



the scope

the challenges

the possibilities

**NRL has been in existence for over 30 years and was originally established as part of the Australian Government's HIV/AIDS Strategy to evaluate HIV test kits and adjudicate on the interpretation of HIV test results.**

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

In achieving this, NRL's scope is extensive, providing a number of services that individually and collectively support its mission.

**Such services include:**

- Pre-market evaluation of in vitro diagnostic devices (IVDs)
- High standard quality assurance programmes
- Training and mentorship for the sustainability of self-sufficient laboratory systems
- Patient sample reference testing
- TGA-licensed screening of samples collected from blood and tissue donors



**Director's Report**

**Welcome to NRL's 2016 Annual Report.**

**NRL made some important changes during 2016, in our internal structure and operations, and in the major collaborations that help us to deliver our services.**

NRL has collaborative arrangements with manufacturers who produce the Quality Control (QC) samples used in our QConnect™ QC programme. Eleven years ago, we entered into a contract with AcroMetrix to produce QC samples; this collaboration continued when AcroMetrix merged with Life Technologies Corporation, which was subsequently acquired by Thermo Fisher Scientific. The contract with Thermo Fisher ended in April 2016, after which NRL started working with two new manufacturers. DiaMex GmbH in Germany now produces the QConnect™ serology range of QC samples, and Exact Diagnostics LLC in USA produces the QConnect™ range of molecular controls. With the change in manufacturers, we took the opportunity to further customise and expand the range of QC samples that we offer.

Changing QC manufacturers, while ensuring ongoing supply and consistent quality, was a significant undertaking and I owe particular thanks to NRL's QC and Communications teams for achieving this with minimal disruption.

After several years of outsourcing, NRL in 2016 resumed in-house manufacture of its serology External Quality Assessment Scheme (EQAS) panels. Outsourcing was originally undertaken because NRL had neither the equipment nor the manpower to manufacture panels for an increasing number of EQAS participants. Outsourcing EQAS panel

manufacture was originally cost-effective, but recently became unsustainable because of price rises. We therefore employed a small group of people to establish our new Production team, who successfully manufactured their first round of serology EQAS panels ... 28,000 vials ... by the end of 2016.

The Testing team has moved towards more automated testing processes, partly in response to changes in the regulation of the IVDs, and partly because of increasing numbers of specimens for testing. NRL implemented two fully automated testing platforms in 2016, one to handle the majority of serology testing and the other to manage our molecular testing requirements. Now fully validated and implemented, these instruments are creating significant testing efficiencies.

Overall, NRL's staff numbers increased by two in 2016. We were sorry to say farewell to Stirling Dick and Steve Gilmour, who had been with us for nine and six years respectively. Anna Swierc-Lech was recruited as the leader of the new Production team and Jaya Prada Chaparala as her assistant. We recruited Jenny Catimel and Sadaf Mohiuddin to assist with increased workloads in the Testing and Evaluations teams respectively. Our former highly valued staff member Sandy Walker re-joined the Training team on a casual basis.

**Susan Best**

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

2016

02 About NRL 03 Director's Report 04 Our Global Reach 06 NRL Training 07 NRL Quality Assurance 08 This is my NRL 10 NRL Evaluations 11 NRL Testing 12 NRL Workshops 13 Presentations 14 Publications



Our Global Reach



stakeholders

NRL gratefully acknowledges those organisations that have provided support to NRL services and individuals throughout 2016.

- Australasian Society for HIV Medicine
- Australian Government Department of Health
- Australian Red Cross Blood Service
- Biotherapeutics Association of Australasia
- Blood and Tissue Donation Services
- Foundation of Innovative New Diagnostics
- ICAP at Columbia University, Myanmar
- Infectious diseases testing laboratories
- Institutions for providing samples for NRL programmes
- International Plasma Fractionation Association
- IVD Manufacturers
- Ministry of Health and Sports, Myanmar
- National AIDS Program, Myanmar
- National Association of Testing Authorities, Australia
- National Health Laboratory, Myanmar
- New Zealand Blood Service
- One World Accuracy, Canada
- Other selected QA programme providers
- Republican AIDS Centre, Tajikistan
- St. Vincent's Institute of Medical Research
- The Global Fund to fight AIDS, TB and Malaria
- Therapeutic Goods Administration
- United Nations Development Program, Tajikistan
- United States Centers for Disease Control and Prevention
- United States President's Emergency Plan for AIDS Relief
- World Health Organization Headquarters and Regional Offices
- World Health Organization Member States

NRL Training

High quality testing is essential in achieving accurate diagnosis and appropriate treatment for patients.

