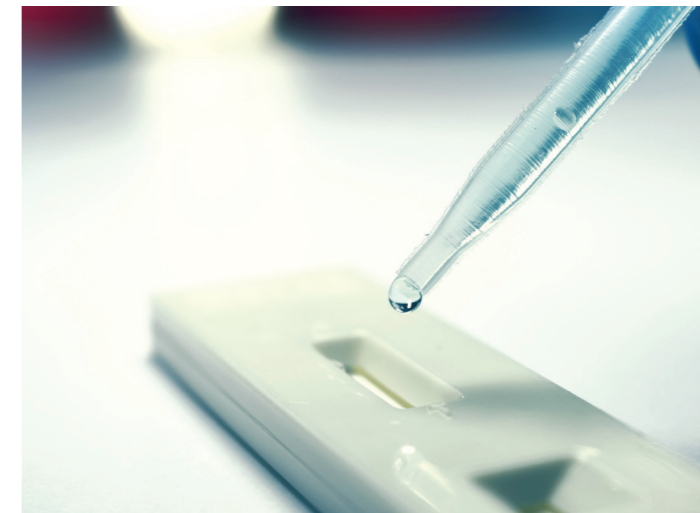
2. IVD assessments on behalf of the WHO Prequalification of Diagnostics Program which aims to increase access to affordable and high-quality diagnostic technologies for use in resource limited settings in WHO member states.
3. Formal performance evaluations on behalf of IVD manufacturers.

NRL Evaluations provides post market IVD performance checks, drafting of evaluation, validation and verification protocols for laboratories and WHO; and customised panels comprised of well-characterised serum or plasma samples for use in assay verifications or validations.



HIGHLIGHTS

- NRL is the only Australian laboratory among 14 WHO endorsed Prequalification laboratories globally and participated in the Prequalification Evaluation Laboratory meeting in Geneva
- NRL was designated the reference laboratory for the clinical study supported by Foundation of Innovative Diagnostics (FIND), in assessing HCV viral load assays for non-standard sample types including dried blood spot and plasma separation cards



OUR IMPACT **NRL collaborates in an International Multi-Site Clinical Study to Evaluate the Performance of HCV Viral Load Assays in Remote Settings**

The introduction of highly effective treatment for hepatitis C viral (HCV) infection means that HCV has now become a curable disease. However, testing methods to detect HCV are complex and costly, creating a barrier to diagnosis in resource-limited settings. Often, access to HCV testing is restricted to those who can attend a blood collection centre located at a central laboratory.

During 2019, FIND began coordinating a prospective diagnostic accuracy study of HCV viral load assays for patient samples obtained using dried blood spot or plasma separation cards. Use of this sample type meant

specimens were collected at clinics and sent safely and cheaply to central laboratories for testing. Capillary, venous blood and plasma specimens were collected from over 900 participants.

NRL was designated the reference laboratory for this study and received specimens from clinical collection sites located in Georgia, Cameroon, Rwanda and Greece. NRL was responsible for processing and storing specimens, performing reference testing, sending specimens to collaborating laboratories in Sydney and Hobart for additional testing; and the collation of data from all Australian test sites.

SERVICES DELIVERED

- 6 IVD dossier assessments completed
- 2 IVD change requests performed
- 2 Laboratory performance evaluations undertaken
- 5 Customised panels devised



“NRL was designated the reference laboratory for this study and received specimens from clinical collection sites located in Georgia, Cameroon, Rwanda and Greece.”

TESTING

“NRL performs TGA-licensed screening of blood and tissue donors for HIV, HBV, HCV, HTLV and Syphilis.”

As a means to ensure accurate patient diagnosis, NRL provides a range of specialist testing for the detection and confirmation of infectious diseases including reference testing, screening of blood and tissue donors and contract testing.

Utilising validated testing strategies, *NRL Testing* operates as a reference point for HIV, HCV and HTLV specimens whose status cannot be resolved by routine screening or other diagnostic laboratories. NRL performs TGA-licensed screening of blood and tissue donors for HIV, HBV, HCV, HTLV and Syphilis. In the absence of IVDs validated for alternative sample types, NRL offers validated testing of cadaveric samples for use in certain serology and molecular IVDs.

