2018

NRL YEAR

SVI
ST VINCENT'S INSTITUTE
MEDICAL RESEARCH

NRL
Science of Quality

ABOUT NRL

NRL is an operating division of St Vincent's Institute of Medical Research that supports the quality of testing for infectious diseases, globally. NRL collaborates with partners to promote and assure accurate diagnosis and management of human communicable diseases including, but not limited to blood-borne and sexually transmitted infections.

MISSION

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

SERVICES

NRL is accredited to ISO 15189 as a Medical Testing Laboratory and ISO 17043 as a Proficiency Test Scheme Provider; and licensed by TGA as following Good Manufacturing Practice. NRL's scope includes a number of integrated services that underpin its mission including:

- Highly sophisticated quality assurance (QA) programs including External Quality Assessment Schemes (EQAS) and Quality Control (QC);
- Training and mentorship in laboratory systems with sustainable, self-sufficient outcomes;
- 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.

NRL is the only organisation in the world that delivers this full suite of services.

NRL is designated a World Health Organization (WHO) Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Blood-borne Infections.

NRL acknowledges the Aboriginal lands on which we live and work and pays respect to Traditional Owners, ancestors and Elders.

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DIRECTOR'S REPORT

"NRL has continued to make a significant difference to improving the quality of infectious disease testing globally..."

For a very small organisation, I am continually surprised and delighted at the significant impact made by NRL in Australia and internationally. With a compelling mission and a highly motivated workforce, NRL has continued to make a significant difference to improving the quality of infectious disease testing globally over these last twelve months.

NRL was redesignated as a WHO Collaborating Centre for the twelfth time since 1985 and we welcomed a visit from our WHO Responsible Officer in Geneva, Gaby Vercauteren in January. Throughout this year, there were many opportunities for us to contribute directly to WHO programs including the assessment of elimination of mother-to-child transmission of HIV and syphilis in Malaysia, Quality Improvement of Laboratory Services for Viral Hepatitis in the Western Pacific Region and participation at the Third Western Pacific Regional Office (WPRO) Forum for Collaborating Centres in Ho Chi Minh City.

One key highlight for the year was the publication in Clinical Chemistry and Laboratory Medicine of a paper authored by Wayne Dimech, Marina Karakaltsas and Joe Vincini titled *"Comparison of four methods of establishing control limits for monitoring quality controls in infectious disease serology testing"*. The paper demonstrates how QConnect™ limits ensure meaningful QC results for infectious diseases testing especially when compared with traditional QC methods. It has been exciting to see that NRL's QConnect™ program is becoming increasingly well established as the global standard for QC of infectious diseases by both blood services and diagnostic pathology laboratories. Together with our QC manufacturing partners DiaMex GmbH and Exact Diagnostics, NRL has seen a significant expansion of QC use including a pilot program conducted in association with the Shanghai Blood Centre to introduce the QConnect™ program to China.

Our support for the investigation by the Baker Institute of HTLV-1 infection and associated diseases in remote communities in Central Australia has continued and NRL has also participated in the Collaborative Forum on HTLV-1 convened by the Central Australian Academic Health Sciences Centre and the Australian Government Chief Medical Officer and the HTLV-1 Special Interest Group co-ordinated by the Australasian Society for HIV, Hepatitis & Sexual Health Medicine (ASHM). We will continue our involvement and work in the detection of HTLV to ensure that good access to appropriate testing services is provided.

Finally, over the last twelve months, NRL has seen a number of changes in senior

staff with the retirement of Sue Best, my commencement as NRL Director in March, and appointments throughout the year of Megan Kean as Finance Business Partner and Diana Piccoli as Quality and Risk Manager. It has been a very busy year of significant change and we sincerely appreciate all of the support that we have received from our partners and stakeholders including the Australian Government.

OUR ROLE AS A WHO COLLABORATING CENTRE

World Health Organization

NRL is designated a WHO Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Blood-borne Infections

NRL has been designated as a WHO Collaborating Centre for Diagnostics and Laboratory Support for HIV/AIDS and Other Blood-borne Infections since 1985 and in November 2018, was redesignated as a Collaborating Centre until 2022. NRL's work supports WHO's mission to improve the quality and safety of medicines and other health technologies through standards and guidelines, strengthening of regulatory systems and prequalification of reagents.

OUR IMPACT

QUALITY IMPROVEMENT OF LABORATORY SERVICES FOR VIRAL HEPATITIS IN THE WESTERN PACIFIC REGION TO REDUCE THE BURDEN OF HEPATITIS

Worldwide, there are 1.34 million deaths from hepatitis each year with 96% of these attributed to hepatitis B virus (HBV) and hepatitis C virus (HCV)[1]. About 60% of those living with HBV and 34% living with HCV are found in South East Asia and the Western Pacific region, where liver cancer and cirrhosis are in the top 10 causes of death for all age groups over 30 years of age[1]. As a major public health issue, hepatitis has a significant burden on those countries' healthcare budget and economy.

Many Western Pacific countries are implementing health intervention strategies to address the high level of hepatitis. With the advent of new and effective anti-viral medication, improved vaccination programs, and test and treat initiatives; some countries are seeking to reduce, and possibly eliminate, hepatitis. However, critical to the success of these interventions is laboratory testing.

Without well-selected, quality assured assays, trained testers and appropriate quality management systems, such interventions will be less successful. Laboratory testing underpins the cascade of care for patients, including the initiation and monitoring of treatment and the reporting of prevalence and incidence to appropriate bodies.

