

THE SCOPE. THE CHALLENGES.
THE POSSIBILITIES.

**ANNUAL
REPORT
2014**

ABOUT NRL

In 1985, NRL was originally established as part of the Australian Government's HIV/AIDS Strategy to evaluate HIV testing and adjudicate on the interpretation of HIV test results. The organisation has remained a non-for-profit service as its area of expertise has expanded greatly.

NRL provides pre-market evaluation of test kits, high standard quality assurance programs, training for the sustainability of self-sufficient laboratory systems, patient sample reference testing and TGA-licensed screening of samples collected from blood and tissue donors.

**NRL's focus on these key areas underpins its mission:
To promote the quality of tests and testing for infectious diseases globally.**

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THE DIRECTOR'S REPORT 2014

During 2014, NRL continued to deliver quality assurance, testing and training services to existing and new clients. These included the Australian Government, national and international laboratories, blood and tissue banks, ministries of health, WHO, US Centers for Disease Control and other stakeholders. The year also brought some significant milestones.

The biennial International AIDS Conference, held in Melbourne in July 2014, provided NRL and partner organisations with an opportunity to dovetail and coordinate their activities. NRL brought 16 fellows from six countries to Australia to participate in a program designed to support emerging leaders in the fight against HIV. This resulted from collaboration with the Australasian Society for HIV Medicine (ASHM), and was supported by the Australian Department of Foreign Affairs and Trade.

These fellows - part of a group of about 200 delegates from Africa and the Asia Pacific region - each participated in an ASHM Leadership Course, the AIDS Conference, and a short course run by their respective Australian host organisation. The hosting of the AIDS Conference in Australia provided a once-in-a-decade chance for these synergistic activities.

The year 2014 was to have seen the completion of Australia's transition to the new in vitro diagnostic device (IVD) framework, but this was delayed by a year for the benefit of IVD sponsors and manufacturers. The new IVD framework, driven by a quest for global harmonisation, is designed to create efficiencies by taking into account the decisions of competent overseas regulatory authorities. Its implementation, however, has detrimental aspects, especially the loss from Australia of some specialised IVDs that are only used by few laboratories.

In November 2014, NRL was redesignated as a WHO Collaborating Centre for Diagnostics and Laboratory Support for HIV/AIDS and Other Blood-borne Infections. The redesignation application process allowed adjustment of the Collaborating Centre's terms of reference. These now include increased and more specific activities related to the WHO Prequalification of Diagnostics Programme.

On the staff front, Thu-Anh Pham resigned from NRL to start her own business just two months short of her 10-year anniversary, while John Tomasov reached his 20-year anniversary. There were no new staff appointments in 2014.

SUSAN BEST

NRL WORKSHOP

In 2014, NRL held the 31st Annual NRL Workshop on Infectious Diseases in Melbourne from 29 July-1 August.

The Workshop continued to facilitate the annual coming together of scientists, regulators, test kit manufacturers/sponsors and clinicians, with a primary focus on the challenges associated with the laboratory detection and diagnosis of infectious diseases.

Reviewing traditional techniques for pathogen diagnosis, diagnosing age-old infections in today's world, shining a light on Hepatitis B, the challenges in diagnosing retroviral infections and the relevance of molecular testing in current diagnostic pathology were all topics under the microscope at the 2014 Workshop.

With 162 delegates from 11 countries in attendance, NRL welcomed international guest speaker Ms Tasanee Sakuldamrongpanich who addressed 'Blood Transfusion System and Quality Assurance in Thailand'. The Workshop also hosted several national speakers renowned in their field.



