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THE DIRECTOR'S REPORT

2012 was a characteristically busy year for NRL. While our existing work and programs continued, our WHO Collaborating Centre activities increased, with requests for technical assistance to countries both previously visited and new to NRL. In addition, NRL was a member on a number of national committees related to the development or review of testing policies and to the planning for the introduction in Australia of point-of-care (PoC) testing for HIV. In anticipation of increasing program scope and numbers of participants, we focused on improving the efficiency of our existing program delivery and on conducting the extensive preparatory and validation activities necessary to introduce new programs. Information about our 2012 activities is included in the following pages of this report.

Overall, staff numbers at NRL increased by two full time equivalents in 2012. Roseena

Taqi was recruited to join the NRL Quality Assurance team, the scope of which had increased to include delivery of more quality assurance programs to a greater number of participants. In addition, Marlene Tschaepe joined the NRL Training team whose activities were confirmed to increase through the funding of a two-year project by the Australian Agency for International Development (AusAID). From the start of the year we engaged Dr Katrina Watson as a regular consultant to NRL. Dr Watson adds valuable clinical perspectives to the development of NRL's programs. We were fortunate to have no staff departures in 2012.

In 2012, the first rapid test for HIV intended to be used at PoC was registered on the Australian Register of Therapeutic Goods. This, along with revision of the national HIV Testing Policy to support this type of

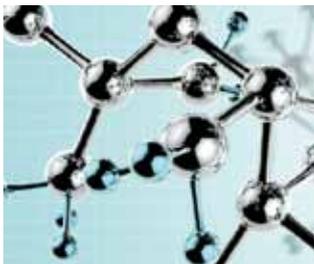
testing, precipitated wide interest from many stakeholders. NRL was a member of the expert reference committee that revised the HIV Testing Policy. Testing for HIV at PoC is a significantly different approach to testing compared with the other, more conventional approaches in use. Despite the benefits of encouraging more people to access HIV testing, significant planning is necessary to ensure the successful implementation of HIV PoC testing. A national training curriculum covering all aspects of HIV PoC testing is in development with NRL making significant contribution.

NRL played a key advisory role to the Biotherapeutics Association of Australasia (BAA, formerly Australasian Tissue and Biotherapeutics Forum) in 2012. An unintended consequence of the In vitro Diagnostic Device (IVD) policy implemented in 2010 by

the Therapeutic Goods Administration (TGA) came to light in 2012. It means that once the IVD policy is fully transitioned in July 2014, testing of deceased donors for infectious diseases could be restricted to laboratories using particular tests. This has the potential to impact on the number of deceased donors who can be tested, and therefore from whom tissues can be collected and banked. As this report goes to press, the situation is not resolved, although efforts are being made to find a solution.

The scope and volume of NRL's work continues to increase. Staff are asked to accept new challenges while continuing to perform their existing duties in a professional and collegiate manner. They constantly strive to meet expectations, looking for improvement opportunities along the way. For this I offer them my sincere thanks.

Susan Best



NRL continues to offer a comprehensive range of services to meet the needs of laboratories testing for infectious diseases.



NRL EVALUATIONS

NRL Evaluations assess the performance of test kits under local conditions. The focus is on the quality of test kit performance (rather than manufacture) to provide a realistic expectation of how that kit will behave under laboratory conditions.

The introduction of the new regulatory framework for IVDs in Australia in July 2010 has seen the role of NRL Evaluations change. NRL maintains its

relationship with the TGA, acting as an independent contractor conducting design examinations of Class 4 IVDs.

In 2012, the NRL Evaluations team expanded its services, commencing the assessment of dossiers under WHO's Prequalification of Diagnostics program. The WHO Prequalification of Diagnostics program aims to increase access to affordable diagnostic

technologies of assured quality that are appropriate for use in resource limited settings. The program provides WHO Member States, UN agencies and other partners with technical information and advice on the quality of currently available HIV/AIDS, Malaria and Hepatitis B and C test kits and technologies.

NRL QUALITY ASSURANCE

Applying over 20 years of experience, NRL Quality Assurance provides programs that maximise the quality and efficiency of tests and test processes, resulting in increased productivity and reduced costs for participating laboratories.

The NRL Quality Assurance team continued to deliver world-class programs to laboratories in Australia and around the world in 2012. In Australia, 104 laboratories participated in NRL Quality Assurance programs, supported by the Australian Government.

Internationally, participation in NRL EQAS continued to increase with 586 participants in 64 countries choosing to enrol in the 16 programs offered. The accuracy and precision of daily testing in 177 laboratories in 17 countries was assured through NRL QC. Through the activities of NRL EQAS and NRL QC, over 1000 instances of potential error were identified.