Accomplishing this in under-resourced laboratories lacking basic processes and quality assurance can be challenging. NRL understands the impact of such limitations and can provide a range of training and mentoring services to help overcome this.

The NRL Training team provides advocacy, customised training and mentorship based on identified needs in a culturally sensitive manner. NRL is a World Health Organization (WHO) Collaborating Centre and the NRL Training team are sought as consultants or technical experts by Ministries of Health, WHO and similar agencies to participate in countries' current programme reviews or in the development of technical guidance or recommendations.

2016 highlights

Training

Through a cooperative agreement between United States Centers for Disease Control and Prevention (CDC); and the Foundation of Innovative New Diagnostics (FIND) and under the auspices of the United States President's Emergency Plan for AIDS Relief (PEPFAR), NRL was involved in Strengthening of HIV Laboratory Testing and Quality Management Systems in Myanmar

Supported by the United Nations Development Program (UNDP) Tajikistan, NRL provided technical assistance for the implementation of EQAS for the Republican AIDS Centre HIV/AIDS Laboratory Network in Tajikistan

Consultancies

NRL provided technical assistance at the Second Intercountry Meeting of the Directors of Public Health Laboratories regarding the Eastern Mediterranean Region Strategic Framework for Strengthening Health Laboratory Services 2016-2020

As part of the Asia-Pacific Economic Cooperation(APEC) 2020 Blood Supply Chain Roadmap to improve the safety and sustainability of the blood supply in APEC economies, NRL participated in the 2nd Partnership Training Network Workshop which focused on "Leadership's Role in Advancing Good Manufacturing Practice in Blood Centers". NRL provided guidance on major laboratory elements of Quality Systems and Good Manufacturing Practice from the leadership perspectives and systems that need to be in place for effective delivery of safe and consistent blood and blood products

NRL Quality Assurance

NRL sets the standard for a range of comprehensive Quality Assurance (QA) services that include External Quality Assessment Schemes (EQAS), Quality Control (QC) and Specificity Monitoring programmes for infectious diseases testing.

Laboratories from around the world participate in NRL QA programmes to assure the quality of laboratory testing processes and IVDs in use.

NRL EQAS assess the integrity of the entire testing process from sample receipt through to administration of test results to identify and resolve any potential sources of error, ultimately preventing misdiagnosis.

NRL's QConnect™ is a complete and integrated QC programme to monitor the precision and accuracy of test results. Specifically designed QC samples are optimised for testing systems

and the internet application EDCNet allows laboratories to independently assess variation of results in real time.

Specificity Monitoring is a specialist service offered by NRL and is utilised to identify rates of false positive reactivity that can be attributed to different IVD lots or laboratory practices. Especially relevant to Blood Transfusion Services, Specificity Monitoring is a mechanism to ensure false positive reactivity is minimised and unnecessary wastage of blood and blood products is reduced.

2016 highlights

An HTLV EQAS pilot programme was successfully completed by laboratories who perform HTLV DNA qualitative and/or quantitative molecular testing

An HPV Molecular EQAS pilot programme for the qualitative detection of HPV was successfully delivered to a small number of Australian participants

A Leptospirosis molecular EQAS pilot programme was successfully completed by thirteen participants world-wide who perform Leptospirosis DNA qualitative testing

A Dried Tube Sample HIV-1 Viral Load EQAS became available. This low cost EQAS was specifically designed to service point of care testing facilities in resource limited settings

services delivered

5

Countries that received NRL Training services

6

Training Projects

4

Consultancies

services delivered

2286

EQAS Subscriptions

1039

QConnect Members

20

Countries using QConnect QCs

24

EQAS Available

21

QConnect QCs Available



this is my **NRL**



**Sadaf** I am a member of the Evaluations team at NRL and our work involves assessment of IVDs before pre-qualification by WHO. My time is normally divided between working in the laboratory and performing desk top work which I greatly enjoy. My position also means I usually work on short term and long term projects which provide a lot of variety. I joined NRL in 2016 and this is my first job in Australia (having migrated from France) so this year has been one of discovery for me – a new job, meeting new colleagues and living in an entirely different country! Working at NRL has not only helped me improve my English but has given me a lot of confidence, expanded my knowledge and showed me what good teamwork is.



**Alison** I am the Executive Assistant to NRL's Director Susan Best and recently also became a part of the Quality Team as a Quality Officer. The things I enjoy most about my job are the colleagues I work with every day and the diversity of my dual roles. I am especially proud of transitioning from a purely administrative role to becoming an integral member of the Quality Team. As part of this I conducted six internal audits which greatly expanded upon my knowledge in quality and I continue to learn more each day. Through my time at NRL I have learnt and valued that communication and respect for one another is essential for all systems to run efficiently.



