Bleeding Love: NRL's Plasma Biobank.

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Introduction

- The National Serology Reference Laboratory (NRL) is a WHO Collaborating Centre for Diagnostics and Lab support, and a global leader in the science of quality for infectious disease testing, supporting laboratories in more than 70 countries to ensure accurate, consistent, and reliable results.
- We provide: Quality Assurance Programs and Blood/tissue donor screening to pathology labs and hospitals; Public Health training in the APAC region; Evaluations of test kits on behalf of WHO.
- Underpinning all these activities is a repository of well-characterised and annotated human plasma, collected globally over several decades.

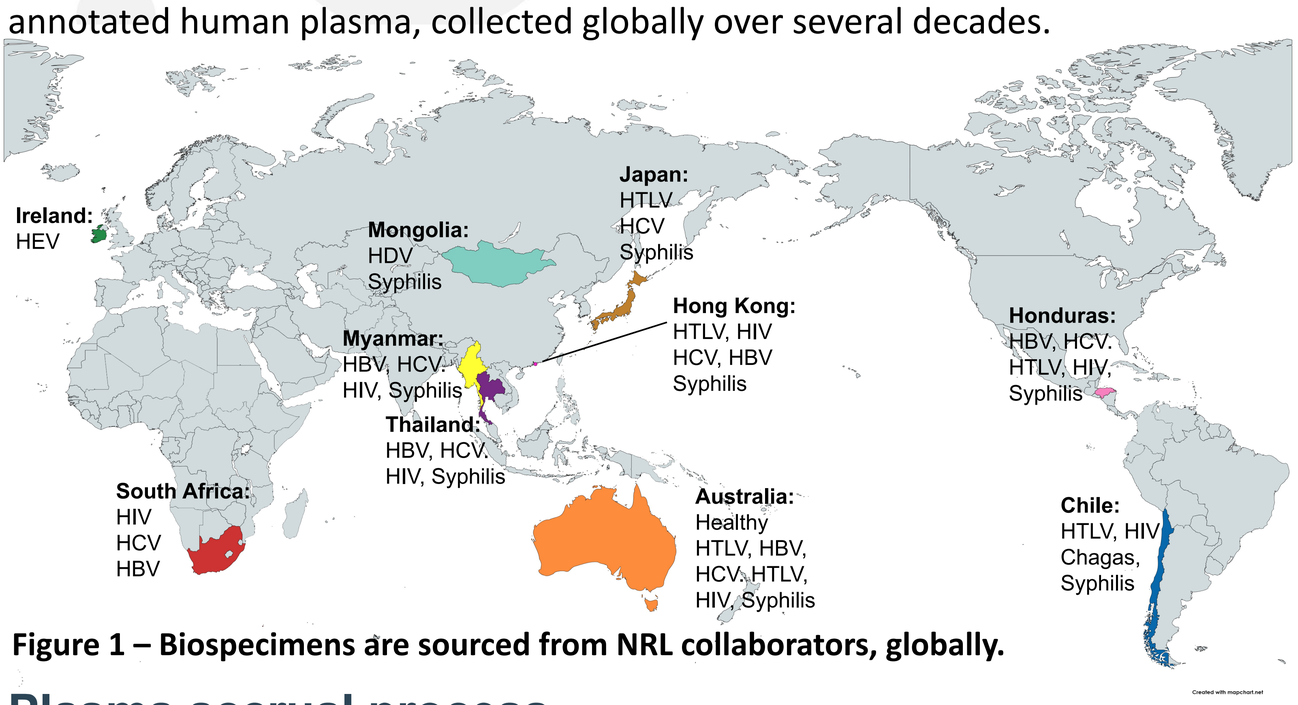

Figure 1 – Biospecimens are sourced from NRL collaborators, globally.

Plasma accrual process

- NRL has established and maintained over 30 years, a sample repository of over 14,000 plasma samples from participants infected with a range of pathogens, including HIV, HBV, HCV, HTLV, Syphilis, alongside healthy donor plasma.
- Samples are sourced primarily from national blood services within endemic areas across the globe (figure 1). They are obtained under MTA and exchanged for in-kind or financial incentive (figure 2).

