# Screening Strategies: Serology / NAT screening algorithms

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NRL, Melbourne, Australia

IPFA 3rd Workshop on Plasma Quality and Supply
Kuala Lumpur, Malaysia

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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

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# NRL – Major Activities

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

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# Insight into donor screening

- 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

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# What is ‘The Region’?

- The Asia Pacific Region comprises two regions as defined by WHO
  - Western Pacific Region (WPRO)
  - South-east Asia Region (SEARO)

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# “The Region”




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http://www.wpro.who.int/countries/en/

# WHO Western Pacific Region

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

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http://www.wpro.who.int/countries/en/

# WHO Western Pacific Region

- Australia
- Cambodia
- Hong Kong (China)
- Japan
- Macao (China)
- Malaysia
- Mongolia
- New Zealand
- Papua New Guinea
- Philippines
- Republic of Korea
- Singapore
- Viet Nam

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http://www.wpro.who.int/countries/en/

# WHO South-east Asia Region

- Bangladesh
- Bhutan
- Democratic People's Republic of Korea
- India
- Indonesia
- Maldives
- Myanmar
- Nepal
- Sri Lanka
- Thailand
- Timor-Leste

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http://www.searo.who.int/countries/en/

# WHO South-east Asia Region

- Bangladesh
- Bhutan
- India
- Indonesia
- Maldives
- Myanmar
- Nepal
- Sri Lanka
- Thailand

**20 countries in NRL QA programmes**

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# Asian Region

- Has about one third of world population
- Disproportionate burden of disease
- Geographically disparate
  - Large land masses
  - Archipelagos
  - Small island nations
- Vast differences in economies, political stability
- 10 million units
- >3,500 blood banks in eleven countries*

Choudhury; Asian J Transfus Sci 2011 5(2):117-120

# WHO Recommendations

- Each country should have a national policy on blood screening
- National programme for blood screening which sets out the strategy for screening, with algorithms that define the actual tests to be used in each screening facility
- Where feasible, blood screening should be consolidated in strategically located facilities

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**Screening donated blood for transfusion transmitted Infectious – recommendations – WHO 2009**

# WHO Recommendations

- Screening of all blood donations should be mandatory for
  - HIV 1 and HIV 2
  - HCV
  - HBV
  - Syphilis

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# WHO Recommendations

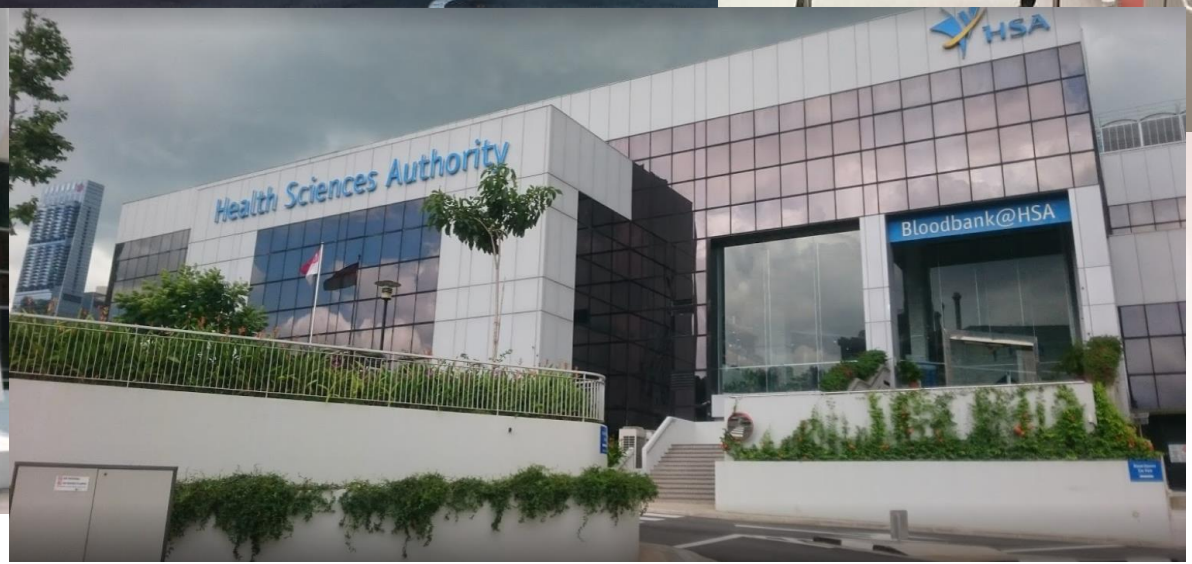
- Adequate resources, including sufficient number of qualified and trained staff be available
- A national system for the evaluation, selection and validation of all assays
- The minimum evaluated sensitivity and specificity levels of all assays used for blood screening should be as high as possible and preferably not less than 99.5%.
- Quality-assured screening of using serology should be in place before nucleic acid testing are considered

