

The Role of NRL

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NRL, Melbourne, Australia

National Serology Reference Laboratory, Australia (NRL)

- Established in 1985
- Service provider to Australian Government
- WHO Collaborating Centre
 - *Diagnostic and laboratory support for HIV / AIDS and other blood borne infections*
- Independent, not-for-profit
- Approx 30 staff



Major Stakeholders

- Australian government
- International partners
 - WHO HQ and regional offices; Regional MoHs; CDC
- Australian Red Cross Blood Service
- Tissue banks
- *In vitro* diagnostic device (IVD) manufacturers
- Laboratories

NRL Mission

***To promote the quality of
tests and testing for
infectious diseases globally***

NRL Credentials

- WHO Collaborating Centre on HIV and Blood Borne Viruses
- Accredited:
 - Medical testing laboratory (ISO 15189)
 - Provider of quality assurance (ISO 17043)
- Licensed to code of Good Manufacturing Practice
- Certified:
 - ISO 9001:2000 (Management standard)
 - AS/NZS 4801:2001 (OHS standard)

NRL Activities

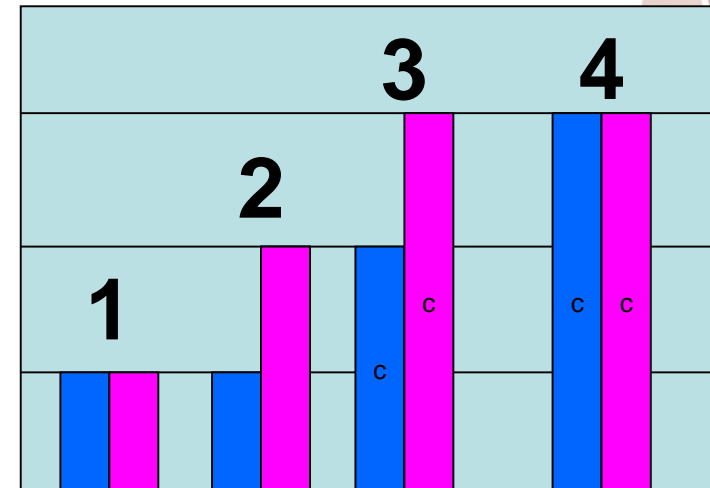
- IVD assessment
- Quality assurance
- Laboratory capacity building and training
- Testing
- Targeted research

IVD assessment in Australia

Australian IVD regulatory framework - risk based

- Class 4 (highest risk)
 - Includes IVDs for blood / tissue screening
 - HIV, HCV, HBV, HTLV, syphilis
 - Stringent pre-market assessment required
- Responsibility of TGA

■ Public Health Risk
■ Personal Risk



NRL's roles in IVD assessment

- Class 4 IVD dossier assessments for TGA
- NRL's role in WHO prequalification of IVDs:
 - Dossier assessment
 - Performance assessment
 - Technical assessor on site inspections
 - Lot release

Quality Assurance Programmes

- QA focus: Tests and testing for infectious diseases
- NRL provides QA materials and programmes to medical testing laboratories
- 2 main mechanisms:
 - Quality Control (QC) : test run to test run validation
 - EQA: periodic assessment of accuracy of entire testing process
 - 550 participants; 55 countries

Roles of EQA & QC

EQA

- Monitors integrity of entire testing process
- At a point in time
- Reveals systematic and random errors
- Comparison b/n labs identify assay and/or lab problems

QC

- Monitors single part of process (test run)
- Continual
- Potential to detect trend towards systematic error prior to aberration
- Precision: Comparison within lab, b/n run;
Accuracy: Comparison b/n lab
- Uncertainty of Measurement

NRL's International QA Presence



Testing

- Reference testing: HIV, HCV, HTLV
- Tissue donation screening:
 - HIV, HCV, HBV
 - Living and deceased donors
 - Serology and NAT
- Sample repository: acquisition, maintenance, cataloguing, retrieval
 - BioBank
 - Supports QA programs