NRL Testing undertakes contract testing for scientific projects and in collaborations with other organisations for a range of services that include:

- Development of new assays;
- Validation of testing algorithms;
- Epidemiological studies;
- Support of clinical trials.

The NRL Testing division maintains an extensive repository of well characterised samples (Sample Bank) that is integral to its QA and Evaluation programs.

HIGHLIGHTS

- Provided review of batch release POC testing used by the peer-led community health service Pronto! based in Victoria, Australia
- Conducted a study investigating the suitability of including the MP Diagnostics HTLV I/II ELISA 4.0 in NRL's HTLV testing algorithm to further clarify infection status
- Assisted in the verification of the HIV-1 Viral Load assay for the Roche COBAS 6800 testing platform for VIDRL



OUR IMPACT

Batch Release Testing for HIV Antigen/Antibody Point-of-Care Tests

PRONTO! is a peer-led service with offices based throughout Victoria, that enables the health needs of lesbian, gay, bisexual, transgender, and intersex (LGBTI) communities by offering free rapid HIV POC testing as part of its sexual health screenings and services.

Historically, the POCT used by PRONTO! had only been able to detect HIV antibody, however a newer version of the assay was developed which enabled detection of HIV antibody and antigen. Due to this change and for quality assurance purposes, NRL developed a modified batch release sample panel that included HIV antigen

positive samples for use in validating the test. The ability and advantage in testing for HIV antigen enables the earlier detection of HIV infection potentially leading to more effective treatment, better prognosis and reduction in community transmission.

HTLV Testing in Remote Australian Indigenous Communities

HTLV-1c is a major cause of morbidity and mortality in Indigenous Australians in central Australia where up to half of all Indigenous adults residing in these remote communities live with HTLV-1c⁵. NRL continued to support HTLV testing in Indigenous Australians in remote communities during 2019. NRL performed parallel HTLV nucleic acid testing on different specimen types

including whole blood; dried blood spots (DBS) and buffy coats; and serology testing using plasma samples. Due to difficulties with transportation and cold chain storage of specimens from remote regions, DBS were considered the preferred specimen type provided that assay sensitivity could be maintained.

NRL performed a validation on the use of DBS for serology testing on the DiaSorin LIAISON XL Murex recHTLV-I/II assay. Decreased sensitivity was observed for the DBS specimens compared to paired plasma specimens, and as a result, further optimization will be required to ensure future DBS testing is viable on this assay.

SERVICES DELIVERED

- 426 Reference tests completed
- 2523 Screening tests performed
- 957 Proficiency verifications undertaken



RESEARCH AND DEVELOPMENT

NRL's Research and Development (R&D) service is an initiative established in 2019 led by NRL's newly appointed Principal Scientist, Associate Professor Rosemary Ffrench.

NRL's R&D division supports the innovation and introduction of new products and enhancements to existing services whilst strengthening collaborations with like-minded organisations in providing improvements to existing scientific technology.

Reformulation of NRL EQAS

The constant evolution of infectious diseases pathology and variations in customer requirements is of priority to NRL leading to an ongoing review of product and service offerings. As part of this, a significant review of NRL EQAS design was undertaken leading to the reformulation of many programs. By late 2019, the NRL R&D team began working on a program of improvements to EQAS operational processes and in particular, amendments to participant assessment reports which have been redesigned to enhance the user experience. The scientific review has included the calibration of all HBV, HCV and HIV molecular materials used for NRL EQAS which will be standardised

against the WHO International Standards allowing NRL to generate more meaningful scientific reports for these schemes.

ACH² Grant Awarded to NRL

The Australian Centre for HIV and Hepatitis Virology Research (ACH²) is one of Australia's four national centres for HIV and Hepatitis research and is funded by the Commonwealth Government as represented by the Department of Health and Ageing. NRL was successfully awarded an ACH² grant for the Validation of VL-Plasma[®] device for use in HTLV proviral load and antibody testing. This initiative will aid in the detection and treatment of HTLV, particularly in indigenous communities within Australia.