The WHO Western Pacific Regional Office (WPRO) is working with Collaborating Centres, including NRL, to support regional hepatitis reference laboratories.

During 2018, the WHO WPRO organised an informal consultation to discuss improvements to laboratory quality in the region that included key collaborating centres: NRL and the Victorian Infectious Diseases Reference Laboratory, Australia; CDC Atlanta, USA; the Korean Red Cross, the National Centre for Clinical Laboratories, China and the Pacific Paramedical Training Centre, New Zealand.

The objectives of the review focused on laboratory capacity, sustainable quality laboratory management and accessibility to appropriate diagnostics for viral hepatitis.

QUALITY CONTROL

NRL sets the global standard in delivering comprehensive QA services including a comprehensive QC program. Incorporating QC into infectious diseases testing, independent of the assay manufacturer's kit controls is either a regulatory requirement or highly recommended by international guidelines and professional bodies. The monitoring of QC test results allows the detection of unexpected shifts or trends that indicate a change in the testing system and ultimately aids in identifying and resolving the source of variation.

QCONNECT

Developed by NRL, QConnect is an independent and integrated QC program designed to monitor the precision and accuracy of infectious disease testing. The QConnect concept comprises a number of features which include QC samples optimised for a specific IVD, an internet-based application (EDCNet) for QC data management and a novel method for establishing control limits for each QC/IVD combination. It is for this reason that NRL's QConnect QCs and EDCNet are utilised and valued by laboratories all over the world.

As part of the QConnect concept, NRL provides constant monitoring and investigations of unexpected QC results and generates Uncertainty of Measurement reports necessary for laboratories' regulatory requirements.

NRL's QConnect serology QC samples are manufactured in partnership with DiaMex, Germany and QConnect NAT QC samples are manufactured in partnership with Exact Diagnostics, USA.

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.

OUR IMPACT

NRL'S QCONNECT LIMITS PROVIDES A NOVEL UNDERSTANDING OF INFECTIOUS DISEASES QC TESTING

Developed and published by NRL, QConnect Limits use historical data to establish the acceptance criteria for QC performance. NRL has been collecting QC results from QC/assay combinations for more than 15 years and normal variation has been taken into consideration when establishing the Limits. As a result, NRL has detected many testing abnormalities which have been investigated and published.

In December 2018, at the Stepwise Laboratory Improvement Process Towards Accreditation and the Stepwise Laboratory Quality Improvement Process Towards Accreditation Symposium at the African Society for Laboratory Medicine conference, invited keynote speaker Wayne Dimech took part in an interactive session focusing on "Understanding QC for Infectious Diseases" alongside Sten Westgard and other African laboratory experts including Dr John Nkengasong. The session highlighted and explored the difference between monitoring quality control results for clinical chemistry and infectious disease serology.

Team Leader Joe Vincini

In 2018, NRL published a paper on its novel QConnect Limits in Clinical Chemistry and Laboratory Medicine titled *"Comparison of four methods of establishing control limits for monitoring quality controls in infectious disease serology testing"* authored by Wayne Dimech, Marina Karakaltsas and Giuseppe A Vincini.

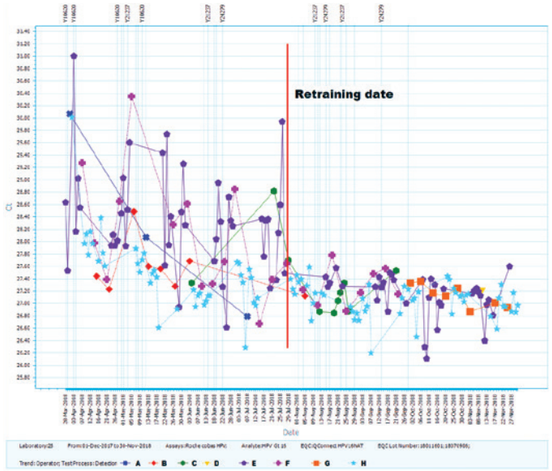


Figure 1 – Data for QConnect HPV16NAT before and after retraining of staff.

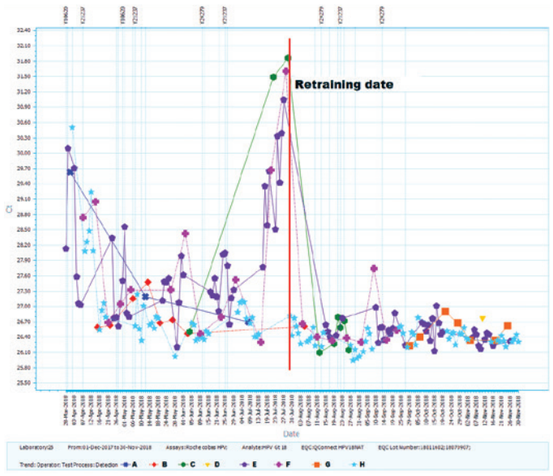


Figure 2 – Data for QConnect HPV18NAT before and after retraining of staff.

QCONNECT- HELPING TO IDENTIFY LABORATORY VARIATION IN AUSTRALIA

In December 2017, the National Cervical Screening Program mandated using human papillomavirus (HPV) NAT to replace cytology as the primary cervical cancer screening method. HPV NAT is intended to identify the risk of developing cervical cancer, with limited HPV typing used to stratify risk. Subsequently, programs used to monitor quality assurance of HPV tests were modified to correlate with these new testing guidelines.