Invited International Speaker

Ms Tasanee Sakuldamrongpanich
Deputy Director
National Blood Centre
The Thai Red Cross Society

Invited National Speakers

Dr Brendan Crockett
Staff Health Clinic
St. Vincent's Hospital Melbourne

Grant Hill-Cawthorne
Communicable Disease Epidemiology
School of Public Health
University of Sydney

Professor Robert Batey
Senior staff specialist
Sydney University and Flinders University
Alice Springs Hospital

Kevin Freeman
Supervising Scientist Serology
Royal Darwin Hospital

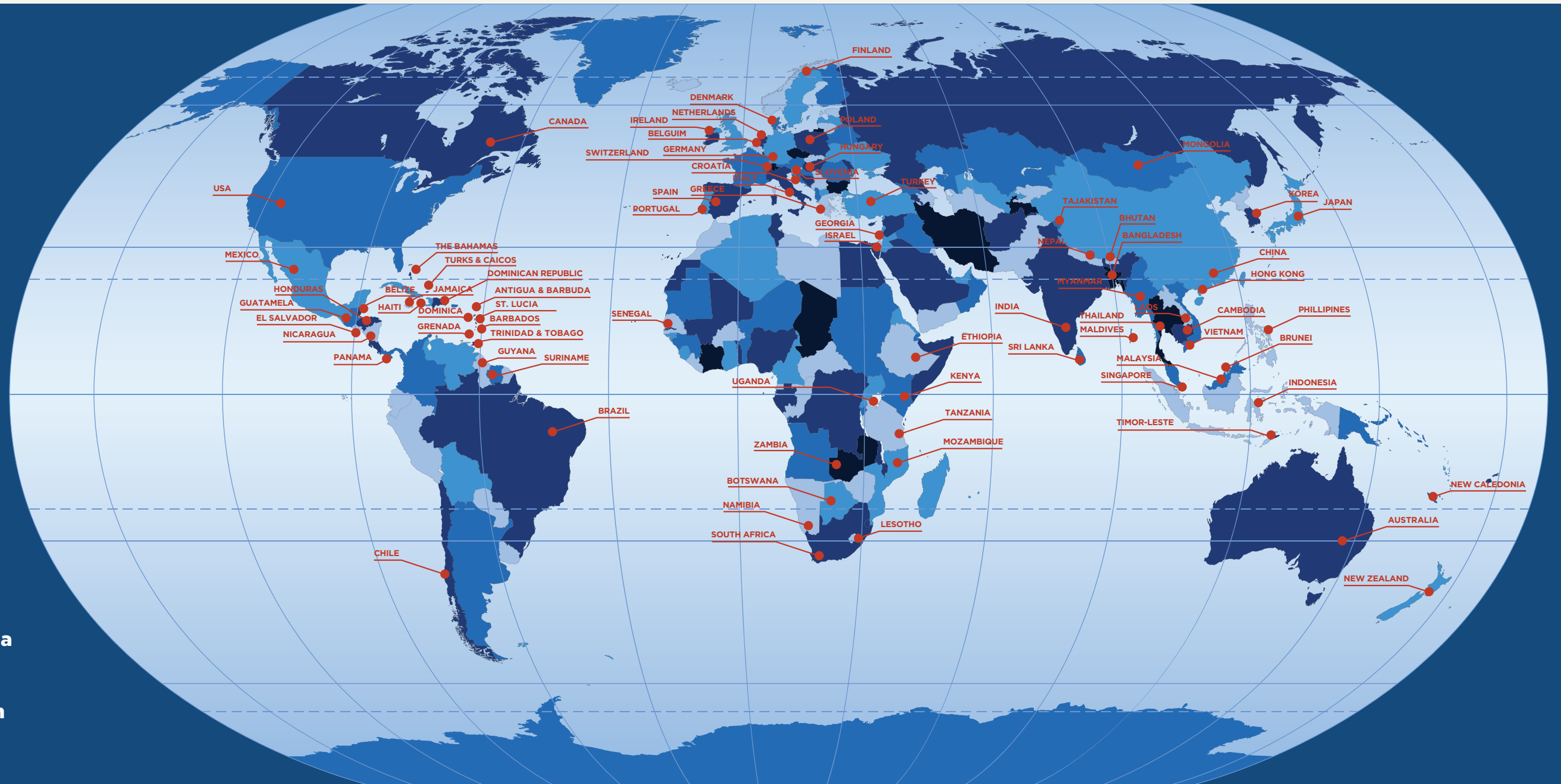
Dr Linda Heuston
Principal Hospital Scientist
ICPMR Westmead Hospital

