



ANNIVERSARY





In 1985, NRL 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. Thirty years later, it remains a non-profit organisation with expertise that has expanded greatly both in scope and reach. NRL provides:

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

NRL's emphasis on these key areas is integral to supporting its mission: To promote the quality of tests and testing for infectious diseases globally.

NRL exists for the benefit of the public as it strives to achieve its goal of supporting laboratories in Australia and internationally for the diagnosis and management of human infectious disease.

NRL

1985

2015

DIRECTOR'S REPORT

Welcome to NRL's 2015 Annual Report. 2015 marked the 30th anniversary of NRL's establishment. It has been a remarkable 30 years.

When I joined NRL, five years after its creation, it was suggested that the organisation would become redundant within a few years, because HIV tests and testing had improved significantly over the first years of NRL's existence. However the then Director of NRL, Dr Elizabeth Dax, saw the importance of quality assurance in laboratory testing, and had a vision to establish NRL as a key provider of quality assurance in Australia.

Over the years, NRL has progressively expanded its scope of activities to include programmes for infectious diseases other than those caused by blood borne viruses, and its influence now extends well beyond Australia's shores. The timeline on pages 6 and 7 shows the major highlights in NRL's activities and when these have occurred.

This report showcases the extent of NRL's quality assurance, evaluations, training and testing activities in 2015. In addition, there have been other major developments, two of which are described below.

- The Australian Government, recognising NRL's expertise in serology and in independent evaluation of serological tests, commissioned NRL to conduct an independent study of the serological tests used to detect antibodies to *Borrelia burgdorferi*, the organism that causes Lyme Disease. The existence of Lyme Disease in Australia has been a matter of scientific controversy and considerable public interest. Collaborating with laboratories in Australia,

UK, Germany and USA, NRL will seek to determine the effectiveness of the serological tests commonly used to test for Lyme Disease in Australia.

- Philanthropic donations, from the Helen Macpherson Smith (HMS) Trust and the Marian and E.H. Flack Trust, enabled St Vincent's Institute of Medical Research (SVI) to build and fit out a chronic disease Biobank, which opened in September 2015. The Biobank is housed at NRL. SVI, NRL's host institution, recognised the synergy between researchers' need to have access to well curated specimens and NRL's expertise in delivering the required services. The specimens in the Biobank will be mainly blood derivatives, and will facilitate research into a number of diseases including type 1 diabetes, viral hepatitis, cirrhosis and liver cancer, and heart disease.

We said farewell in 2015 to two of our long-standing staff members. Kim Richards had been with NRL for 13 years and her partner Mark Lanigan for 8 years. Kim accepted a position at WHO Headquarters in Geneva as a Good Manufacturing Practice (GMP) inspector. Mark, Kim and their two daughters left for Geneva in November.

We were fortunate to recruit Shannon Curley to the role of Communications Officer. Apart from these changes, NRL's staff remained stable, as it has done for many years.

SUSAN BEST

-30 YEARS-

NRL

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GLOBAL REACH



COUNTRIES USING NRL'S SERVICES



NRL

QUALITY ASSURANCE

Having over 20 years' experience, the NRL Quality Assurance team sets the global standard in offering External Quality Assessment Schemes (EQAS), Quality Control (QC) services and Specificity Monitoring programmes.

NRL EQAS assess the integrity of an entire testing process to identify and resolve problems. Laboratories from around the world voluntarily participate in NRL EQAS to assure the quality of their testing processes and test kits used.

NRL's QConnect™ is a multi-faceted QC programme to monitor the precision and accuracy of test results. Through using specifically designed QC samples and the internet based application EDCNet, laboratories can assess the variation of their results in real time, providing an independent mechanism to assure reliable test results.

Uniquely offered by NRL, the Specificity Monitoring programme identifies rates of false positive reactivity that can be attributed to different test kit batches or laboratory practices. Specificity Monitoring data are entered into and analysed by EDCNet. Especially relevant to Blood Transfusion Services, NRL's Specificity Monitoring programme seeks to ensure that false positive reactivity is minimised meaning unnecessary wastage of blood and blood products is reduced.