# Blood Screening in the Region







# Blood Screening in the Region










# Examples of Blood Transfusion Services

| Country | No of labs | Centralised services | Type of services | National policies |
|---|---|---|---|---|
| Australia | 4 | Yes | Red Cross | Yes |
| Bhutan | 27 | Yes | Hospital | Yes |
| Bangladesh | >100 | No | Private/Red crescent | Yes |
| China (mainland) | >400 | Partial | Government | Yes |
| India | >2750 | No | Provincial, hospital, private, charitable, government | Yes (+/-) |
| Indonesia | >200 | No | Red cross, hospital | ? |
| Malaysia | 14 | Yes | Government | Yes |
| Myanmar | | Yes | ? | Yes |
| Nepal | ~70 | ? | Hospital, district | Yes |
| New Zealand | 2 | Yes | Red Cross | Yes |
| Thailand | 13 | Yes | Red Cross | Yes |
| Timor-Leste | 1 +/- | Yes | Government | Yes |
| Sri Lanka | ~80 | Yes | Hospital, private | Yes |

# Serology Screening – anti-HIV

| Assay | Sensitivity | Specificity |
|---|---|---|
| Abbott Architect | 100% | 99.62% |
| Abbott PRISM | 100% | 99.98% |
| DiaSorin Liaison XL | 100% | 99.69% |
| DiaSorin Murex EIA | 100% | 99.91% |
| Ortho VITROS | 100% | 99.92% |
| Roche Elecsys (combi PT) | 100% | 99.88% |
| Siemens ADVIA Centaur | 100% | 99.74% |
| Siemens Enzygnost EIA | 100% | 99.3 – 100% |

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# Serology Screening







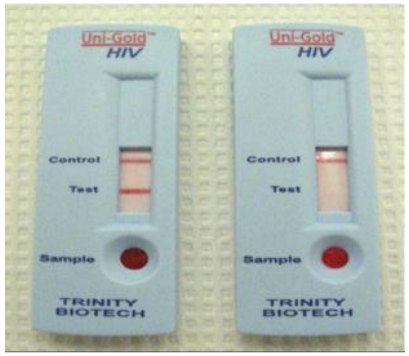




# Serology Screening – anti-HIV

| Rapid Tests used in NRL EQAS | WHO Prequalified |
|---|---|
| ACON HIV 1/2 Ultra Rapid Test Device (Serum/Plasma) | No |
| Alere Determine HIV-1/2 Ag/Ab Combo Rapid Test | Yes |
| Alere Determine HIV-1/2 Rapid Test | Yes |
| Bio Focus BioTracer HIV 1/2 Rapid Card | No |
| Blue Screen HIV 1/2/O Tri-line HIV Rapid Test Device (WB/S/P) | No |
| Core Diagnostics Core HIV 1&2 | No |
| Green Cross GENEDIA HIV 1/2 Rapid 3.0 | No |
| Human HEXAGON HIV Rapid Test | No |
| Orgenics ImmunoComb II HIV 1 & 2 CombFirm | No |
| PMC FIRST RESPONSE HIV 1-2.O Rapid Card test (v.3.0) | No |
| Standard Diagnostics SD Bioline HIV-1/2 3.0 Rapid Test | Yes |
| J. Mitra HIV TRI-DOT | No |
| Wondfo One Step HIV 1/2 WB/S/P Rapid Cassette Test (2 Lines) | No |

# Serology Screening

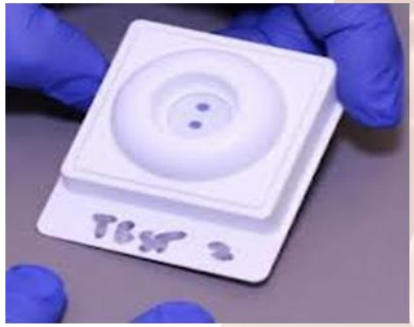






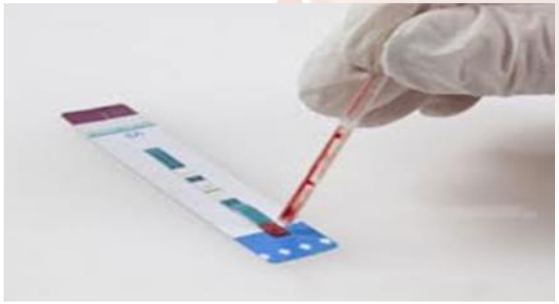










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# Testing Reported in NRL EQAS