“NRL was successfully awarded an ACH² grant for the Validation of VL-Plasma device for use in HTLV proviral load and antibody testing. This initiative will aid in the detection and treatment of HTLV, particularly in indigenous communities within Australia.”



EVENTS

NRL hosts annual educational events for medical laboratory scientists, regulators, IVD manufacturers and clinicians working in the field of infectious diseases.

NRL's two main events- the 36th Annual Symposium on Infectious Diseases Testing and the Asian Workshop on Quality are renowned for providing a forum to foster discussion and the sharing of diverse perspectives, attracting a large number of national and international participants seeking to expand upon their knowledge.

NRL Asian Workshop on Quality 2019

NRL held the NRL Asian Workshop on Quality 2019 in Hanoi, Vietnam from 4-5 March 2019. One hundred and forty participants from 16 countries attended the meeting which focussed on improving the quality of testing in laboratories and community settings. The invited speakers from laboratories, WHO programs, regulation, blood services, diagnostic and reference laboratories, non-government agencies and industry presented a broad range of perspectives.

Workshop sessions covered the WHO Western Pacific Regional Viral Hepatitis Laboratory Network, Diagnosis

and Testing Strategies, Blood Screening, Competency, EQAS, QC, Achieving Compliance and Quality Improvements through Audits. The Workshop was specifically designed to host regional speakers from Asia to enable discussions around commonly encountered challenges and solutions found.

36th Annual NRL Symposium on Infectious Diseases Testing

The 36th Annual NRL Symposium on Infectious Diseases Testing was held on the Gold Coast in Australia from 14-16 October 2019, attended by 170 delegates from within Australia and overseas.

In 2019, the Symposium replaced the traditional NRL Workshops on molecular pathology and broader infectious diseases; as an event that ran over three days, incorporating both molecular and serology technical and clinical content.

The NRL Symposium scientific program broadly focused on a number of topical infectious disease themes. NRL welcomed international guest speaker Dr Micha Nubling from the Paul Ehrlich Institute in Germany who presented on the standardisation of HIV viral load testing in the “Standardisation and Accuracy of Testing” session.



Dr Nubling provided a second presentation on the European approach to IVD regulation in the “Regulation and Validation of IVDs” session where the Australian Red Cross Blood Service's shared their experience in validating and managing in-house IVDs and the TGA provided information on requirements for performance validation of rapid test kits. A session devoted to HPV included the recent update of the NPAAC guidelines, with another session focusing on “New Technologies” providing information for improved laboratory workflow and rapid test kits for remote settings. There was an “Emerging Infections” session which focused on mosquito-borne viral diseases, a session on the challenges of HTLV in Australia; health emergency preparedness from the public

health perspective; and the implications of blood-borne infections from the Australian and Malaysian viewpoint. The “Advancements in Testing” session was supported by the Symposium sponsors showcasing their recent developments within the industry and a session devoted to “Quality Assurance” focused on the benefits of QC. The final session of the meeting centred on “STIs and Hepatitis” addressing concerns of how some Neisseria gonorrhoeae strains have become antibiotic resistant; and utilising new technologies to diagnose hepatitis B which affects an estimated 290 million people world-wide.

“NRL's two main events are renowned for providing a forum to foster discussion and sharing of diverse perspectives”