In preparation for this change, NRL designed a negative control- QConnect HPVNEG; and QConnect HPV16NAT and QConnect HPV18NAT QCs which contain the HPV genotype 16 and genotype 18 respectively, which are known to cause cervical cancer. Once molecular testing commenced, NRL reviewed the first year of data generated for QConnect HPV16NAT and HPV18NAT QC samples which revealed evidence that the QC sample preparation by different operators was a source of variation. As the QC sample type is identical to the patient sample, this issue highlighted concern that operator variation could result in the inaccuracy of HPV detection leading to misdiagnosis.

These images show QConnect HPV16NAT and HPV18NAT QC results from a participant in the NRL QConnect program where retraining of staff in QC sample preparation, as prescribed in the HPV test instructions for use, corrected the variation observed.

EXPANSION OF THE QCONNECT QC PRODUCT RANGE

During 2018, NRL continued to develop the scientific expertise behind the QConnect QC program and expanded the product range to include eight new QCs. Multi-marker QConnect HEPA-1 and HEPA-2 QCs, used to monitor testing for acute hepatitis A, B and E, were released in 2018 along with QConnect Pediatric G QC used to monitor testing for parvovirus B19 IgG; and vaccine preventable diseases - measles, mumps and VZV IgG.

Single marker QConnect Measles M, Parvo M, Mumps M and VZV M were also developed for acute serology testing as was QConnect Syphilis G for use in Anti-*Treponema pallidum* IgG agglutination testing. All QConnect QCs have been optimised for specific testing platforms to monitor the consistency of IVD lot numbers and laboratory testing over time.

SPECIFICITY MONITORING

NRL provides Specificity Monitoring as a specialist service to Australian and overseas blood banks. The program identifies rates of false positive reactivity due to the use of different IVD reagent lots or laboratory practices. Specificity Monitoring is a mechanism to ensure false positive reactivity is minimised and unnecessary wastage of blood and blood products is reduced which is essential for blood transfusion services.

HIGHLIGHTS

- **The release of 8 new QConnect QC samples for infectious diseases serology testing**
- **The publication of the study entitled:** *Comparison of four methods of establishing control limits for monitoring quality controls in infectious disease serology testing* **in the Clinical Chemistry and Laboratory Medicine Journal**
- **Multiple QConnect QC Investigations performed for Australian and overseas laboratories identifying potential sources of error that may have otherwise affected the accuracy of patient test results**

SERVICES DELIVERED

140
Sites using EDCNet

1,122
QConnect members

32
QConnect QC samples

216,423
total - Serology and NAT QC data points entered into EDCNet

15
Countries using QConnect QC

16
QConnect QC investigations undertaken

EQAS

EQAS is part of the comprehensive suite of QA services that NRL provides.
Proficiency programs such as NRL EQAS are designed to assess the integrity of the entire testing process by identifying and resolving any potential sources of error, ultimately preventing misdiagnosis.

EQAS

NRL EQAS incorporates scientifically designed panels comprised of positive and negative samples which are representative of samples typically received by a testing laboratory. Assessment begins from sample receipt through to the reporting of the test results via the internet-based application- OASYS (developed by Oneworld Accuracy, Canada). NRL reviews submitted results and provides a final report of assessment which incorporates peer comparison data and recommendations when required.

Accredited to ISO 17043, NRL has specifically designed a range of EQAS for Blood Screening, Clinical NAT, Clinical Serology and Point-of-Care (POC) testing and includes a global network of laboratories in more than 50 countries. NRL EQAS ensures sample types such as plasma are representative of a sample that would normally be received by the laboratory whilst also able to provide alternatives such as dried tube samples for those working in remote communities or in under-resourced regions thereby overcoming importation difficulties and minimising cost of transport.

NRL is able to provide genuine and diverse samples for its EQAS 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.

The importance and value of NRL EQAS is evident based on the thousands of laboratories and POC sites across the world that subscribe to NRL's programs to assure the quality of their laboratory testing processes and IVDs utilised. Significantly, NRL is the only provider of a Leptospirosis EQAS in the world.

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

"In 2018, there were 37 participants from countries such as Mongolia, Myanmar, Vietnam and Georgia who successfully completed these EQA"

Team Leader Liza Cabuang

OUR IMPACT

ASSURING THE ACCURACY OF TESTING THROUGH EQAS IN LOW RESOURCE REGIONS

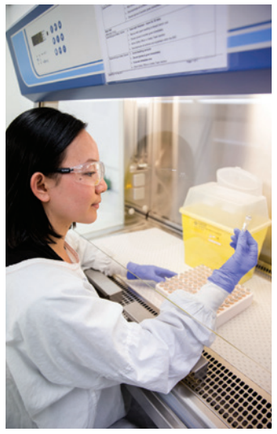
World-wide at the end of 2016, there were only 3 million out of an estimated 71 million people living with chronic HCV; and only 4.5 million out of 257 million people living with chronic HBV infection that had access to treatment[2].

In high disease burden areas where resources are often limited, the reliability of diagnostic testing for infectious diseases is vital. This is especially important in areas where POC testing facilities have been established in the endeavour to slow the spread of infection.

In responding to the need for accurate testing under these conditions, NRL introduced two new dried tube sample EQAS for HBV and HCV viral load. The use of dried tube samples format overcomes difficulties associated with the importation of infectious materials and the high cost of shipping frozen samples. In 2018, there were 37 participants from countries such as Mongolia, Myanmar, Vietnam and Georgia who successfully completed these EQAS.