Capacity Building and Training

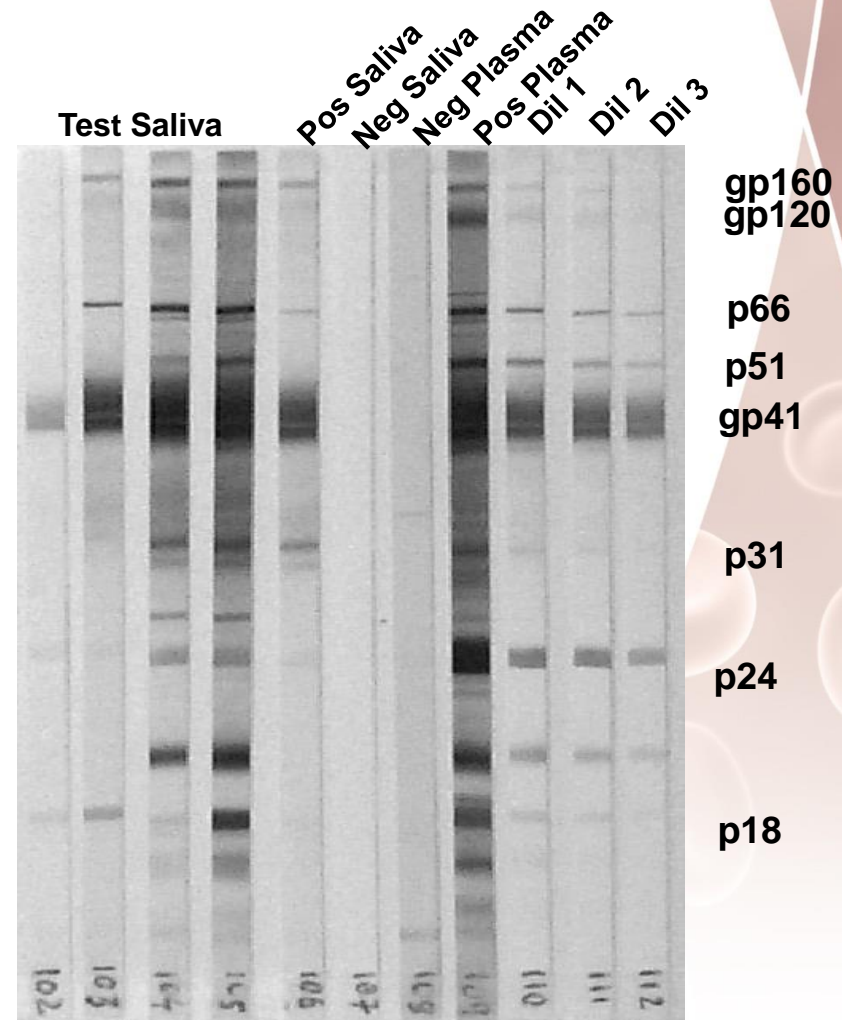
- Recognised training organisation
- Consulted / commissioned regularly by international partners
- Training and mentorship
 - Laboratory QMS
 - National EQA systems
 - National systems for IVD assessments
 - Laboratory and POC testing

NRL Workshops

- Quality workshops each year
 - Australia and Europe
 - Serology and NAT
 - Directed at laboratory scientists

Research

- Laboratory services for clinical research
- Particularly for HIV HCV, HTLV
- Development of HTLV viral load RT-PCR
- Testing in different sample types e.g. saliva, Dried blood spots



Summary

- Focused on quality assurance for infectious diseases
- Pre-, post-market activities for IVD assessment
- Niche testing services
- Training, mentoring in testing and lab QMS

A scenic view of a city skyline, likely Melbourne, Australia, featuring a river, a bridge, and a rowing team. The sky is clear blue with two hot air balloons. The water reflects the city buildings and the sky. A rowing team is visible in the foreground, moving across the water. A bridge spans the river in the middle ground. The city skyline is composed of various skyscrapers and buildings, including the Crown Melbourne building on the right. The overall atmosphere is bright and clear, suggesting a sunny day.

**Acknowledgements:
All NRL staff**