

Donor Screening in The Region

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NRL

- Established in 1985
- Not-for-profit organisation that exists to support laboratories that perform testing for the diagnosis and management of human infectious disease
- Contracts with the Australian Government

Donor Screening and NRL

- How does NRL gain insight into donor screening?
 - NRL provides QC and EQAS to the majority of donor screening laboratories
 - Globally – over 1000 participants
 - ‘The Region’
- NRL has a leading role in ‘The Region’
 - Not just provision of Quality Assurance programmes
 - Laboratory Strengthening
 - Training (QMS, testing algorithms, QA programmes)
- WHO Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and other Blood-Borne Infections

What is 'The Region'?

- The Asia Pacific Region comprises two regions as defined by WHO
 - South East Asia Region
 - Western Pacific Region

“The Region”



WHO Western Pacific Region

	American Samoa		Macao (China)		Philippines
	Australia		Malaysia		Pitcairn Islands (UK)
	Brunei Darussalam		Marshall Islands		Republic of Korea
	Cambodia		Micronesia, Federated States of		Samoa
	China		Mongolia		Singapore
	Cook Islands		Nauru		Solomon Islands
	Fiji		New Caledonia (France)		Tokelau* (New Zealand)
	French Polynesia (France)		New Zealand		Tonga
	Guam (USA)		Niue		Tuvalu
	Hong Kong (China)		Northern Mariana Islands		Vanuatu
	Japan		Palau		Viet Nam
	Kiribati		Papua New Guinea		Wallis and Futuna
	Lao People's Democratic Republic				

WHO Western Pacific Region



Australia



Macao (China)



Philippines



Malaysia



Republic of Korea



China



Mongolia



Singapore



New Zealand



Hong Kong (China)



Japan



Viet Nam

WHO Western Pacific Region



Australia



Brunei Darussalam



Cambodia



China



Macao (China)



Malaysia



Mongolia



Philippines



Republic of Korea



Singapore



New Zealand



Hong Kong (China)



Japan



Viet Nam



Papua New Guinea



Lao People's Democratic Republic

WHO South East Asia Region



Bangladesh



Myanmar



Bhutan



Nepal



Democratic People's Republic of Korea



Sri Lanka



India



Thailand



Indonesia



Timor-Leste



Maldives

WHO South East Asia Region



Bhutan



India



Indonesia



Myanmar



Nepal



Thailand

WHO South East Asia Region



Bangladesh



Bhutan



India



Indonesia



Maldives



Myanmar



Nepal



Sri Lanka



Thailand

NRL – Major Activities

- NRL Evaluations
- NRL Quality Assurance
 - EQAS
 - QC
 - Specificity Monitoring
- NRL Training
- NRL Testing
- NRL Workshop

NRL Donor Screening NAT – A Brief History...

- First distributed in 2000
 - NRL provided schemes for HIV RNA and HCV RNA
 - Primarily for Australian Blood Service
- 2001: First international participant
- 2006: introduction of HBV DNA
- 2008: Current format NATA4315 implemented

NRL Donor Screening Serology – A Brief History...

- 1985: HIV Serology
- Over the years introduction of other serology schemes
- All provided as 10 sample panels
- 2013: current format (MMBS4320) implemented
 - Single analyte HBV and HCV panels were discontinued at the same time (HIV serology remains)
 - Hepatitis serology panel introduced as well (clinical)

MMBS4320 and NATA4315...

**Why different schemes?
Why multimarker?**

Differences in objectives of testing

● Diagnostic testing

- Usually have a target in mind
- Use tests to get to this conclusion
- Testing for unlimited markers
- Moderate-high public health consequences

● Donor screening

- Asymptomatic popⁿ
- Screening 'blind'
- Limited number of markers tested for
- Very high public health consequences

Donor Screening:

The ultimate driver...

*“Need for safe blood/blood products
through infectious diseases
screening excellence”*

- Joe Vincini

MMBS4320 and NATA4315

- Panel of 20 (MMBS) and 15 (NATA) samples
- Why so many samples?
 - High throughput laboratories
 - Room to provide good mix of pos/neg
 - Multiple replicates of same sample
 - Allows for inclusion of other markers
 - Serology - Syphilis? HTLV? Others?
 - NAT – CMV? HEV? HAV/PVB19? Others?