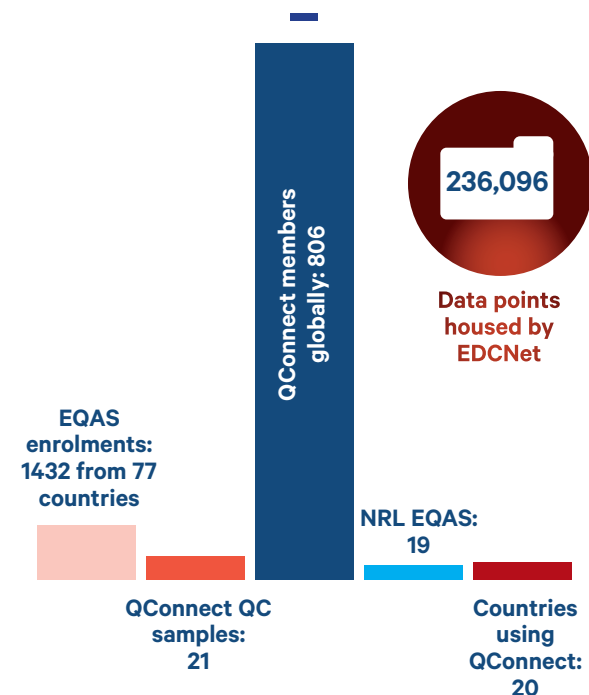
2015 HIGHLIGHTS

An HIV Tropism EQAS was implemented in 2015 for laboratories that perform genotypic HIV tropism testing to determine which co-receptor the HIV uses to enter a cell within a host.

The QConnect™ range was expanded to include QC samples for Rubella IgG and IgM antibodies, CMV IgG and IgM antibodies, Toxoplasma IgG and IgM antibodies and EBV IgG and IgM antibodies.

-30 YEARS-

SERVICES DELIVERED



NRL

TRAINING

High quality testing underpins accurate diagnosis and appropriate treatment for patients. Each year, millions of tests are performed in under-resourced laboratories lacking basic processes and quality assurance. Through understanding these limitations NRL provides a range of training and consultancy services.

The NRL Training team aims to develop the capacity of laboratories and laboratory systems, globally. Specifically, NRL provides high quality education through its Sustainable Training, Education and Partnerships (STEPs) programme thereby providing advocacy, mentorship and customised training delivered in a culturally sensitive manner.

Through its status as a World Health Organization (WHO) Collaborating Centre and its reputation for understanding laboratories' needs in resource limited settings, NRL staff are often sought as consultants or technical experts by ministries of health, WHO or similar agencies. Under these auspices, NRL is called upon to participate in countries' relevant programme reviews or develop technical guidance or recommendations.

2015 HIGHLIGHTS

TRAINING

On behalf of the WHO South East Asian and Western Pacific Regional Offices and in collaboration with the US Centers for Disease Control, NRL conducted an inter-country workshop in Cambodia to 'Improve the Quality of HIV and Syphilis Point-of-Care Testing'.

Supported by the WHO South East Asian Regional Office, NRL provided an inter-country training session on 'Capacity Building in WHO Measles and Rubella Laboratory Accreditation' in Bangkok, Thailand.