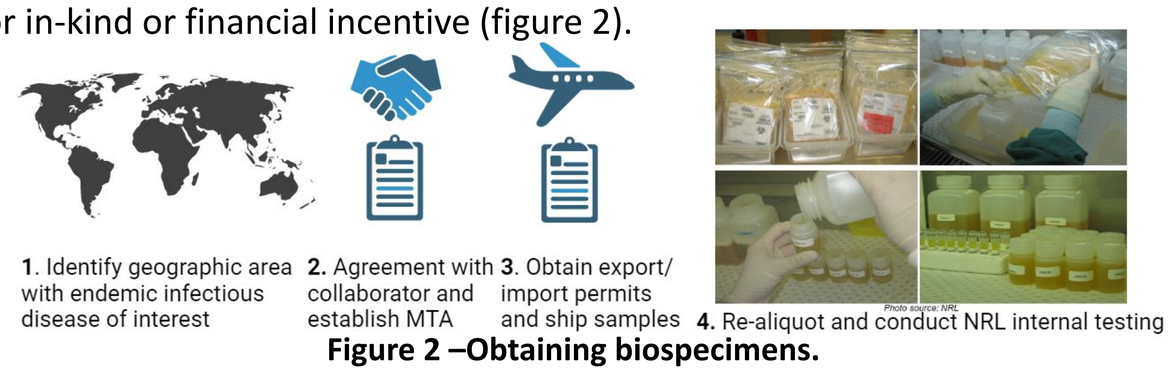

Figure 2 –Obtaining biospecimens.

Testing and Characterisation

- NRL is certified to ISO 9001, accredited as a Medical Testing Laboratory (ISO 15189), and licenced by the TGA under the cGMP.
- Plasma packs received undergo internal confirmatory testing according to a validated algorithm for accurate characterisation (example in figure 3).

