

Guidelines for interpreting HIV testing results

**Developed through consultation
between the National and State
Reference Laboratories in
Australia**

Disclaimer: The information contained herein was developed through consultation and contains the majority consensus views of Australian laboratory scientists and their Directors.

Introduction

At a recent NRL Workshop, a satellite meeting was held to discuss specific aspects of HIV testing algorithms and the subsequent reporting of results. A specific aim was to achieve consensus between views. It was decided at the meeting that those aspects achieving majority or unanimous consensus would be presented to laboratory directors for approval. The following slides show the goal of the meeting, relevant points of discussion and the consensus outcomes.

Aim

- **To standardise algorithms for HIV supplemental testing, their interpretation and the comments accompanying HIV test results, between the State Reference Laboratories in Australia.**

Goals

To reach consensus on:

- **Interpretation of HIV test results**
- **Comments issued with laboratory reports on HIV testing**
- **Reporting WB indeterminate results**
- **The recommended interval between initial and follow-up samples**
- **The use of HIV Proviral DNA PCR in HIV confirmatory testing algorithms**

Methods (1)

The NRL conducted a survey of the participants in its anti-HIV external quality assessment scheme with a view to determining the range of comments used to interpret anti-HIV testing results for diagnostic purposes in Australia.

The survey was presented as a set of nine testing result scenarios and laboratories were asked to provide the interpretive comments they would use for each of the scenarios.

Methods (2)

Based on the survey results, the NRL developed a proposed algorithm and standard interpretive comments, including recommended intervals between initial and follow-up testing. These were circulated to all Australian laboratories conducting HIV confirmatory testing for their comment. Interested parties met to discuss the outcomes at the NRL Workshop.

The algorithms developed from the discussion at the Workshop follow in slides 13 – 19. Slides 7 – 12 include specific discussions in the development of the algorithms.

Discussion (1)

Australian laboratories conducting HIV confirmatory testing test differing populations. While some laboratories test individuals attending STD and/or IDU clinics, others test populations including very few from these specific groups at higher risk of HIV infection. Hence the confirmatory testing laboratories preferred a “low risk” algorithm to be available for those individuals being tested who are known to be at low risk for HIV infection.

Laboratories are advised to use the “low-risk” strategy with caution. HIV infection in individuals with no declared risk or exposure occurs, sometimes more often than may be expected.

Discussion (2)

In Australia, WB indeterminate reactivity was described by patterns of reactivity in 1987. These patterns were divided into groupings that have assisted with the interpretation of WB profiles. These groupings are still used today. They are:

- **WB negative:**

- No reactivity to viral proteins

- **WB positive:**

- Reactivity to glycoproteins and three other viral proteins

Discussion (3)

- **WB indeterminate group 1:**
 - **Reactivity to viral proteins, but not to p18, p24 or any envelope glycoproteins**
- **WB indeterminate group 2:**
 - **Reactivity to viral proteins including p18, but not to p24 or any envelope glycoproteins**

Discussion (4)

- **WB indeterminate group 3:**
 - **Reactivity to viral proteins including p24 but not to any envelope glycoproteins**
- **WB indeterminate group 4:**
 - **Reactivity to envelope glycoproteins but to less than three other viral proteins**

Discussion (5)

Because each of the algorithms under consideration include p24 immunoassay (IA) supplemental testing, they can apply equally to situations where antigen/antibody combination or antibody only IAs are used for screening.

The algorithms assume that confirmatory testing always includes WB.

When results of serological testing on a sample indicate that a repeat collection is necessary, the consensus recommended interval between the first and second specimens was 6 weeks. However, all WB indeterminate reactivity should be followed up for 12 weeks (slides 18 and 19).

Discussion (6)

- **Since this consultation the production of the only commercial assay for detection of HIV DNA has been discontinued.**
- **Caution should be exercised when interpreting HIV test results from an individual who received treatment early in infection. Seroconversion fulfilling the criteria for positive WB may be delayed or incomplete.**

Results

The results of the consultative process are shown on the following slides, where the following key is used:

Green = Test results

Yellow = Anti-HIV status reported

Blue = Test used

White = Comments included on report

Italicised comments are discretionary

Result scenario following negative results on anti-HIV1/2 immunoassay

Anti-HIV-1/2 IA*: neg
(IA performed on a single aliquot of a sample)

Negative

If the sample were collected less than 12 weeks after exposure, this result may not exclude infection with HIV-1/2.

* IA = immunoassay

Result scenario (1) following RR* on anti-HIV1/2 immunoassay (*Risk high or unknown*)

HIV-1/2 WB neg, p24 Ag IA neg

No status reported

Reactivity in screening assay could not be confirmed by supplemental testing.
Please submit follow-up sample 6 weeks after the index sample was collected.