Multimarker Blood Screening NAT (NATA4315)

NATA4315 – The Scheme

- Designed for donor screening laboratories
- Three distributions = 45 samples/pa
- Includes samples positive for HIV-1, HCV, HBV, dual infection or negative samples
- Occasionally rare genotypes and HIV-2
- Three analytes evaluated:
 - HIV-1 RNA, HCV RNA and HBV DNA
 - Multiplex and single analyte screening tests

Asia Pacific Participants: n = 57

NAT assays used in 2015

- Multiplex assays (n = 11):
 - Grifols Procleix Ultrio HIV-1/HCV/HBV TMA
 - Grifols Procleix Ultrio Plus HIV-1/HCV/HBV TMA
 - Grifols Procleix TIGRIS Ultrio HIV-1/HCV/HBV TMA
 - Grifols Procleix TIGRIS Ultrio Plus HIV-1/HCV/HBV TMA
 - Grifols Procleix Ultrio Elite HIV/HCV/HBV TMA (Panther)
 - HY Nucleic Acid Test Kit for HBV, HCV, HIV-1 Real-Time PCR
 - Kehua HBV-HCV-HIV PCR-Fluorescence Diagnostic Kit
 - Roche COBAS TaqScreen MPX Test
 - Roche COBAS TaqScreen MPX Test v.2.0
 - Suzhou Bacme HBV HCV HIV (1+2) Real-Time PCR
 - Shanghai Haoyuan Gene Amplification and Gene Chip Detection

NAT assays used in 2015

- Single marker assays (n = 3):
 - Roche COBAS AmpliScreen HBV Test
 - Roche COBAS AmpliScreen HCV Test v.2.0
 - Roche COBAS AmpliScreen HIV-1 Test v.1.5
- Also used as discriminatory assays for:
 - Roche COBAS TaqScreen MPX Test
 - MPX2 and 6800 do not require discriminatory assays
- Soon to be out of production

NAT assays used in 2015

- Discriminatory assays (n = 15):
 - Grifols Procleix TIGRIS Ultrio HBV Discriminatory TMA
 - Grifols Procleix TIGRIS Ultrio HCV Discriminatory TMA
 - Grifols Procleix TIGRIS Ultrio HIV-1 Discriminatory TMA
 - Grifols Procleix TIGRIS Ultrio Plus HBV Discriminatory TMA
 - Grifols Procleix TIGRIS Ultrio Plus HCV Discriminatory TMA
 - Grifols Procleix TIGRIS Ultrio Plus HIV-1 Discriminatory TMA
 - Grifols Procleix Ultrio HBV Discriminatory TMA
 - Grifols Procleix Ultrio HCV Discriminatory TMA
 - Grifols Procleix Ultrio HIV-1 Discriminatory TMA
 - Grifols Procleix Ultrio Plus HBV Discriminatory TMA Assay
 - Grifols Procleix Ultrio Plus HCV Discriminatory TMA Assay
 - Grifols Procleix Ultrio Plus HIV-1 Discriminatory TMA Assay
 - Grifols Procleix Ultrio Elite HBV Discriminatory TMA
 - Grifols Procleix Ultrio Elite HCV Discriminatory TMA
 - Grifols Procleix Ultrio Elite HIV Discriminatory TMA



Results: NATA4315 2015

- For the Asia Pacific laboratories:
 - >7,000 results reported
 - 2 false negative results reported (MPX2)
 - One in Test Event 2
 - One in Test Event 3
 - No false reactive results reported

Multimarker Blood Screening Serology (MMBS4320)

MMBS4320 – The Scheme

- Designed and announced in 2012 for 2013 distribution
- Designed for donor screening laboratories
- Three distributions = 60 samples/pa
- Included samples positive for HIV, HCV, HBV, dual infection or negative samples
- Potential for identical samples within/across distributions

NRL Donor Screening Serology

- MMBS4320 - Five markers evaluated:
 - HBsAg, anti-HBc total, anti-HCV, anti-HIV and HIV-1 p24 Ag
 - Syphilis included in 2017
- Also to consider for 2015...
 - HTLV Serology EQAS (HTLV4310)
 - Syphilis Serology EQAS (TREP4310)
- **38,319** results reported in 2015!!!

Serology assays used in 2015

- 30 Chemilluminescence assays (ChLIA)
 - 26 from Abbott, Roche and Siemens
- 79 Enzyme immunoassays (EIA)
- 10 immunoblot assays (Blot)
 - 4 manufacturers!
- 26 Particle agglutination assays (PAA)
 - Majority for syphilis (2 HIV and 1 HTLV)
- 34 Rapid test devices (RTD)
 - Only 2 are on the WHO Prequalification List!!!
 - Used in 5 countries only... Thailand, Mongolia, Myanmar, Indonesia and Bhutan

Results – Serology

- Very few instances of false negative results!
- More common – RTD and PAA used for screening
 - Multiple instances in HIV, HCV and HBsAg RTDs
- One ChLIA – false negative for one sample 8/12 participants
- Anti-HIV only tests (3rd Gen)
 - Many participants used these with HIV combo as dual screen
 - Some performed anti-HIV only and risk not detecting early infection
 - Many laboratories using RTDs in this situation

General conclusions

- NAT screening – the ‘Big Two’
 - Grifols and Roche
- Serology
 - Diverse technologies and manufacturers
 - Assay selection driven by cost, availability and practicality
 - Higher error rates seen in manual testing

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- NRL Quality Assurance
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Workshop



33rd
Annual NRL
Workshop
on Infectious
Diseases

18 - 20 October 2016,
The Langham, Melbourne



Thank-you!