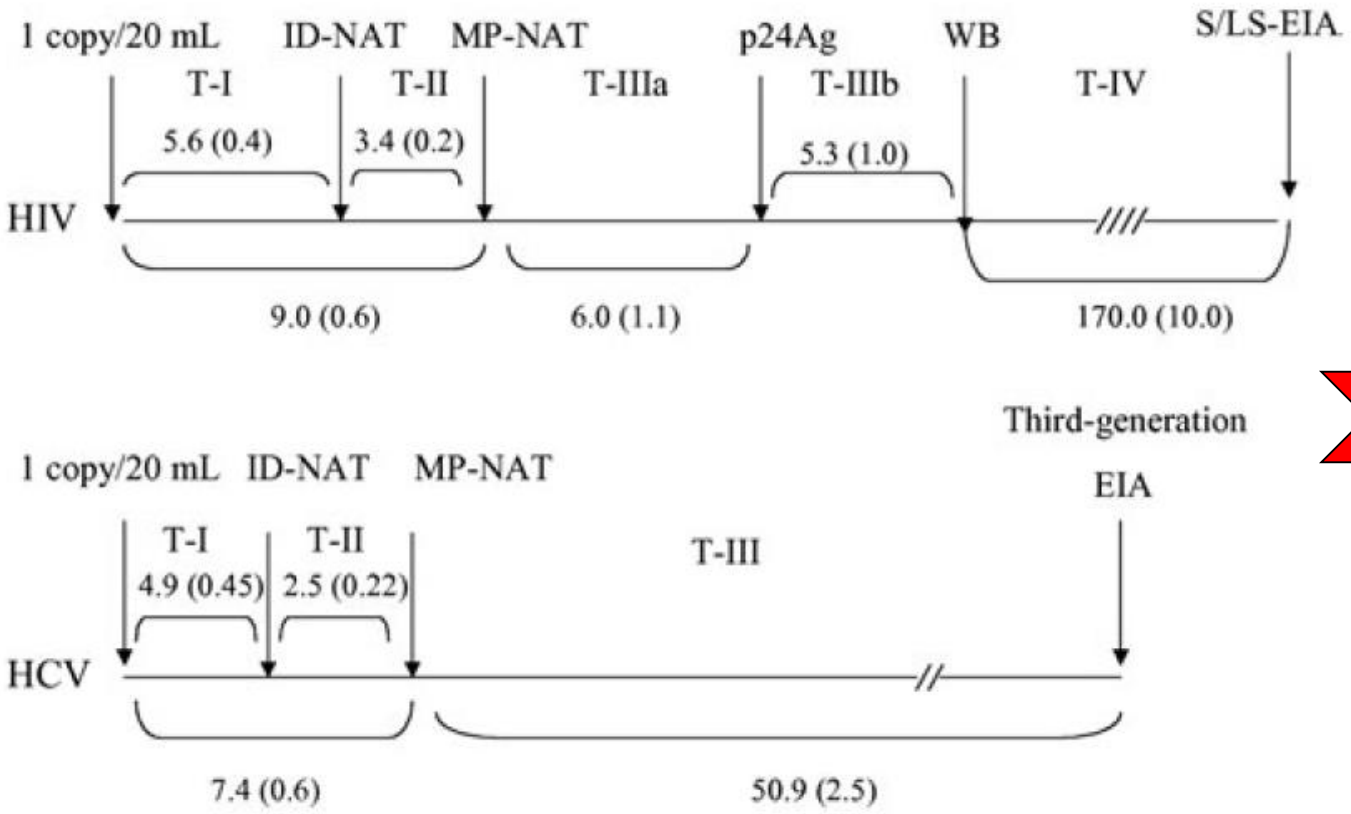
| Country | Serology | Nucleic Acid Testing |
|---|---|---|
| AUSTRALIA | ChLIA, EIA, Blot, PAA | Yes |
| BANGLADESH | ChLIA, EIA, | No |
| BHUTAN | EIA , PAA | No |
| CHINA (mainland) | ChLIA, EIA, Blot, PAA | Yes |
| INDIA | ChLIA, EIA, Blot, PAA, RTD | Partial |
| INDONESIA | ChLIA, EIA, Blot | Yes |
| JAPAN* | ChLIA, EIA, Blot, PAA | |
| MALAYSIA | ChLIA, Blot, PAA | Yes |
| MONGOLIA | ChLIA, EIA, Blot, PAA, RTD | Yes (+/-) |
| NEPAL | EIA, RTD | No |
| NEW ZEALAND | ChLIA | Yes |
| VIETNAM | ChLIA, PAA, RTD | Yes |