Dr Darren Jardine
Senior Scientist
St. Vincent's Hospital Melbourne

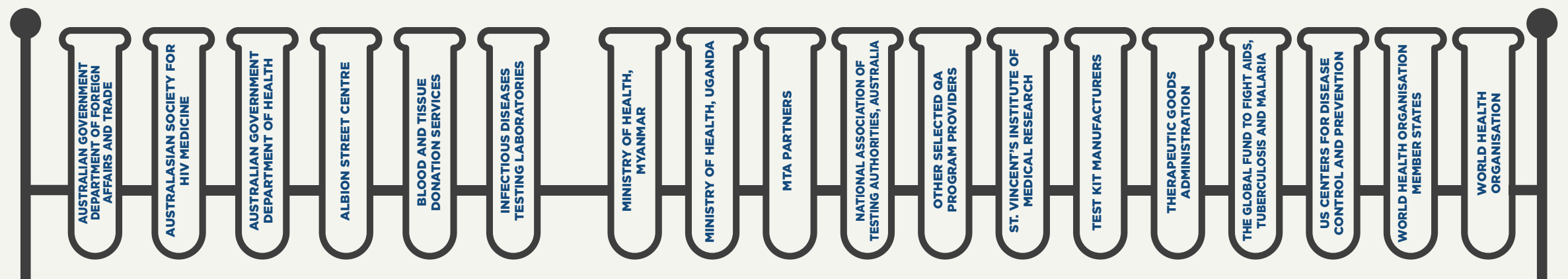
Professor Margaret Hellard
Head, Centre of Population Health
Burnett Institute

NRL'S GLOBAL REACH

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



NRL gratefully acknowledges those organisations that have provided support to NRL services and individuals throughout 2014.



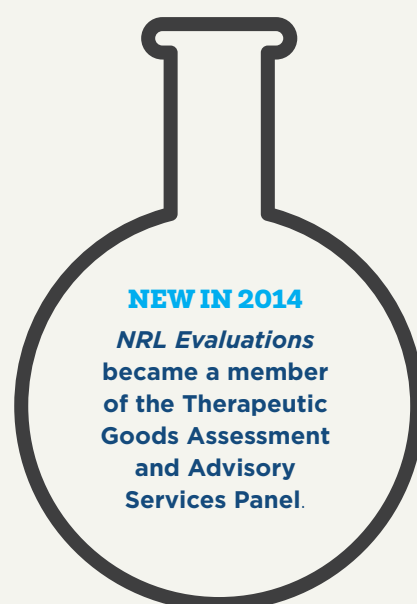
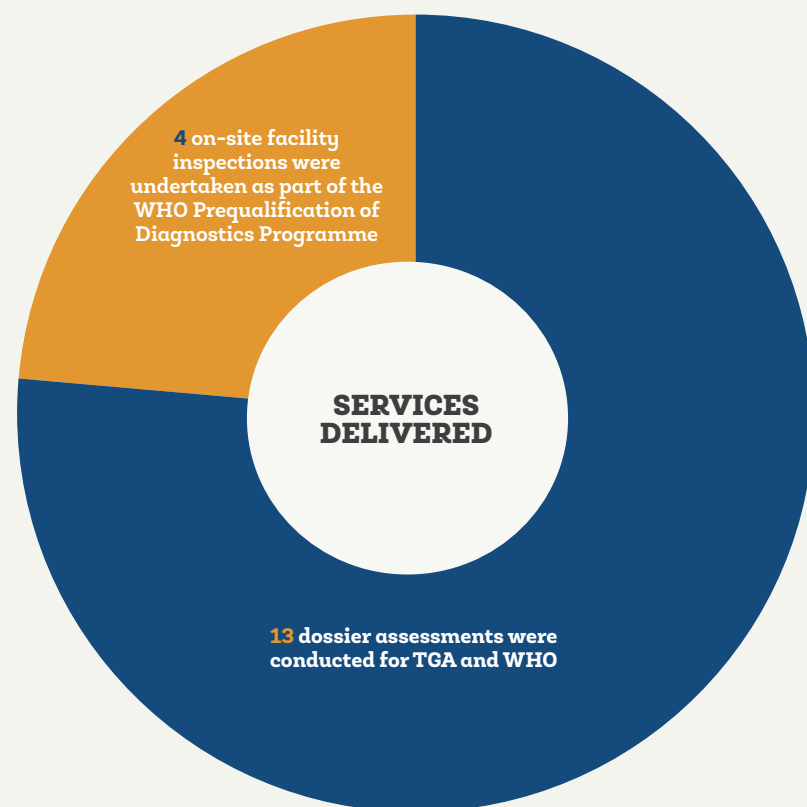
NRL EVALUATIONS