NRL Quality Assurance programs also assure the quality of donated blood in Australia and New Zealand. Uniquely

offered by NRL is the NRL Specificity program which monitors and minimises unnecessary blood wastage in the blood transfusion services in Australia and New Zealand.

**SUPPORTING
LABORATORIES
TO ACHIEVE
HIGH QUALITY
AND ACCURATE
TESTING RESULTS**



**potential
laboratory
errors
identified**

NRL TESTING

NRL Testing delivers a range of specialised services for reference testing and screening of blood and tissue donors. Using robustly validated testing algorithms and employing high quality processes, NRL Testing services are provided to 43 clients within Australia and in the surrounding South-east Asian and Western Pacific regions.

Routine reference and screening test numbers increased in 2012 for the NRL Testing team. As one

of the few TGA licensed facilities, NRL was chosen to be the testing site for a validation being conducted by a client, resulting in increased test numbers.

In addition to routine activities, the NRL Testing team was involved in projects with collaborators, including:

- Testing saliva for antibodies to HIV for the Dept of Public Medicine, Kobi House, Toowoomba Health Services.

- Testing for HTLV proviral load in a cohort of patients from the Alice Springs renal dialysis unit.
- Performing HIV-2 Western blots looking for antibodies to SIV in monkeys that had been vaccinated with an attenuated SIV for the Department of Microbiology and Immunology, University of Melbourne.
- ELISA, Western blot and HAI testing for Rubella to investigate low level

anti-rubella virus IgG results reported by commercial assays.

- Contract testing for a client whereby Western blots were performed on batches of HIV viral lysate for quality control purposes.



screening and reference tests performed

NRL TRAINING

NRL Training provides laboratory capacity building and training services that enhance quality in laboratory systems. Working with NRL's partners in the region, our programs are designed to promote self-sufficiency and sustainability.

The NRL Training team commenced or continued projects in Fiji, Indonesia, Mongolia, Myanmar,

The Philippines and Turkmenistan, covering topics including quality management systems, development and validation of testing strategies / algorithms, provision of EQAS / QC and laboratory testing. The projects were made possible through funding by AusAID, the Secretariat of the Pacific Community, the Global Fund to Fight AIDS, Tuberculosis & Malaria, WHO and the

United States Agency for International Development (USAID).

The NRL Training team was also successful in obtaining funding from AusAID under the Regional HIV/AIDS Capacity Building Program 2012-2014, to undertake the project "Establishment of Laboratory Quality Systems in Myanmar".



consultancies / training programs conducted





SUPPORT SERVICES

SAMPLE BANK

NRL's Sample Bank is a repository of samples that support NRL's Evaluations, Quality Assurance and Testing activities. In 2012, NRL banked 621 plasma packs that were donated by collaborating institutions with which NRL holds material transfer agreements.

LOGISTICS

With participants all over the world participating in NRL Quality Assurance programs, streamlined logistics processes allow NRL to ensure the safe and timely distribution of materials. In 2012, 1011 shipments left NRL bound for 60 countries.

NRL WORKSHOP

The annual NRL Workshop unites national and international scientific, manufacturing and regulatory groups in the field of infectious diseases. It provides a forum for the discussion and resolution of important issues facing laboratory scientists. In 2012, the 29th Annual NRL Workshop on Infectious Diseases was held in Melbourne, with 210 delegates from 11 countries attending.



621

BANKED PLASMA
PACKS

210

DELEGATES



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
Sally Land
Mark Lanigan
Tamara Mc Donald
Alison Natoli
Louie Opasinov

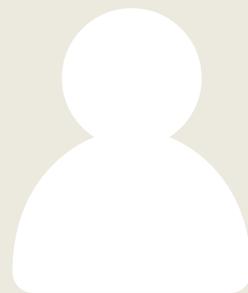
Thu-Anh Pham
Kim Richards
Terri Sahin
Kathy Smeh
Roseena Taqi
John Tomasov
Frank Torzillo
Rosanna Torzillo
Marlene Tschaepe
Joe Vincini
Kim Wilson

74

COUNTRIES REACHED
THROUGH NRL ACTIVITIES

32

NRL STAFF



649

QA PARTICIPANTS

10,000

SAMPLES TESTED

FOR PATIENTS,
SAMPLE BANK,
EVALUATIONS
& QA MATERIAL

HIGHLIGHTS YEAR

FROM
THE

72

TRAINEES TRAINED