# Testing Reported in NRL EQAS

| Country | Serology | Nucleic Acid testing |
|---|---|---|
| PR OF CHINA | ChLIA, EIA, Blot, PAA, RTD | Yes |
| PHILIPPINES | ChLIA, EIA, Blot, PAA, RTD | |
| REPUBLIC OF KOREA | ChLIA, EIA, Blot, PAA, | Yes |
| REPUBLIC OF MALDIVES | ChLIA | |
| REPUBLIC OF SINGAPORE | ChLIA, PAA | Yes |
| SRI LANKA | ChLIA, EIA, Blot | |
| THAILAND | ChLIA, EIA, Blot, RTD | Yes |
| UNION OF MYANMAR | ChLIA, EIA, RTD | |
| VIETNAM | ChLIA, EIA, Blot, PAA, RTD | Yes |

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# Window Period for HIV and HCV

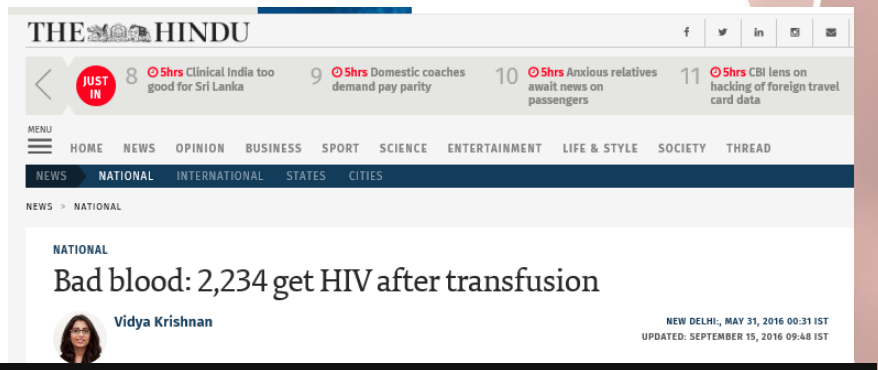



Rapid tests

Busch, M. *et al* Transfusion 2005; 45:254-264

# Testing Strategies in Asia Pacific

- Diverse
- Dangerous
- Difficult
- Developing


THE HINDU

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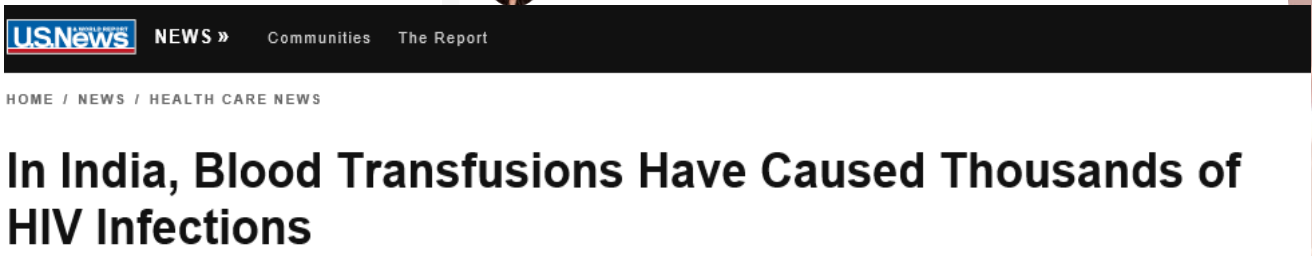
NEWS > NATIONAL

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Bad blood: 2,234 get HIV after transfusion

Vidya Krishnan

NEW DELHI:, MAY 31, 2016 00:31 IST
UPDATED: SEPTEMBER 15, 2016 09:48 IST


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In India, Blood Transfusions Have Caused Thousands of HIV Infections


Nepal | March 13, 2018

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Bloody hell! Transfusion happening without testing blood for deadly diseases

NO HOSPITAL IN NEPAL HAS KIT TO TEST HIV DURING THE 'WINDOW PERIOD'

Published: June 14, 2017 5:31 am On: Nepal

# Where to From Here?

- Assay evaluation and selection
- Assay procurement
- Validated testing algorithms
- Quality management systems
- Quality assurance / quality control
- Training

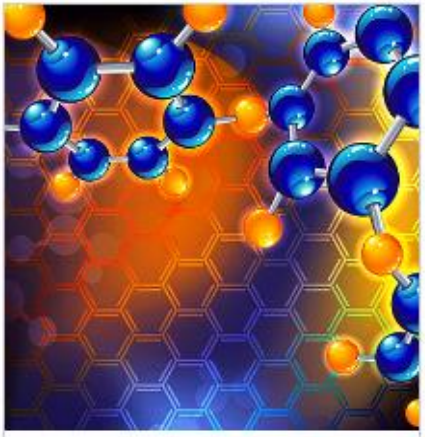
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NRL Asian Workshop on Quality 2018 (19-20 Mar 2018)



NRL European Workshop on Quality 2018 (15 May 2018)



NRL Workshop on Molecular Diagnostics 2018 (15-16 Oct)



35th Annual NRL Workshop on Infectious Diseases (16-18 Oct)