NRL understands that full knowledge of the analytical performance of test kits is essential to ensuring high quality test results.

NRL Evaluations reviews manufacturer's 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.

NRL Evaluations conducts assessments of in vitro diagnostic devices (IVDs) for both the Therapeutic Goods Administration (TGA) and the World Health Organisation (WHO). In partnership with TGA, NRL acts as an independent contractor conducting pre-market evaluations of IVDs for the testing of infectious diseases that pose the highest risk to the Australian community.

NRL Evaluations continues to conduct IVD dossier assessments under the WHO Prequalification of Diagnostics Programme. The aim of this program is to increase accessibility to affordable, high quality diagnostic technologies for use in resource-limited settings of WHO Member States. The program provides WHO Member States, UN agencies and other partners with technical information and advice on the quality of current test kits and technologies available for HIV/AIDS, Malaria and Hepatitis B and C. As part of this program *NRL Evaluations* also provides technical expertise during on-site manufacturing facility inspections.



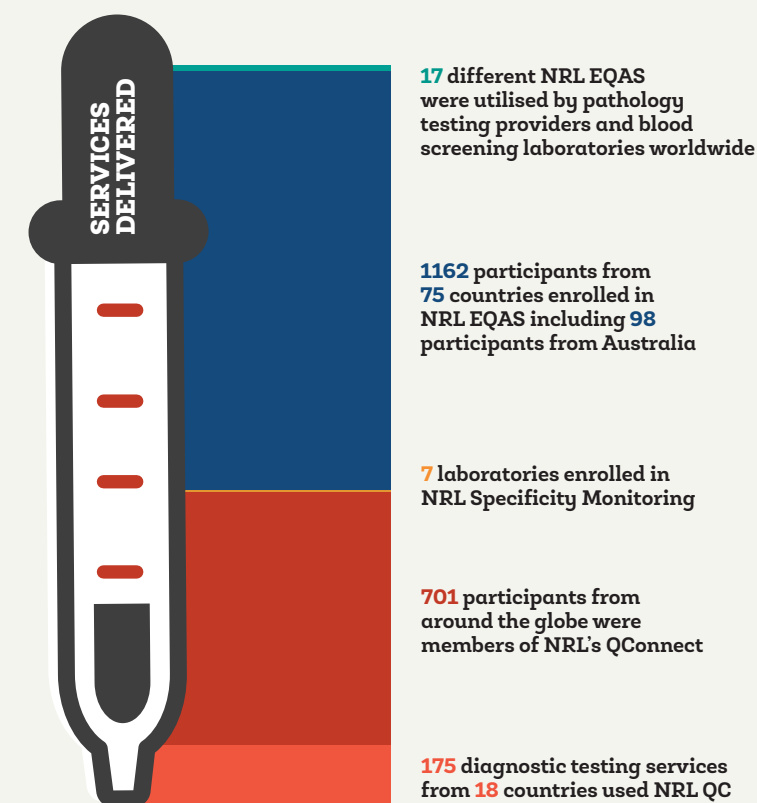
NRL QUALITY ASSURANCE

NRL sets the global standard for a range of comprehensive External Quality Assessment Schemes (EQAS), Quality Control (QC) and Specificity Monitoring programs for a range of infectious diseases.

Laboratories around the world participate voluntarily in NRL programs to assure the quality of laboratory testing processes and test kits used. EQAS assess the integrity of the entire testing process from sample receipt through to the administration of test results thereby identifying potential sources of error and ultimately preventing misdiagnosis.

The NRL QC program facilitates the monitoring of precision and accuracy of test results through using specifically selected QC samples. This is part of the unique NRL QConnect QC compendium.