DNA PCR
(for resolution in < 6 weeks)

IA, (→ supplemental testing if IA RR)

* RR = repeatedly reactive

Result scenario (2) following "RR" on anti-HIV1/2 immunoassay
Known low risk / no suspicion of seroconversion

HIV-1 WB neg (+/- p24 IA Ag neg)

Negative

If the sample were collected less than 12 weeks after exposure, this result may not exclude infection with HIV 1/2.

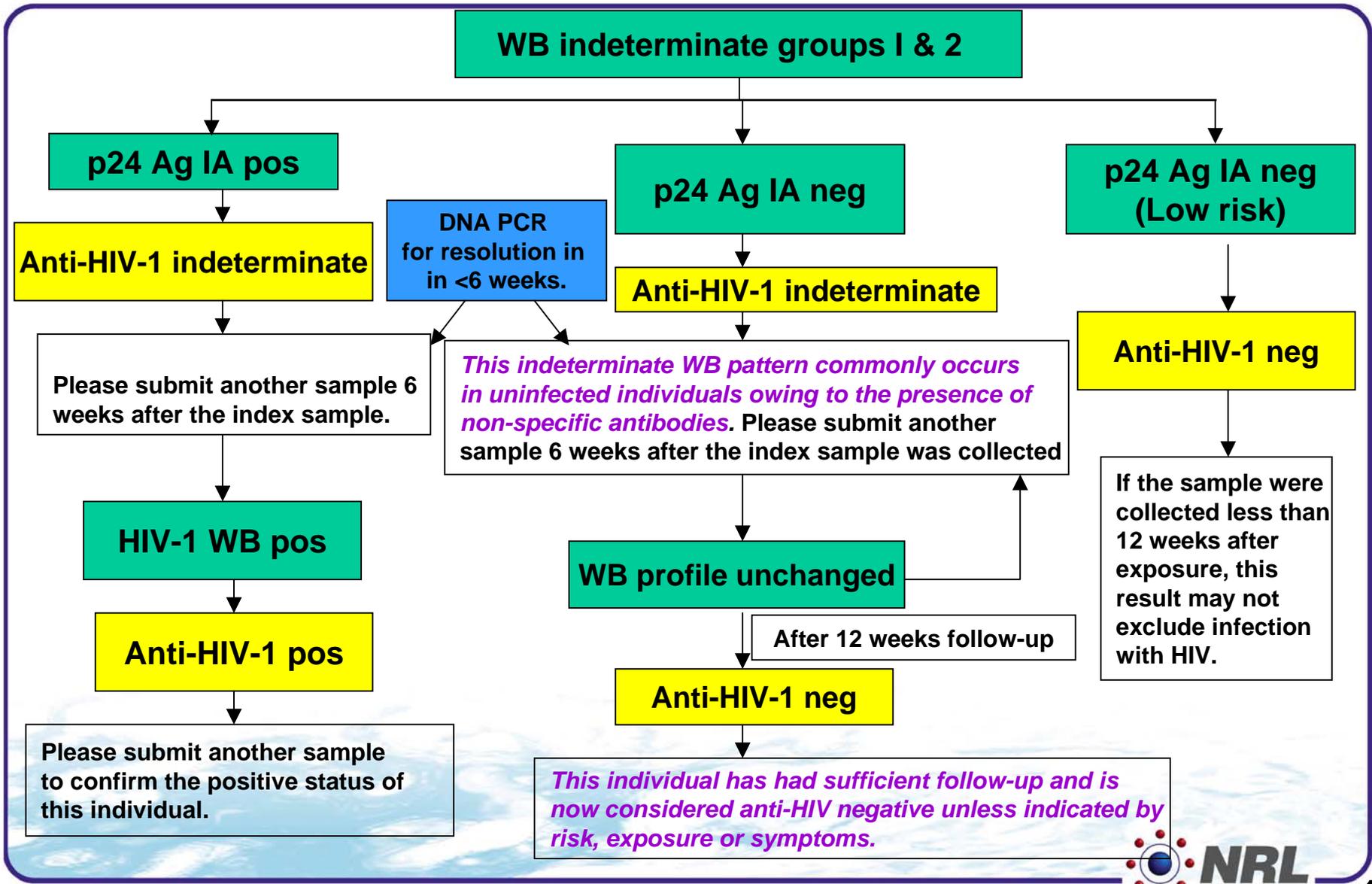
Result scenario (3) following "RR" on anti-HIV1/2 immunoassay

HIV-1 WB pos

Anti-HIV-1 pos

Please submit another sample to confirm the positive status of this individual.

Result scenario (4) following "RR" on anti-HIV1/2 immunoassay



Result scenario (5) following "RR" on anti-HIV1/2 immunoassay