IDENTIFYING TRENDS IN IVDS THROUGH PEER GROUP COMPARISON

NRL EQAS has a high participation rate and as such, gains insight regarding changes or potential issues associated with IVDs in use through its peer comparison data analysis. Many participants that use different IVDs subscribe to the same NRL EQAS and on occasion throughout the three test events in 2018, NRL identified particular IVDs in use that exhibited different test results and analysis in comparison to other testing systems. This recognition allowed participants to assess suitability of IVDs for different testing processes and early detection of potential erroneous results. NRL actively works with IVD manufacturers to investigate any NRL EQAS result variances observed.



HIGHLIGHTS

The introduction of two new dried tube sample EQAS for HCV viral load and HBV viral load, successfully completed by 37 participants

A new POC Serology EQAS containing multiple analytes such as HBsAg, HIV p24 , anti-HCV, anti-HIV and anti-Treponema completed by 59 participants

SERVICES DELIVERED

2,777
EQAS subscriptions from 80 countries

24
EQAS available

1,268
EQAS participants globally

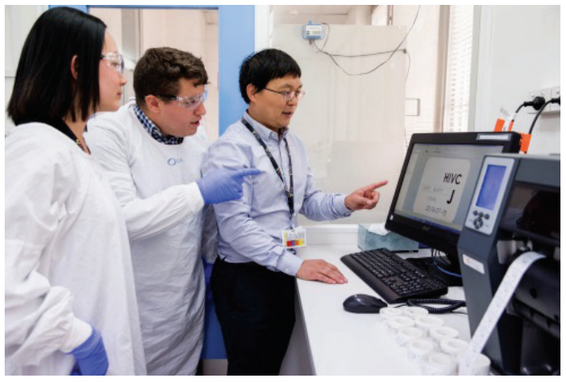
TRAINING AND SCIENTIFIC CONSULTING SERVICES

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.

TRAINING AND SCIENTIFIC CONSULTING SERVICES

Quality of testing for infectious diseases is vital to ensure accurate diagnosis and appropriate treatment for patients. NRL's training and consulting services are culturally sensitive and customised based on locally identified needs.

As part of a WHO Collaborating Centre, NRL staff are highly regarded as consultants or technical experts by Ministries of Health, non-government agencies and WHO. NRL staff participate in, or review countries' capacity building programs and the development of technical guidance or recommendations in line with national and international strategies.



OUR IMPACT

IMPROVING THE QUALITY OF HIV TESTING SERVICES IN MYANMAR

At the end of 2017, the WHO estimated that globally, 36.9 million [31.1–43.9 million] people were living with HIV including 220,000 people in Myanmar[3]. In an effort to address the global AIDS epidemic, UNAIDS was called upon to support country and region-led efforts to establish new targets for HIV treatment. A set of goals were established to address and enhance universal testing and treating of HIV based on the 90-90-90 concept:

- By 2020, 90% of all people living with HIV will know their HIV status
- By 2020, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy
- By 2020, 90% of all people receiving antiretroviral therapy will have viral suppression

In an effort to attain the UN 90-90-90 goals, Myanmar sought to decentralise HIV testing as a means to deliver

Team Leader Geraldine Kong

improved testing services to key populations, many of whom remain undiagnosed. However, this was not without its challenges. Accuracy of testing, adequacy of staff training, introduction of correct interpretation of algorithms and overall quality of testing had to be addressed. Ultimately the aim was to identify those infected, improve treatment regimens and prevent the spread of HIV.

With funding from President's Emergency Plan for AIDS Relief (PEPFAR) and through a Cooperative Agreement between the US Centers for Disease Control and Prevention (CDC) and the American Society of Clinical

Pathologists (ASCP), NRL was involved in a number of training initiatives to support improvements in the quality of HIV testing services in Myanmar. Specifically, NRL provided technical assistance to support the quality of HIV viral load testing services through the validation of the national HIV testing algorithm and conducted "Train-the-Trainer" training for HIV community-based screening. NRL co-presented with CDC Atlanta in a training Workshop on "HIV Rapid Test Continuous Quality Improvement Training" aimed at high- and mid-level laboratory professionals from the National Health Laboratory in Yangon, various states and regions, as well as program leads and managers from the National AIDS Program.

"NRL provided technical assistance to support the quality of HIV viral load testing services through the validation of the national HIV testing algorithm and conducted "Train-the-Trainer" training for HIV community-based screening."

SERVICES DELIVERED

3
New projects

2
Continuing Projects

7
Consultancies

6
Countries that utilised NRL Training

HIGHLIGHTS

- **A training workshop on IVD evaluation establishment, management and operations conducted in the Philippines**
- **In partnership with Roche Vietnam, NRL delivered a Workshop on EQAS Evaluation and Reporting to local participants aimed at improving the quality of infectious diseases testing across Vietnam**
- **On behalf of Abbott, NRL delivered a series of presentations in India, Greece and the Netherlands focusing on enhancing the quality of blood transfusion services**
- **On behalf of WHO SEARO, NRL provided support for strengthening Laboratory Quality Management Systems at the National Health Laboratory in Dili, Timor-Leste**
- **Under 2 sub-contracts funded by the U.S. PEPFAR and through a Cooperative Agreement between the US CDC and the ASCP, NRL provided technical assistance to support the quality of HIV testing services in Myanmar**
- **NRL took part in the assessment granting certification to Malaysia as being the first country in the WHO Western Pacific Region to successfully eliminate mother-to-child transmission of HIV and Syphilis**

TESTING

NRL provides validated testing strategies for the detection and confirmation of infectious disease to ensure accurate patient diagnoses. The range of specialised services NRL offers includes reference testing, screening of blood and tissue donors and contract testing.