The NRL Specificity Monitoring program identifies increased rates of false positive reactivity, which may be associated with different test kit batches or sub-optimal laboratory processes. Increased rates of false positive reactivity are particularly detrimental in blood transfusion services and can lead to unnecessary wastage of blood and blood products. The NRL Specificity Monitoring program provides a mechanism to minimise this wastage.



NEW IN 2014

TORC 435 EQAS: A program to provide clinical serology laboratories with the means to quality assure their testing for congenital diseases: Toxoplasmosis, Rubella and Cytomegalovirus.

HIV Point of Care (POC) EQAS: A program for Australian community based POC testing providers as a way to assure the quality and consistency of associated rapid test devices and the results delivered by the POC testing sites.

HIV co-receptor tropism EQAS: The pilot program conducted in 2014 involved 24 laboratories from 15 countries. The program identified inter-laboratory variability in determining HIV co-receptor tropism highlighting the need for ongoing quality assurance of laboratory test outcomes ensuring competency, consistency and comparability.

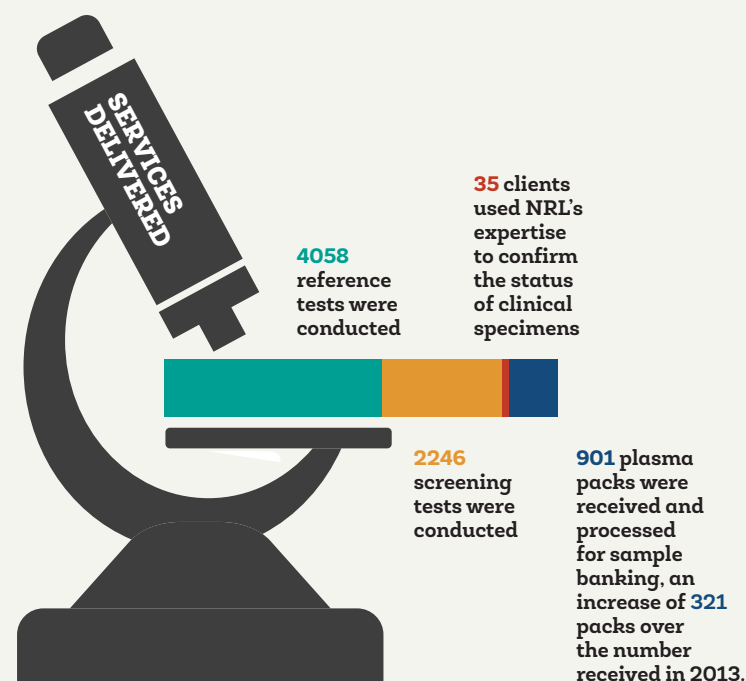
NRL TESTING

NRL Testing delivers a range of specialised services including reference testing and TGA-licensed screening of blood and tissue donors.

NRL Testing serves as a reference point for HIV, HCV and HTLV specimens whose status cannot be resolved, by utilising testing strategies that include selective tests not widely used by other testing laboratories. Additionally, specimens collected from blood and tissue donors are screened for HIV, HBV, HCV, HTLV and Syphilis. This testing is required to be licensed to the Australian Code of Good Manufacturing Practice.

NRL Testing maintains an extensive repository (Sample Bank) of well characterised samples that are integral to NRL Quality Assurance and Evaluations. NRL holds Material Transfer Agreements (MTA) with collaborating blood transfusion services under which plasma packs identified for discard are provided to NRL for use in its programs.

NRL Testing also undertakes contract testing in the form of scientific projects and collaborations with a variety of organisations for epidemiological studies and assessments of new test kits.



NRL TRAINING

NRL Training provides a range of training and consultancy services in building and enhancing quality in laboratory systems, globally.