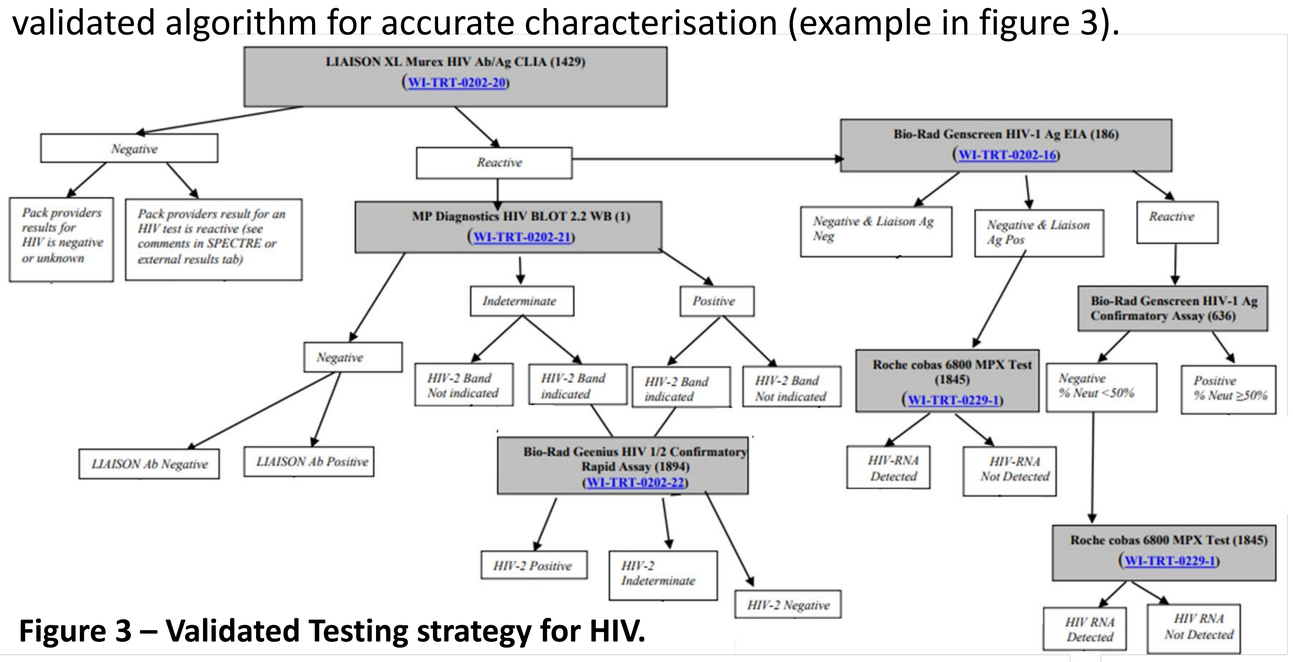

Figure 3 – Validated Testing strategy for HIV.

Storage and Management

- Samples stored in a walk-in freezer at -20oC
- Inventory is documented and managed in a purpose-designed LIMs which records:
  - Provider information (origin, test results)
  - In house characterisation results
  - Tagging/Reserving for intended use.
- Processes are in place to:
  - -Monitor rounds of freeze/thaw
  - -Review older samples to discard
  - -Consolidate dead space

Figure 4 –Sample storage and management.

Specimen usage

- Annotated biospecimens in the repository support a range of NRL activities:
  - **EQAS**: External Quality Assessment Schemes. Samples are used to design panels to assess the accuracy of our customer's testing programs worldwide (see below)
  - **Quality Control:** Samples are used to provide an extensive range of QC materials, allowing testing laboratories to monitor test performance
  - **Evaluations**: NRL is designated by WHO as a Pre-qualification Evaluation Laboratory. We conduct both pre- and post-market contract-based independent evaluations of tests, using the samples in our repository
  - **Staff training and competency**: Testing labs have a requirement for well validated and annotated samples of different varieties and reactivities, to test their staff competency across various pathology tests
  - **New Assay Development**: The samples are used to create a range of customised validation and verification panels to support development of new assays or *in vitro* diagnostic test kits (see below)

External Quality Assurance Scheme (EQAS)

- NRL is ISO 17043 accredited as a Proficiency Testing Scheme Provider and has provided Serology and Molecular EQA programs for infectious diseases internationally for over 2 decades.

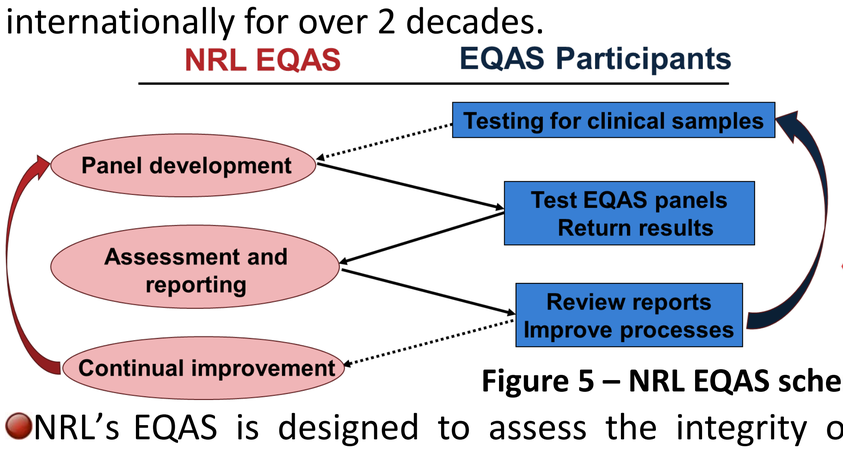

Figure 5 – NRL EQAS schema

- NRL's EQAS is designed to assess the integrity of pathology laboratories' entire process for infectious disease testing.
- A panel of positive and negative samples, representative of those typically received by a testing laboratory, is created from the repository and provided to each EQAS participant.
- Each laboratory's testing data is analysed and a report is provided.
- Laboratories can assess results and compare performance with peers.
- In 2024 NRL will provide 25 programs across 4 categories (Table 1 below)