TESTING

Using robustly validated testing algorithms, NRL provides reference testing for HIV, HCV and HTLV specimens whose statuses cannot be resolved by routine screening or diagnostic laboratories.

TGA-licensed screening of blood and tissue donors for HIV, HBV, HCV, HTLV and Syphilis is provided by NRL. 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 in the form of scientific projects and collaborations with other organisations for a range of services including:

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

NRL maintains and characterises an extensive repository of samples (Sample Bank) that is integral to its QA and Evaluation programs. NRL has MTAs with local and international blood transfusion services for the supply of plasma packs that have been found reactive on screening tests for infectious disease markers and identified for discard.

OUR IMPACT

CONTRIBUTING TO A BIO-BEHAVIOURAL STUDY TO ASSESS THE RATE OF UNDIAGNOSED HIV AMONG GAY AND BISEXUAL MEN IN SYDNEY, AUSTRALIA

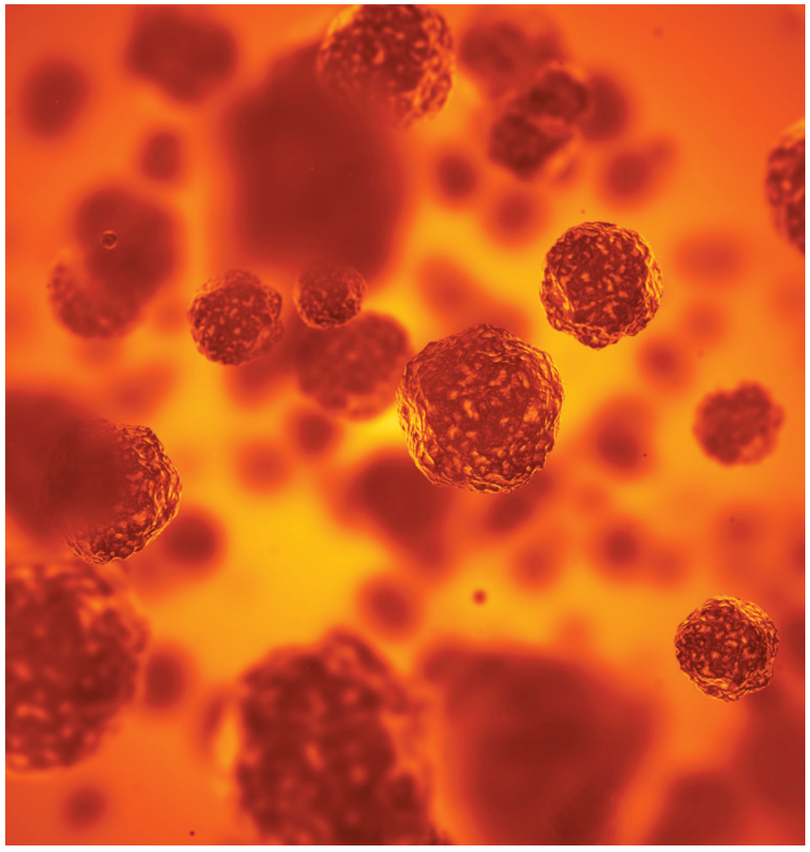
Despite the number of new HIV diagnoses in Australia declining by 5% between 2016 and 2017, male-to-male sex continued to be the major HIV risk exposure accounting for 63% of new cases in 2017[4]. Within this group those with HIV who remain undiagnosed have been found to contribute disproportionally to the epidemic.

Therefore, recent HIV intervention strategies have focused on increased testing, treatment and prevention of HIV among gay and bisexual men (GBM) with the aim to reduce the prevalence of undiagnosed infection in this group.

The NSW Ministry of Health funded a National Health and Medical Research Council (NHMRC) Project Grant with the Kirby Institute to determine the rate of undiagnosed HIV in GBM in Sydney, through a self-administered questionnaire and testing of an oral fluid sample. As part of this study, NRL conducted the HIV screening of the oral fluid specimens using an anti-HIV-1 IgG capture enzyme linked immunoassay (GACELISA) based on the method developed by Parry et al. All specimens that tested positive by this method were confirmed by an in-house western blot validated for saliva as the sample type.

Team Leader Penny Buxton

"As part of this study, NRL conducted the HIV screening of the oral fluid specimens using an anti-HIV-1 IgG capture enzyme linked immunoassay (GACELISA) based on the method developed by Parry et al."