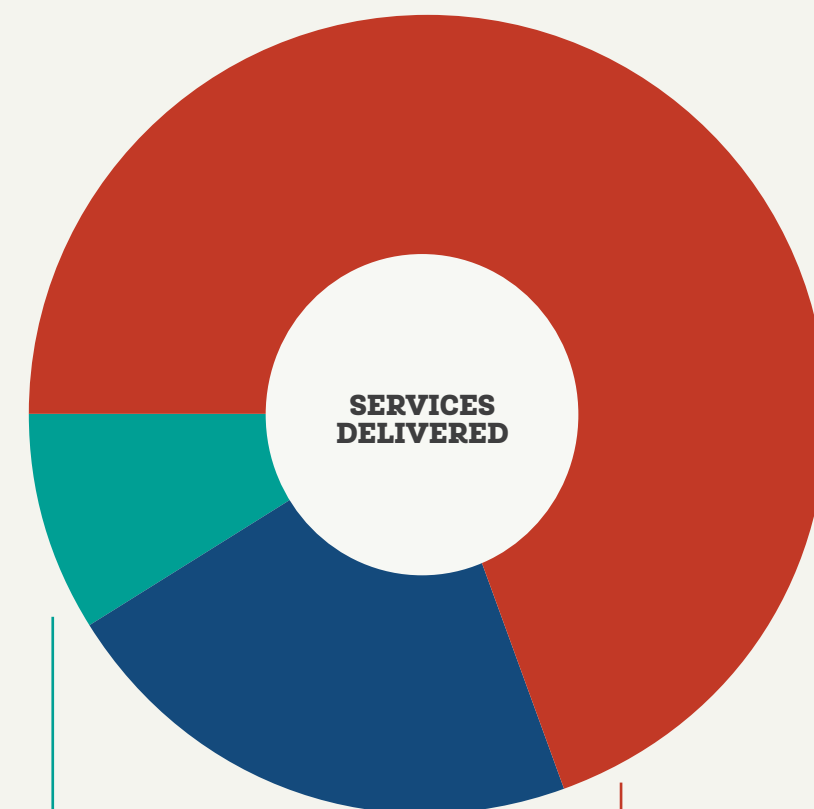
NRL collaborates with partners in health systems to support the delivery of accurate diagnoses thereby facilitating better patient care. Capitalising on NRL's extensive experience and the development of Sustainable Training, Education and Partnerships (STEPS) program, NRL provides advocacy, customised training and mentorship based on identified needs in a culturally sensitive manner.

This year, NRL Training was focused largely in the Asia and Pacific region.

NEW IN 2014

Two NRL scientists were trained to facilitate the CDC Strengthening Laboratory Management Toward Accreditation (SLMTA) program.

NRL's Director participated in the National HIV Health Sector Programme Review for Vietnam.



2 training sessions were held for the Research Institute for Tropical Medicine in the Philippines in relation to developing capacity to provide EQAS nationally

Under the Regional HIV Capacity Building Program, training on quality and strategy of HIV testing processes in Timor Leste, was continued. NRL Training in affiliation with the Albion Street Centre was part of The Timor-Leste Australia Collaboration for HIV Testing and Counselling Project (TAC-TAC).

5 government laboratories in Myanmar including the National Health Laboratory in Yangon continued to be supported in establishing laboratory quality management systems as part of the Regional HIV Capacity Building Program that began in 2012

16 fellows from 6 countries participated in an NRL short course on the "Development of National HIV Testing Algorithms: Issues and Considerations" as part of the Australia Awards Fellowship

THE NRL TEAM



PRESENTATIONS AND PUBLICATIONS

Applying the NPAAC Standard to Validate a Class 3 in-house IVD

Braniff S, Lanigan M and Dimech W
NRL
Presented at the Molecular Diagnosis for All (a Satellite Meeting for ASM 2014)
5 July 2014
Melbourne, Australia.

External Quality Assessment for HIV Co-receptor Tropism Testing

Land S, Vincini G, Swenson L and Harrigan PR
NRL and BC Centre for Excellence in HIV/AIDS, Vancouver, British Columbia, Canada
Presented at the 20th International AIDS Conference
20-25 July, 2014
Melbourne, Australia.

NRL EQAS: Observations from the NRL Serology Blood Screening Program 2013

Vincini GA, Smeh K, Cabuang LM, Dimech W and Best SJ
NRL
Presented at the 31st NRL Workshop on Infectious Diseases
29 July - 1 August 2014.
Melbourne, Australia.