Blood Screening Programs	Comprehensive Serology Programs	Comprehensive Molecular Programs	POC & Specialised Programs
Multimarker Blood Screening Serology	HEPM435	Sexually-Transmitted Infections Molecular	HTLV Molecular
Multimarker Blood Screening Molecular	TRCH435	Viral Exanthems Molecular	Leptospirosis Molecular
Multimarker Plasma Fractionation Molecular	RVSS435	HPV Molecular	Mycobacterium Molecular POC
		Transplant-Transmitted Infections Molecular	
		Single Analyte Programs :HBVL, HCVQ, HIVL, CMVN	C.trachomatis, N.gonorrhoeae & T.vaginalis Molecular POC
		Viral Respiratory Molecular	
		Extended Viral Respiratory Molecular	
		Bacterial Plus Respiratory Molecular	

Validation panels for new assay development

- Validation and verification panels are required at many stages throughout the development phases of new assays/ tests or *In Vitro* Diagnostic Devices (IVDs).

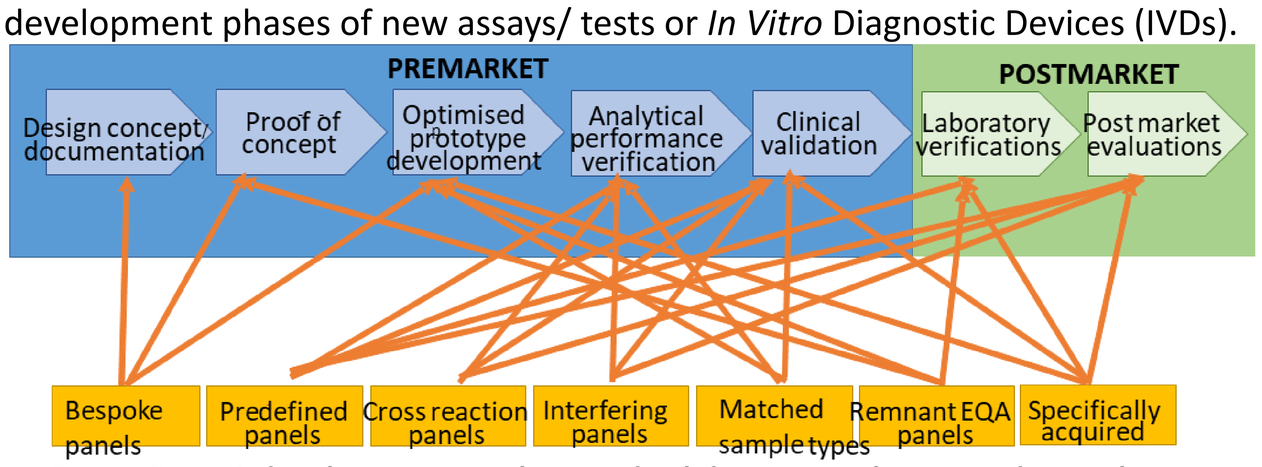

Figure 6 – IVD development pipeline, and validation panels required at each stage

- Biospecimens in the repository are used in the design and manufacture of such panels, including the following:
  - Panels for regulatory Test Registration: analytical, clinical, seroconversion
  - Pathology and Blood Screening Laboratory verification panel
  - Bespoke panels for test manufacturers
  - Supply of specific sample types/collection conditions as requested

Summary

- The NRL plasma repository contains a large number of samples with varying characteristics that can be used for many purposes
- Samples are used to support laboratories worldwide in quality assurance programs, validation & implementation of assays, & staff competency testing.
- Carefully considered accrual of ethically-collected, well-annotated, appropriately-stored material is essential to facilitate these programs.

Acknowledgments: NRL acknowledges the significant contribution of our partner organisations in providing human biological material to our Sample Bank. These include: Lifeblood Australia, VIDRL, Melbourne University, CSIRO, South African National Blood Service, Thai Red Cross, Irish Blood Transfusion Service, Japanese Red Cross, Cruz Roja Hondurena, Hong Kong Red Cross, National Blood Centre Mongolia, National Centre for Communicable Diseases Mongolia, Centro de Sangre y Tejidos Valparaíso Chile.