SERVICES DELIVERED

972
Reference Tests

11,850
Screening Tests

274
Plasma packs processed

11,000
Routine testing performed

12,000
Sample Bank Characterisation Testing

HIGHLIGHTS

- **As part of a NHMRC grant to investigate HTLV-1 infections amongst indigenous Australians in remote communities, NRL validated and conducted HTLV-1 proviral load testing on dried blood spots samples**
- **Contributing to the publication of the study:** *Human T-Lymphotropic Virus Type 1c Subtype Proviral Loads, Chronic Lung Disease and Survival in a Prospective Cohort of Indigenous Australians* **in the PLOS Neglected Tropical Diseases Journal**
- **Participating in the Australian Government's Collaborative Forum and Special Interest Group on HTLV-1**
- **Funded by the NSW Ministry of Health as part of an NHMRC Partnership Project Grant with the Kirby Institute, NRL provided testing for HIV oral saliva samples using two in-house assays for a study to detect undiagnosed HIV among gay and bisexual men in Sydney, Australia**

EVALUATIONS

NRL specialises in assessing the analytical performance of IVDs that detect infectious diseases. Understanding the analytical performance of IVDs is an essential part of implementing an effective testing strategy. A well-designed, laboratory-based assessment of IVD performance can provide a realistic expectation of how the IVD will perform in local conditions, using samples representative of the local population.

EVALUATIONS

NRL PROVIDES TWO MAIN IVD EVALUATION SERVICES:

1. IVD assessment by reviewing manufacturer's evidence to ensure that key performance, quality and safety criteria are being met and the evidence presented is scientifically sound. This includes assessments on behalf of the WHO Prequalification of Diagnostics Program, whose aim is to increase accessibility to affordable and high-quality diagnostic technologies for use in resource limited settings in WHO member states

2. Design, preparation and provision of custom panels comprising well-characterised serum or plasma samples for use in assay evaluations, verifications or validations

OUR IMPACT

NRL'S CONTRIBUTION TOWARD THE WHO PREQUALIFICATION OF IN-VITRO DIAGNOSTICS PROGRAM TO INCLUDE SYPHILIS RAPID DIAGNOSTIC TESTS

Congenital Syphilis is the second leading cause of still births globally[5].

In 2014, the WHO initiated the Global Guidance on Criteria and Processes for Validation:

Team Leader Susie Braniff

Elimination of mother-to-child transmission of HIV and syphilis. The aim of this strategy was 95% coverage of syphilis screening of pregnant women and rapid treatment of penicillin for those found to be positive. Syphilis rapid diagnostic tests (RDTs), as recommended in the WHO guidelines for syphilis screening and treatment of pregnant women, were assessed based on safety, quality and performance for inclusion on the WHO list of prequalified IVD products.

As a WHO Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Blood-borne Infections, the NRL Evaluations team participated in the technical consultation for WHO prequalification requirements of syphilis RDTs and contributed to the laboratory evaluations protocol.

"the NRL Evaluations team participated in the technical consultation for WHO prequalification requirements of syphilis RDTs and contributed to the laboratory evaluations protocol"

HIGHLIGHTS

The development and preparation of a HCV molecular sample panel in collaboration with the Foundation for Innovative New Diagnostics that will be used for the validation of newly introduced HCV IVDs

Participation in the technical consultation and laboratory evaluations protocol for WHO prequalification requirements of RDTs

SERVICES DELIVERED

1
IVD evaluated

7
IVD Change Reviews completed

1
Laboratory Performance Evaluation

7
Verification Panels produced

12
Dossier Assessments conducted

WORKSHOPS

As part of our role providing scientific education, NRL hosted a number of annual workshops for medical laboratory scientists, regulators, IVD manufacturers and clinicians working in the field of infectious diseases throughout the year. NRL Workshops are educational events that allow participants from Australia and overseas to expand upon their knowledge in a forum fostering open discussion through the sharing of diverse perspectives.

2018 HIGHLIGHTS

NRL ASIAN WORKSHOP ON QUALITY 2018

NRL held the NRL Asian Workshop on Quality 2018 in Kuala Lumpur, Malaysia from 19-20 March 2018. This Workshop hosted 136 delegates from 16 countries including Malaysia, Indonesia and the Philippines. Speakers from laboratories, non-government agencies and industry all shared their perspectives on quality of infectious diseases testing. Workshop sessions focused on Laboratory Strengthening and Capacity Building; Pre-Analytical Processes, EQAS Implementation, the Importance of QC, Selection and Validation of IVDs; Performing IVD Evaluations and QMS.

This Workshop was specifically designed to host regional participants from Asia to speak on their experiences and discuss commonly encountered challenges.

EUROPEAN WORKSHOP ON QUALITY 2018

NRL held the European Workshop on Quality 2018 in Athens, Greece on 15 May 2018, focusing on maintenance and improvement of laboratory quality for those in the region.

The Workshop attracted 30 registrants from 16 countries reflecting a truly global community and offered a diverse range of perspectives through high-calibre and productive discussions.

Presentations focused on standardisation of testing as well as quality assurance programs allowing European participants of NRL EQAS and QC programs to discuss their experience and learn from others.

NRL WORKSHOP ON MOLECULAR DIAGNOSTICS 2018

The NRL Workshop on Molecular Diagnostics 2018 was held in Melbourne, Australia from 15-16 October 2018. Overall, 150 national and international delegates attended the 1.5 day meeting that focused on themes relevant to medical scientists working in molecular pathology for infectious diseases. Many diverse presentations were delivered with strong representation from leading health care providers and organisations ensuring that the meeting delivered high quality and up-to-date information in this rapidly expanding field.

35TH ANNUAL NRL WORKSHOP ON INFECTIOUS DISEASES

The 35th Annual NRL Workshop on Infectious Diseases was held in Melbourne, Australia from 16-18 October 2018. The scientific program provided a number of engaging and topical themes addressed by invited speakers and delegates in the field.