SERVICES DELIVERED



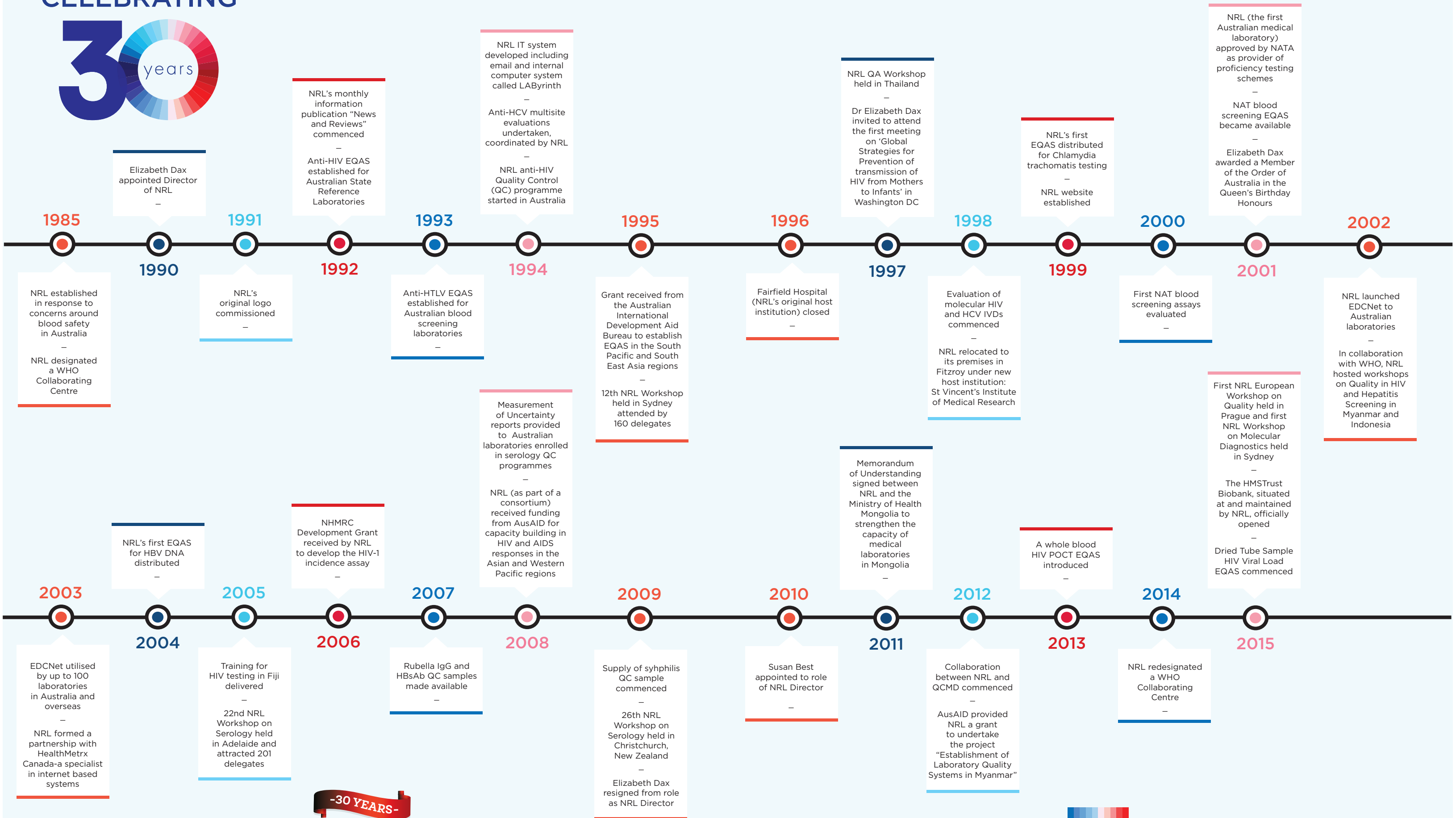
CONSULTANCIES

In collaboration with the Ministry of Health of the Republic of Azerbaijan and the Global Fund to fight AIDS, TB and Malaria, NRL reviewed and made recommendations regarding systems for HIV testing in Azerbaijan.

NRL was commissioned by the Viet Nam country office of WHO to conduct a review of HIV point-of-care and confirmatory testing systems for HIV, diagnostic testing for Hepatitis B and C; and blood safety systems in Viet Nam.



CELEBRATING



-30 YEARS-



NRL



EVALUATIONS

The NRL Evaluations team recognises that analytical performance of IVDs is an essential part of an effective testing strategy that will ensure high quality test results.

The performance of an IVD during a laboratory based evaluation provides a realistic expectation of how that test kit will perform relevant to local conditions and samples representative of the local population.

As an independent contractor, the NRL Evaluations team conducts assessments of IVDs for infectious diseases. These are achieved through reviewing manufacturers' dossiers of evidence to ensure that key performance quality and safety criteria are met, and that the evidence presented and the means by which it was gathered are scientifically sound.

Similar assessments are conducted by the NRL Evaluations team under the auspices of the WHO Prequalification of Diagnostics Programme. This programme aims to increase accessibility to affordable, high quality diagnostic technologies for use in resource limited settings. As part of this programme, WHO also inspects facilities at which IVDs being assessed for prequalification are manufactured with the NRL Evaluations team providing technical expertise during such inspections as necessary.

SERVICES DELIVERED



2015 HIGHLIGHTS

NRL was commissioned to draft the document "Establishing stability of an in vitro diagnostic for WHO Prequalification", contributing to the WHO's Technical Guidance Series for IVD Manufacturers.