**Anna** My role is to lead a newly established Production Laboratory at NRL that is responsible for the manufacture of Serology and NAT EQAS proficiency panels for national and international distribution. I'm very proud of the Production team, especially for the dedication and passion demonstrated towards their work and personally I enjoy the fast paced environment, challenges, continuous improvement and growth of the organisation. NRL provides a work environment that is comprised of highly professional colleagues who are able to work towards the company's common goals.



staff

Nilukshi Arachchi  
Lena Arvanitis  
Thein Thein Aye  
Susan Best

Susie Braniff  
Penny Buxton  
Liza Cabuang  
Jing Jing Cai

Roderick Chappel  
Stirling Dick  
Wayne Dimech  
Cathy Dunkley

Stephen Gilmour  
Helen Hasler  
Marina Karakaltsas  
Geraldine Kong



**Roderick** As Quality Manager, I coordinate NRL's quality management system and I am part of NRL's Management Team, which manages NRL's strategic approaches and the development of its role. In terms of quality management, I am proud of the way the Quality Team operates, and how we have been able to develop and improve NRL's quality systems over my 18 years at NRL. Disease diagnosis and disease management are highly dependent on the quality of laboratory testing. In a range of ways, NRL contributes to keeping laboratory testing for infectious disease at the best possible standard. I enjoy working in an organisation that trusts and encourages its staff, puts a high value on teamwork, and is making an important contribution to human health and wellbeing.



**Terri** As a member of the NRL Testing and EQAS Teams my current position is wonderful because I get to split my time across these two areas which offers a good balance between theoretical scientific applications and practical bench work. My newer role in the EQAS team commenced in 2016 and has allowed me to design and manufacture panels for new projects. As part of this, I enjoy interacting and communicating with professionals in the same field and I'm proud to participate in projects that aim to improve the quality of test results for NRL customers.



**Marlene** In 2016, as a member of the Training team, I took part in a project with the United Nations Development Program (UNDP) Tajikistan on providing assistance for the implementation of EQAS for the Republican AIDS Centre HIV/AIDS Laboratory Network. In my job I travel extensively and am afforded opportunities to visit places such as Tajikistan. These types of assignments are always interesting and educational because they are places I have not previously explored. The Workshop trainees we meet are always very welcoming and appreciate the opportunity to collaborate with other like-minded scientists in their field which I find very rewarding.



Sally Land  
Tamara McDonald  
Alison Natoli  
Louie Opatinov

Jaya Prada Chaparala  
Shannon Curley  
Terri Sahin  
Kathy Smeh

Roseena Taqi  
John Tomasov  
Frank Torzillo  
Rosanna Torzillo

Marlene Tschaepe  
Joe Vincini  
Kim Wilson  
Sadaf Mohiuddin

Jenny Catimel  
Anna Swierc-Lech  
Sandy Walker



NRL Evaluations

The analytical performance of IVDs is an essential part of an effective testing strategy as a means to ensure high quality test results.

The performance of an IVD through a laboratory based assessment provides a realistic expectation of how the IVD will perform relevant to local conditions using samples representative of the local population.

As an independent contractor, the NRL Evaluations team conducts assessments of IVDs by reviewing manufacturer's evidence to ensure key performance, quality and safety criteria are met and the evidence presented is scientifically sound.

In addition, the NRL Evaluations team conducts assessments of IVDs' laboratory performance on behalf of the World Health Organization (WHO) Prequalification of Diagnostics Programme. The aim of this programme is to increase accessibility to affordable and high quality diagnostic technologies for use in resource limited settings in WHO member states.

The NRL Evaluations team also provides customised panels comprised of predetermined, well characterised samples for use in assay validations or verifications.

2016 highlights

The NRL Evaluations team was contracted by WHO to conduct the performance evaluations of HCV IVDs for the WHO Prequalification Programme and produced a number of validation and verification panels

services delivered



NRL Testing

NRL offers validated testing strategies for quality test results ensuring accurate diagnosis. The NRL Testing team provide a range of specialised services including reference testing and TGA-licensed screening of blood and tissue donors for HIV, HBV, HCV, HTLV and Syphilis.

Through utilising testing strategies that include selective tests not widely used, NRL Testing services operate as a reference point for HIV, HCV and HTLV specimens whose status need to be resolved.

The NRL Testing team maintains an extensive Sample Bank of well characterised samples that are integral to the NRL Quality Assurance and Evaluations teams. NRL has Material Transfer

Agreements with Blood Transfusion Services by which plasma packs that were initially identified for discard are provided to NRL for use within its programmes.