Sessions focused on HPV testing using molecular techniques, antimicrobial resistance of STIs, the use of PrEP for HIV infections, community screening and the challenges around point-of-care testing; as well as infections that pose significant threat to public health such as influenza, TB and measles. Overall, there were 135 delegates from ten countries in attendance including representation from China, Indonesia and Canada.

SERVICES DELIVERED

470
NRL Workshop delegates

31
Countries represented by NRL Workshop delegates

"The Workshop attracted 30 registrants from 16 countries reflecting a truly global community and offered a diverse range of perspectives through high-calibre and productive discussions."

OUR GLOBAL REACH

NRL gratefully acknowledges those organisations that have provided support for NRL services and staff throughout 2018.

- Abbott Diagnostics
- African Society for Laboratory Medicine
- Alice Springs Hospital
- American Society for Clinical Pathologists
- Australian Government Department of Health
- Australian Red Cross Blood Service
- Australasian Society for HIV, Hepatitis & Sexual Health Medicine
- BD Life Sciences
- Biotherapeutics Association of Australasia
- 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, Papua New Guinea
- DiaMex GmbH
- DiaSorin
- Exact Diagnostics
- Genetic Signatures
- Foundation for Innovative New Diagnostics
- Grifols
- Hologic
- Infectious diseases testing laboratories
- Integrated Sciences
- International Leptospirosis Society
- International Plasma Fractionation Association
- Irish Blood Transfusion Service
- Logical Freight Solutions
- Ministry of Health and Sports, Myanmar
- ICAP, Myanmar
- Institutions providing samples for NRL programs
- IVD Manufacturers
- Japan International Co-operation Agency, Myanmar
- Kirby Institute
- National AIDS Program, Myanmar
- National Association of Testing Authorities, Australia
- National Health Laboratory, Myanmar
- National Health Laboratory, Timor Leste
- National Reference Laboratory / San Lazaro Hospital STD AIDS Cooperative Central Laboratory, Philippines
- New South Wales Ministry of Health
- New Zealand Blood Service
- Other selected QA program providers
- One World Accuracy, Canada
- Peter Doherty Institute for Infection and Immunity
- PRONTO!
- President's Emergency Plan for AIDS Relief
- Research Institute for Tropical Medicine, Philippines
- Roche
- Save the Children (Myanmar)
- Shanghai Blood Centre
- Siemens Healthineers
- SpeeDx
- South African National Blood Service
- 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
- United Nations Development Program Myanmar
- UNOPS Myanmar
- US Centres for Disease Control and Prevention
- Victorian Infectious Diseases Reference Laboratory
- World Health Organization Member States
- World Health Organization Headquarters and Regional Offices

PUBLICATIONS AND PROFESSIONAL PRESENTATIONS

PUBLICATIONS

Human T-Lymphotropic Virus Type 1c Subtype Proviral Loads, Chronic Lung Disease and Survival in a Prospective Cohort of Indigenous Australians
Lloyd Einsiedel, Hai Pham, **Kim Wilson,** Rebecca Walley, Jocelyn Turpin, Charles Bangham, Antoine Gessain, Richard J Woodman
PLOS Neglected Tropical Diseases, 2018 Mar 12;12(3):e0006281

The new screening program to prevent cervical cancer using HPV DNA: getting the balance right in maintaining quality
Garland SM, **Dimech W,** Collignon P; Australian Clinical Microbiologists Infectious Diseases Group, Cooley L, Nimmo GR, Smith DW, Baird R, Rawlinson W, Costa AM, Higgins G.
The Journal of Pathology: Clinical Research, 2018 July 30. Published online in Wiley Online Library DOI: 10.1002/cjp2.110

Comparison of four methods of establishing control limits for monitoring quality controls in infectious disease serology testing
Wayne Dimech, Marina Karakaltsas, Giuseppe A Vincini Clinical Chemistry and Laboratory Medicine (CCLM), 2018 Oct 25;56(11):1970-1978. doi: 10.1515/cclm-2018-0351.

Monitoring the Control of Sexually Transmissible Infections and Blood-Borne Viruses: Protocol for the Australian Collaboration for Coordinated Enhanced Sentinel Surveillance (ACCESS).
Denton Callander, Clarissa Moreira, Carol El-Hayek, Jason Asselin, Caroline van Gemert, Lucy Watchirs Smith, Long Nguyen, **Wayne Dimech,** Douglas IR Boyle; Basil Donovan1, Mark Stoové, Margaret Hellard, Rebecca Guy. JMIR Research Protocols 2018 Nov Vol. 7: 11

PROFESSIONAL PRESENTATIONS

Key Steps in IVD Performance Evaluation
Braniff S
NRL, Melbourne, Australia
Presented at the NRL Asian Workshop on Quality 2018, Kuala Lumpur, Malaysia, 19-20 March 2018

The Benefits of Quality Control
Dimech W
NRL, Melbourne, Australia
Presented at the NRL Asian Workshop on Quality 2018, Kuala Lumpur, Malaysia, 19-20 March 2018

Assuring Quality in Blood Services
Hetzel P
NRL, Melbourne, Australia
Presented at the NRL Asian Workshop on Quality 2018, Kuala Lumpur, Malaysia, 19-20 March 2018

Designing Low Cost Proficiency Programs
Vincini G
NRL, Melbourne, Australia
Presented at the NRL Asian Workshop on Quality 2018, Kuala Lumpur, Malaysia, 19-20 March 2018

Interesting QC Case Studies
Vincini G
NRL, Melbourne, Australia
Presented at the NRL Asian Workshop on Quality 2018, Kuala Lumpur, Malaysia, 19-20 March 2018