-30 YEARS-

NRL



TESTING

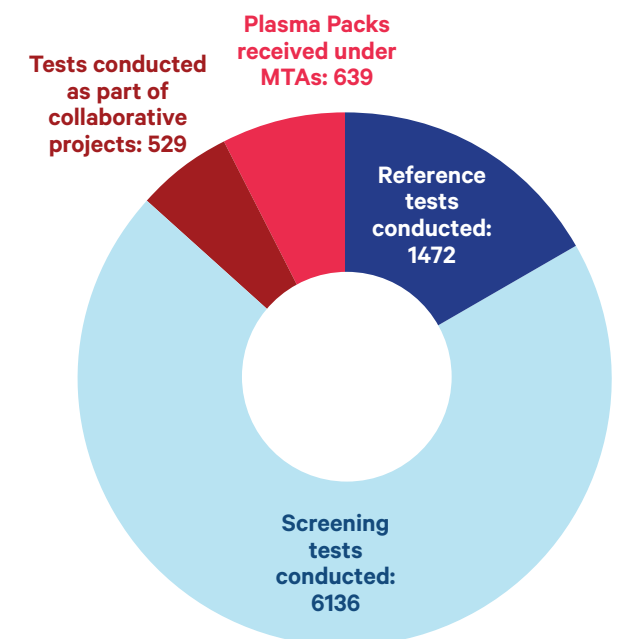
The NRL Testing team provides a range of validated services including TGA licensed screening of blood and tissue donors for HIV, HBV, HCV, HTLV and Syphilis.

In addition, NRL has designed and validated testing strategies for HIV, HCV and HTLV reference testing for samples whose status needs to be resolved.

The NRL Testing team maintains and characterises an extensive repository (Sample Bank) of samples that are fundamental to both the NRL Quality Assurance and NRL Evaluations teams. With Blood Transfusion Services as partners, NRL has Material Transfer Agreements (MTAs) through which plasma packs that have been identified for discard are provided to NRL for use in its programmes.

The NRL Testing team also undertakes contract testing for collaborative scientific projects with a variety of organisations for epidemiological studies and assessments of new test kits. Such projects can include sample types like Dried Blood Spots for HCV detection and HIV determination on oral fluids.

SERVICES DELIVERED



2015 HIGHLIGHTS

NRL undertook responsibility for the batch release of HIV and Syphilis rapid IVDs for Victorian point-of-care testing sites. Batch release involves testing of new batches of IVDs to confirm that their performance is consistent from batch to batch.

NRL participated in the WHO/NIBSC Collaborative Study to Evaluate the Candidate First Antibody Reference Panel for Donor Screening Assays that Detect Antibodies to Human T-Lymphotropic Virus Type I (HTLV-I) and Type II (HTLV-II).

The Helen Macpherson Smith (HMS) Trust Biobank was launched at NRL. The HMS Trust Biobank is an initiative of NRL's Host Institution, St Vincent's Institute of Medical Research (SVI). The Biobank is intended to provide researchers at St Vincent's Hospital Melbourne and beyond, with high quality samples for research into chronic diseases including hepatitis.



NRL



NRL's Workshops are forums designed to facilitate learning and discussion of the challenges laboratories face in infectious diseases testing.

These challenges are continually evolving with technology, emerging and re-emerging pathogens. The Workshops' areas of focus include regulation of laboratories, regulation of IVDs, laboratory quality systems and quality assurance; new molecular and serology technologies; and laboratory challenges faced in WHO Member States.

The NRL Workshops' formats are particularly designed to encourage younger scientists to present their work in supportive environments. NRL's networks are broad, which means we can secure national and international experts' attendance at our Workshops. According to the feedback received, NRL's Workshops are considered premier events, particularly in the Australian infectious diseases conference calendar.

SERVICES DELIVERED



2015 HIGHLIGHTS

The first NRL European Workshop on Quality was held in Prague, Czech Republic on 19 May. Alongside the International Plasma Fractionators Association meeting, the Workshop allowed many European participants in NRL's EQAS and QC programmes to discuss their experiences around quality assurance whilst liaising with and learning from others in the region.

The inaugural NRL Workshop on Molecular Diagnostics was held in Sydney, Australia from 27-28 July. This Workshop was initiated to focus on the technical aspects of molecular diagnostics, filling a gap in the Australian meeting calendar. NRL welcomed guest speakers discussing human papillomavirus and massive parallel sequencing; and held a Discussion Forum to enable conversations around quality assurance programmes for specialised and reference testing.