The NRL Testing team undertakes contract testing in the form of projects and collaborations with a variety of organisations for epidemiological purposes and assessment of new IVDs.

2016 highlights

The NRL Testing team conducted a comparative study on serology IVDs used for the detection of the bacteria *Borrelia burgdorferi* which causes Lyme Disease. This project, funded by the Australian Department of Health used a novel approach to the evaluation of these IVDs and the outcomes will contribute important information and understanding of Lyme Disease testing in Australia

The NRL Testing team evaluated and implemented the DiaSorin LIAISON for serology diagnostic testing as an automated alternative to performing manual assays and as replacement for those that were no longer listed on the Australian Register of Therapeutic Goods

The NRL Testing team evaluated and implemented the Roche cobas 6800 which is an automated system that performs real time polymerase chain reaction based nucleic acid testing for diagnostic and blood screening purposes

services delivered



# NRL Workshops

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

NRL aims to provide a forum that allows the exchange of information and diverse perspectives among those working in this arena nationally and internationally.

### 2016 highlights

NRL held its second European **Workshop on Quality** in Lisbon on 24 May 2016, adjacent to the International Plasma Fractionation Association meeting. The Workshop was well attended with more than 50 registrants from thirteen different countries. There was a strong contingent from the host country Portugal; and registrants from regional blood screening and clinical laboratories as well as industry representatives and regulators. The Workshop allowed European participants of NRL EQAS and QC programmes to discuss their experience and learn from others in the same region.

The **NRL Workshop on Molecular Diagnostics 2016** was held in Melbourne, Australia from 17-18 October 2017. Only in its second year, this meeting attracted 135 delegates (a 20% increase in the number attending in 2015) from eight countries including China, South Korea, Hong Kong and New Zealand. The programme entailed presentations on Respiratory Pathogens in Animals and Humans,

Molecular Methods Revolutionising Microbiology, New Technologies, STI Testing, Hepatitis and HIV. The diversity of presentations and organisations represented ensured the meeting catered to a cross section of delegates providing the most up to date information in this rapidly expanding field.

The **33rd Annual NRL Workshop on Infectious Diseases** was held in Melbourne, Australia from 18-20 October 2017. NRL had two international speakers- Dr Mick Mulders from the World Health Organization, Geneva, speaking on vaccine preventable diseases and Dr Jose Levi from the Institut of Tropical Medicine, Sao Paulo, presenting on the epidemiology of arboviral diseases among blood donors. There were also three national speakers discussing vaccine preventable diseases and malaria. Additional Workshop sessions focused on Mosquito-borne Infections, the Burnet Institute Access Project, Hepatitis and HIV; Quality Assurance, Regulatory Activities and General Serology. Overall there were 145 delegates from seven countries which included Singapore, Brazil and Switzerland, in attendance.

services delivered

330 Total number of delegates who attended NRL Workshops

18 Number of countries represented by delegates attending NRL Workshops

# Professional Presentations

## Donor Screening in the Region

Vincini G  
NRL, Melbourne, Australia  
Presented at the IPFA Asia Pacific 2016 Workshop on Plasma Quality and Supply  
8-9 March 2016  
Taipei, Taiwan

## What is Quality?

Best S  
NRL, Melbourne, Australia  
Presented at the IPFA Asia Pacific 2016 Workshop on Plasma Quality and Supply  
8-9 March 2016  
Taipei, Taiwan

## NRL QConnect

Buxton P & Vincini G  
NRL, Melbourne, Australia  
Presented at the 2016 DiaSorin Infectious Disease Scientific Symposium  
7-9 March 2016  
Sydney, Australia

## A 16-Year Review of Seroprevalence Studies on Measles and Rubella

Dimech W  
NRL, Melbourne, Australia  
Presented at SoGAT 2016, Royal College of Physicians  
6-8 June 2016  
London, UK

## In-field Evaluation of ViveSTM Sample Storage and Transportation Device

Land S  
NRL, Melbourne, Australia  
Presented at the NRL Workshop on Molecular Diagnostics 2016  
17-18 October 2016  
Melbourne, Australia

## Mid-Year Summary of the CTNG NAT EQAS: Observations from Test Events1 and 2, 2016

Cabuang L  
NRL, Melbourne, Australia  
Presented at the NRL Workshop on Molecular Diagnostics 2016  
17-18 October 2016  
Melbourne, Australia

## Appropriate Use of International Standards for Infectious Diseases

Vincini G  
NRL, Melbourne, Australia  
Presented at the 33rd Annual NRL Workshop on Infectious Diseases  
18-20 October 2016  
Melbourne, Australia