GLOBAL REACH



STAKEHOLDERS

We thank all of our supporters throughout 2019

- Abacus dx
- Abbott
- Alice Springs Hospital
- American Society for Clinical Pathologists
- Asian Development Bank, Myanmar
- AusDiagnostics
- Australian Government Department of Health
- Australian Red Cross Lifeblood
- Australasian Society for HIV, Hepatitis & Sexual Health Medicine
- BD Life Sciences
- Blood and Tissue Donation Services
- Burnet Institute
- Central Public Health Laboratory, Papua New Guinea
- Cepheid
- China International Transfusion Infection Control
- CSL Behring Australia
- Department of Health, Hong Kong
- Department of Health, Papua New Guinea
- DiaMEx GmbH
- DiaSorin
- DKSH
- Exact Diagnostics
- Flinders University International Centre for Point-of-Care Testing
- Foundation for Innovative New Diagnostics
- Genetic Signatures
- Hologic
- ICAP, Myanmar
- Infectious diseases testing laboratories
- Institutions providing samples for NRL programs
- International Leptospirosis Society
- International Plasma and Fractionation Association
- Irish Blood Transfusion Service
- IVD Manufacturers
- Japan International Co-operation Agency, Myanmar
- Kirby Institute
- Logical Freight Solutions
- Ministry of Health and Sports, Myanmar
- National AIDS Program, Myanmar
- National Association of Testing Authorities, Australia
- National Health Laboratory, Myanmar
- National Reference Laboratory / San Lazaro Hospital STD AIDS Cooperative Central Laboratory, Philippines
- New South Wales Ministry of Health
- New Zealand Blood Service
- Oneworld Accuracy, Canada
- Other selected QA program providers
- Peter Doherty Institute for Infection and Immunity
- PRONTO!
- QIAGEN
- Research Institute for Tropical Medicine, Philippines
- Roche
- Save the Children (Myanmar)
- Shanghai Blood Centre
- Siemens Healthineers
- South African National Blood Service
- Speedx
- St Vincent's Hospital Melbourne
- St Vincent's Hospital Sydney
- Sysmex
- Technopath Clinical Diagnostics
- Therapeutic Goods Administration
- United States President's Emergency Plan for AIDS Relief
- UNOPS Myanmar
- US Centres for Disease Control and Prevention
- Victorian Infectious Diseases Reference Laboratory
- World Health Organization Headquarters and Regional Offices
- World Health Organization Member States

PUBLICATIONS AND PRESENTATIONS

PUBLICATIONS

Impact of Hepatitis B Virus Coinfection on Human T-Lymphotropic Virus Type 1 Clonality in an Indigenous Population of Central Australia

Turpin J, Yurick D, Houry G, Pham H, Locarnini S, Melamed A, Witkover A, **Wilson K**, Purcell D, Bangham CRM, Einsiedel L
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PRESENTATIONS

HPV Testing- What are EQAS and QC data telling us?

Vincini J and Cabuang LM
NRL, Melbourne, Australia
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Competency-Are Your Staff Adequately Trained?

Braniff S
NRL, Melbourne, Australia
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Put your Auditing Skills to the Test by Participating in our Virtual Audit

Braniff S
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Assuring Quality and Building Trust: Providing High Quality, Low Cost EQAS

Cabuang L
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Presented at the NRL Asian Workshop on Quality 2019, Hanoi, Vietnam, 4-5 March 2019

Theory of QC

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NRL, Melbourne, Australia
Presented at the NRL Asian Workshop on Quality 2019, Hanoi, Vietnam, 4-5 March 2019

Manufacture of QCs and its Challenges

Vincini G
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Interactive QC Case Studies

Vincini G
NRL, Melbourne, Australia
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HIV Viral Load Scale Up Plan using VL-IVT Scorecard v3.1 in Myanmar

Phy MS
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Screening Strategies: Serology/NAT Screening Algorithms

Vincini J and Dimech W
NRL, Melbourne, Australia
Presented at the IPFA 4th ASIA Workshop on Plasma Quality and Supply, Hanoi, Vietnam, 6-7 March 2019

Testing for Toxoplasmosis and Rubella Infections

Dimech W
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Presented at the Roche Days and Oncopathology Forum, Dubai, United Arab Emirates, 14-16 April 2019

Meaningful Internal and External Quality Control Measures to Secure Safety of Blood Donations

Dimech W
NRL, Melbourne, Australia
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Are Patients' Results Affected by Changes in QC Reactivity?

Dimech W
NRL, Melbourne, Australia
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QA in HPV Testing-The First Two Years

Vincini J
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Presented at the 36th Annual NRL Symposium on Infectious Diseases Testing, Gold Coast, Australia, 14-16 October 2019

Improving Access to Human T-Lymphotropic Virus Type I/II Testing

Ffrench R
NRL, Melbourne, Australia
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Guidance for Maintenance of Laboratory Diagnostic Capacity in Emergency Settings

Ffrench R
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