NRL also held the 32nd Annual NRL Workshop on Infectious Diseases in Sydney, Australia from 28-31 July. The Workshop programme included experts discussing topics around the response to Ebola in the developed world, infection and cancer, HIV point-of-care testing and uses for HIV sequence analysis.



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-30 YEARS-



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1985

2015

PUBLICATIONS & PRESENTATIONS

PUBLICATIONS

Increased testing for *Neisseria gonorrhoeae* with duplex nucleic acid amplification tests: implications for surveillance

Donovan B, Dimech W, Ali H, Guy R, Hellard M on behalf of the ACCESS Collaboration
Sex Health 2015 Feb 9. Epub 2015 Feb 9.

Visual and Statistical Assessment of Quality Control Results for the Detection of Hepatitis-B Surface Antigen among Australian Blood Donors

Wand H¹, Dimech W², Freame R³ and Smeh K²
¹ *The Kirby Institute, University of NSW, Sydney, NSW 2052, Australia.*

² *NRL, 4th Floor, Healy Building, 41 Victoria Parade, Fitzroy, VIC 3065, Australia.*

³ *Australian Red Cross Blood Service, 44 Musk Ave. Kelvin Grove, Brisbane, QLD 4059, Australia.*

Annals of Clinical and Laboratory Research, 2015 Vol. 3 No. 2:8.

PRESENTATIONS

Review of serology tests for Lyme Disease

Best S
Presented at the Lyme Disease Patient's Day
26 March 2015
London, UK

QConnect and EDCNet

Vincini G
Presented at the Malaysian Blood Service Laboratory Network Workshop
31 March -1 April 2015
Kuala Lumpur, Malaysia

Performance of DiaSorin assays in NRL's Serology EQAS

McDonald T, Smeh K and Vincini J
Presented at the DiaSorin User Group Meeting
11-13 May 2015
Gold Coast, Australia

NRL QConnect "What's New?"

McDonald T and Vincini J.
Presented at the DiaSorin User Group Meeting
11-13 May 2015
Gold Coast, Australia

Laboratory Capacity Development in Myanmar

Best S and Tin H
Presented at the Australian Myanmar Institute Conference
10-12 July 2015
Yangon, Myanmar

HIV Dried Tube Samples: A Novel Approach for HIV Viral Load EQAS Provision

Cabuang L, Dimech W, Wilson E, Vincini G, and Best SJ
Presented at the NRL Workshop on Molecular Diagnostics
27-28 July 2015
Sydney, Australia

SoGAT and the Standardisation of Testing

Vincini G
Presented at the NRL Workshop on Molecular Diagnostics
27-28 July 2015
Sydney, Australia

HCV Genotyping External Quality Assessment Scheme, 2012-2014

Taqi RS, Cabuang LM, Best SJ
Presented at the NRL Workshop on Molecular Diagnostics
27-28 July 2015
Sydney, Australia

Assessment of ViveST™ Sample Storage and Transportation Device

Land S
Presented at the NRL Workshop on Molecular Diagnostics
27-28 July 2015
Sydney, Australia

QConnect Limits and their impact on Investigations

Karakaltsas M
Presented at the 32nd Annual NRL Workshop on Infectious Diseases
28-31 July 2015
Sydney, Australia

HTLV Western Blot Interpretation Criteria

Wilson K and Stirling D
Presented at the 32nd Annual NRL Workshop on Infectious Diseases
28-31 July 2015
Sydney, Australia

HIV-1 Western Blot Interpretation

Buxton P, Smeh K, Vincini G, Wilson K and Best SJ
Presented at the 32nd Annual NRL Workshop on infectious Diseases
28-31 July 2015
Sydney, Australia

NRL Blood Screening EQAS - Update 2014

Vincini G
Presented at the 32nd Annual NRL Workshop on Infectious Diseases
28-31 July 2015
Sydney, Australia

NRL Whole Blood EQAS for HIV Point-of-care Testing

Braniff S, Vincini G, Wilson K and Best SJ
Presented at the 32nd NRL Workshop on Infectious Diseases
28-31 July 2015
Sydney, Australia

1380
NRL Website members

2006

NRL News Recipients

-30 YEARS-



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1985

2015

STAKEHOLDERS



NRL thanks those organisations that have provided support to NRL services and individuals throughout 2015.

-30 YEARS-



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