Transfusion Transmitted Infections (TTIs) Screening Laboratories and Quality Assurance
Vincini, G
NRL, Melbourne, Australia
Presented at the Abbott Transfusion Medicine - Leading Through Transformation "Raising Blood Safety Standards to the Next Level" meeting, Hyderabad, India, 6 April 2018

Meaningful Quality Control
Dimech W
NRL, Melbourne, Australia
Presented at the 7th Abbott Global Symposium for Transfusion Medicine, Amsterdam, The Netherlands, 17-18 April 2018

Meaningful Quality Control in Blood Services
Dimech W
NRL, Melbourne, Australia
Presented at the 10th Helenic Transfusion Medicine Conference, Ioninna, Greece, 20 April 2018

QC Case Studies
Vincini, G
NRL, Melbourne, Australia
Presented at the NRL European Workshop on Quality 2018, Athens, Greece, 15 May 2018

Are Traditional Approaches to QC Appropriate for Infectious Disease Testing?
Dimech W
NRL, Melbourne, Australia
Presented at the NRL European Workshop on Quality 2018, Athens, Greece, 15 May 2018

Quality Control of CLIA in Blood Screening for Transfusion Transmitted Infections
Dimech W
NRL, Melbourne, Australia
Presented at the Chongqing Blood Transfusion ChLIA Workshop, Chongqing, China, 27-28 June 2018

QConnect Limits
Vincini, G
NRL, Melbourne, Australia
Presented at the Australian Red Cross Blood Service, Melbourne, Australia, 12 July 2018

Laboratory Quality Control in the Serology Testing-Are we truly out of control or jumping at Shadows?
Vincini, GA
NRL, Australia
Presented at the AACB-AIMS Scientific Meeting, Sydney, Australia, 5 September 2018

Quality Assurance of Blood Screening Laboratories
Dimech W
NRL, Melbourne, Australia
Presented at the ROCHE 1st APAC Blood Safety Symposium, Ho Chi Minh City, Vietnam 6 -7 September 2018

HPV Molecular EQAS: Is Quantification Helpful?
Cabuang L
NRL, Melbourne, Australia
Presented at the NRL Workshop on Molecular Diagnostics 2018, Melbourne, Australia, 15-16 October 2018

EQAS Software Reporting Updates
Cabuang L
NRL, Melbourne, Australia
Presented at the Quality Assurance Users' Group Meeting, 35th Annual NRL Workshop on Infectious Diseases, Melbourne, Australia, 16 October 2018

What's New in NRL EQAS?
Cabuang L
NRL, Melbourne, Australia
Presented at the Quality Assurance Users' Group Meeting, 35th Annual NRL Workshop on Infectious Diseases, Melbourne, Australia, 16 October 2018

Interfacing with EDCNet
Dimech W
NRL, Melbourne, Australia
Presented at the Quality Assurance Users' Group Meeting, 35th Annual NRL Workshop on Infectious Diseases, Melbourne, Australia, 16 October 2018

Interesting QC Cases
Vincini G
NRL, Melbourne, Australia
Presented at the Quality Assurance Users' Group Meeting, 35th Annual NRL Workshop on Infectious Diseases, Melbourne, Australia, 16 October 2018

Solving the EQAS Paradox: Can they be Low-Cost and High-Quality?
Cabuang, L
NRL, Melbourne, Australia
Presented at the 35th Annual NRL Workshop on Infectious Diseases, Melbourne, Australia, 16-18 October 2018

Westgard Rules – Appropriate or Are We Jumping at Shadows?
Dimech W
NRL, Melbourne, Australia
Presented at the 35th Annual NRL Workshop on Infectious Diseases, Melbourne, Australia, 16- 18 October 2018

QC Case Studies - How QC Makes the (Testing) World go Round
Vincini, G
NRL, Melbourne, Australia
Presented at the 35th Annual NRL Workshop on Infectious Diseases, Melbourne, Australia, 16-18 October 2018

Community Based HIV Screening in the Philippines
Wilson, K
NRL, Melbourne, Australia
Presented at the 35th Annual NRL Workshop on Infectious Diseases, Melbourne, Australia, 16-18 October 2018

QC in the Serology Laboratory
Vincini, GA
NRL, Melbourne, Australia
Presented at the DiaSorin Users' Group Meeting, Melbourne, Australia, 31 October 2018

Assuring Quality and Building Trust: Providing High Quality, Lost Cost EQAS at Both Laboratory and Community Settings
Cabuang L
NRL, Melbourne, Australia
Presented at the SLIPTA/SLMTA Symposium, Abuja, Nigeria, 9 December 2018

A Roadmap to Establishing a National EQA Program
Dimech W
NRL, Melbourne, Australia
Presented at the SLIPTA/SLMTA Symposium, Abuja, Nigeria, 9 December 2018

Understanding Quality Control for Infectious Disease Testing
Dimech W
NRL, Melbourne, Australia
Presented at the ASLM Quality Control Workshop, Abuja, Nigeria, 9 December 2018

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Retrieved from https://www.avert.org/professionals/hiv-around-world/asia-pacific-/myanmar#Key_affected_populations_in_Myanmar

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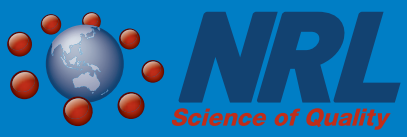

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