## The CMV Global Collaboration Study for Molecular Testing

Cabuang L  
NRL, Melbourne, Australia  
Presented at the 33rd Annual NRL Workshop on Infectious Diseases  
18-20 October 2016  
Melbourne, Australia

## Laboratory Strengthening for HIV Testing Services in Myanmar

Braniff S  
NRL, Melbourne, Australia  
Presented at the 33rd Annual NRL Workshop on Infectious Diseases  
18-20 October 2016  
Melbourne, Australia

## Gonorrhoea epidemiology in the male population (2011-2014) in Victoria, Australia informed by the Australian Collaboration for Coordinated Enhanced Sentinel Surveillance (ACCESS)

Wilkinson AL1,2, Bowring A1, Bartnik N1, Asselin J1, van Gemert C1,2, El-Hayek C1, Fairley C,3,4, Chow E3,4, Stoové M1,2, Guy R5, Dimech W6, Donovan B5, Hellard M1,2,7, on behalf of the ACCESS Collaboration

1. Centre for Population Health, Burnet Institute, 85 Commercial Rd, VIC 3004, Australia.

2. School of Public Health and Preventive Medicine, Monash University, Alfred Hospital, Commercial Rd, Melbourne VIC 3004, Australia.

3. Melbourne Sexual Health Centre, Alfred Health, 580 Swanston St, Carlton VIC 3053, Australia.

4. Central Clinical School, Faculty of Medicine, Nursing and Health Sciences, Monash University, Alfred Hospital, Commercial Rd, Melbourne VIC 3004, Australia

5. The Kirby Institute, UNSW Australia (University of New South Wales), Sydney, NSW 2052, Australia.

6. National Reference Laboratory, 4th Floor Healy Building, 41 Victoria Parade, Fitzroy VIC 3065, Australia.

7. Infectious Disease Department, Alfred Health, Alfred Hospital, Commercial Rd, Melbourne Vic. 3000, Australia

Presented at the Australasian Sexual Health Conference

14-16 November 2016  
Adelaide, Australia

## Advance Blood Screening Quality Standards

Vincini G  
NRL, Melbourne, Australia  
Presented at the Abbott Diagnostic (Transfusion Medicine) Leading Through Transformation-Transforming Blood and Plasma Screening Solutions Meeting  
9 December 2016  
Bangkok, Thailand



# Publications

Parsons MS, Madhavi V, Ana-Sosa-Batiz F, Center RJ, **Wilson K**, Bunupuradah T, Ruxrungtham K, Kent SJ. 'Seminal plasma anti-HIV antibodies trigger antibody-dependent cellular cytotoxicity: Implications for HIV transmission', *J Acquir Immune Defic Syndr*. 2016 Jan 1; 71(1):17-23.

**Dimech W**, Grangeot-Keros L, Vauloup-Fellous C. 'Standardization of Assays That Detect Anti-Rubella Virus IgG Antibodies', *Clin Microbiol Rev*. 2016 Jan; 29(1):163-74.

**Dimech W**. 'Where to Now for Standardization of Anti-Rubella Virus IgG Testing', *J Clin Microbiol*. 2016 Jul; 54(7):1682-3.

**Dimech W**, Mulders MN. 'A 16-year review of seroprevalence studies on measles and rubella', *VACCINE*. 2016 Jul 29; 34(35):4110-8.

**Dimech W**, Mulders MN. 'A review of testing used in seroprevalence studies on measles and rubella', *VACCINE*. 2016 Jul 29; 34(35):4119-22.

Einsiedel L, Woodman RJ, Flynn M, **Wilson K**, Cassar O, Gessain A. 'Human T-Lymphotropic Virus type 1 infection in an Indigenous Australian population: epidemiological insights from a hospital-based cohort study', *BMC Public Health*. 2016 Aug 15; 16:787.

Mark Shephard, Anne Shephard, **Wayne Dimech** and **Susan Best**. "Quality Management of Point-of-Care Testing Devices." *A Practical Guide to Global Point of Care Testing*. Ed. Mark Shephard. Australia: CSIRO Publishing, 2016. 54-65. Print

**Susan Best, Wayne Dimech, Roderick Chappel**. "Best Practice Laboratory Testing for Transfusion Transmissible Infections." *A Textbook on Laboratory and Clinical Transfusion Medicine, Volume 2: Basics of Blood Bank Practices (Process Control)*. Ed. Nabajyoti Choudhury, Ed. Zarin Bharucha. NY: Nova Science Publishers, 2016. Print





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