Development of Whole Blood EQAS for HIV Point of Care Testing

Braniff S-J, Vincini G, Wilson K and Best SJ
NRL
Presented at the 31st NRL Workshop on Infectious Diseases
29 July - 1 August 2014,
Melbourne, Australia.

Summary of HIV-1 Viral Load Nucleic Acid Testing External Quality Assessment Schemes 2013-2014

Taqi RS, Cabuang LM and Best SJ
NRL
Presented at the 31st NRL Workshop on Infectious Diseases
29 July - 1 August 2014,
Melbourne, Australia.

Validation of Non-Western Blot Algorithms for HIV Testing

Best SJ
NRL
Presented at the 31st NRL Workshop on Infectious Diseases
29 July - 1 August 2014,
Melbourne, Australia.

Rubella Reporting-Where did we go wrong and what are we doing about it?

Dimech W
NRL
Presented at the 31st NRL Workshop on Infectious Diseases
29 July - 1 August 2014,
Melbourne, Australia.

Evaluation of Multiplo Rapid TP/HIV Antibody Test

Arachchi N and Dimech W
NRL
Presented at the 31st NRL Workshop on Infectious Diseases
29 July - 1 August 2014
Melbourne, Australia.

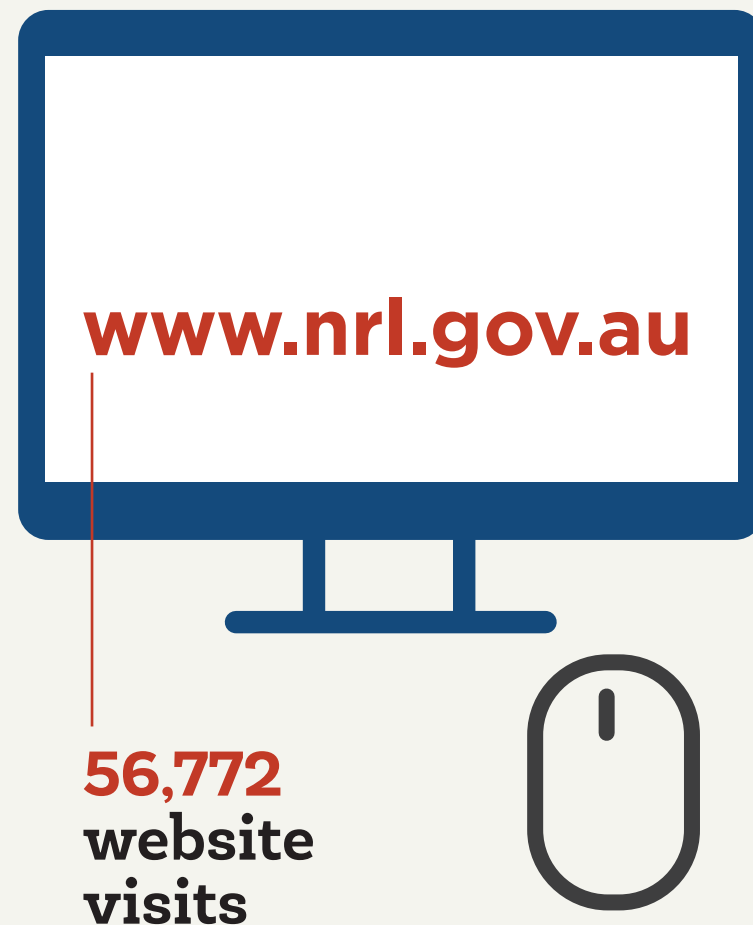
PRESENTATIONS AND PUBLICATIONS CONTINUED

HCV Genotyping EQAS: Guidance and Suggestions from Participants

Cabuang LM
Presented at the 31st NRL Workshop on
Infectious Diseases
29 July-1 August 2014
Melbourne, Australia.

NAT EQAS: Purpose, Design and Utility in Blood Screening

Cabuang LM
NRL
Presented at the CITIC 2014 Annual Conference
of Infection Prevention and Control
October 2014
Jiangxi Province, China.



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