

# Reducing time to new HIV diagnosis – time for change in the HIV diagnostic algorithm?

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## Background

- In Australia, diagnosis of HIV has traditionally relied on a western blot (WB) for confirmation
- Prolonged time to HIV-specific IgG development for WB detection may lead to delays in diagnosis<sup>1</sup>, particularly in acute HIV infection where the WB is negative or indeterminate. Detection of p24 antigen on two separate specimens has traditionally been used in these cases to confirm HIV diagnosis<sup>2</sup>
- The Public Health Laboratory Network (PHLN) has recently updated the HIV laboratory case definition to include nucleic acid amplification tests (NATs) as an alternative confirmatory assay to WB<sup>3</sup>, prompting review of current diagnostic algorithms
- We assessed time to laboratory confirmed HIV diagnosis using the previous laboratory case definition, comparing time to confirmation using either WB or p24 assay

## Methods

Newly diagnosed HIV at the Royal Melbourne Hospital (RMH)  
1<sup>st</sup> July 2017 – 31<sup>st</sup> May 2021  
(n = 31)

Retrospective data collection:

- HIV screening immunoassay
- Western blot
- P24 neutralisation assay
- HIV viral load
- CD4 count
- Time to new HIV diagnosis\*
- Time to antiretroviral therapy commencement

\*Calculated from date of first blood collection for initial HIV testing to the date laboratory case definition for HIV diagnosis was fulfilled

Differences between individuals diagnosed through WB and p24 assay were compared using Wilcoxon rank-sum. P<0.05 were regarded as significant.

## Results

31 cases of HIV were diagnosed in the study period. 25 (81%) fulfilled case definition through WB.

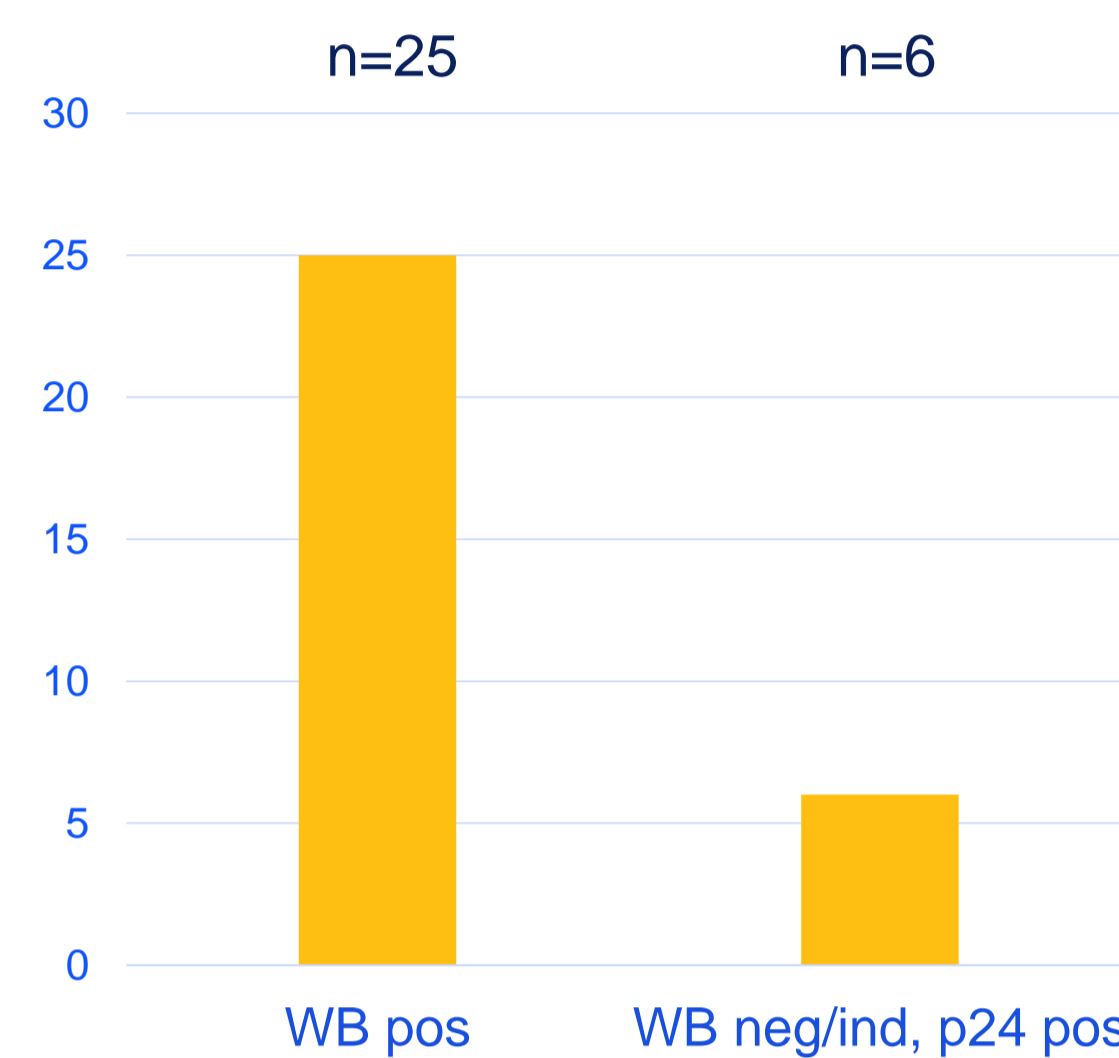


Figure 1. New HIV diagnoses at RMH during the study period diagnosed by western blot (WB) or p24 assay ind, indeterminate; neg, negative; pos, positive.

Median time to laboratory confirmed HIV diagnosis using WB was 5 days. In cases of acute infection, where WB was negative or indeterminate, median time to diagnosis was 10 days using p24 neutralisation assay.

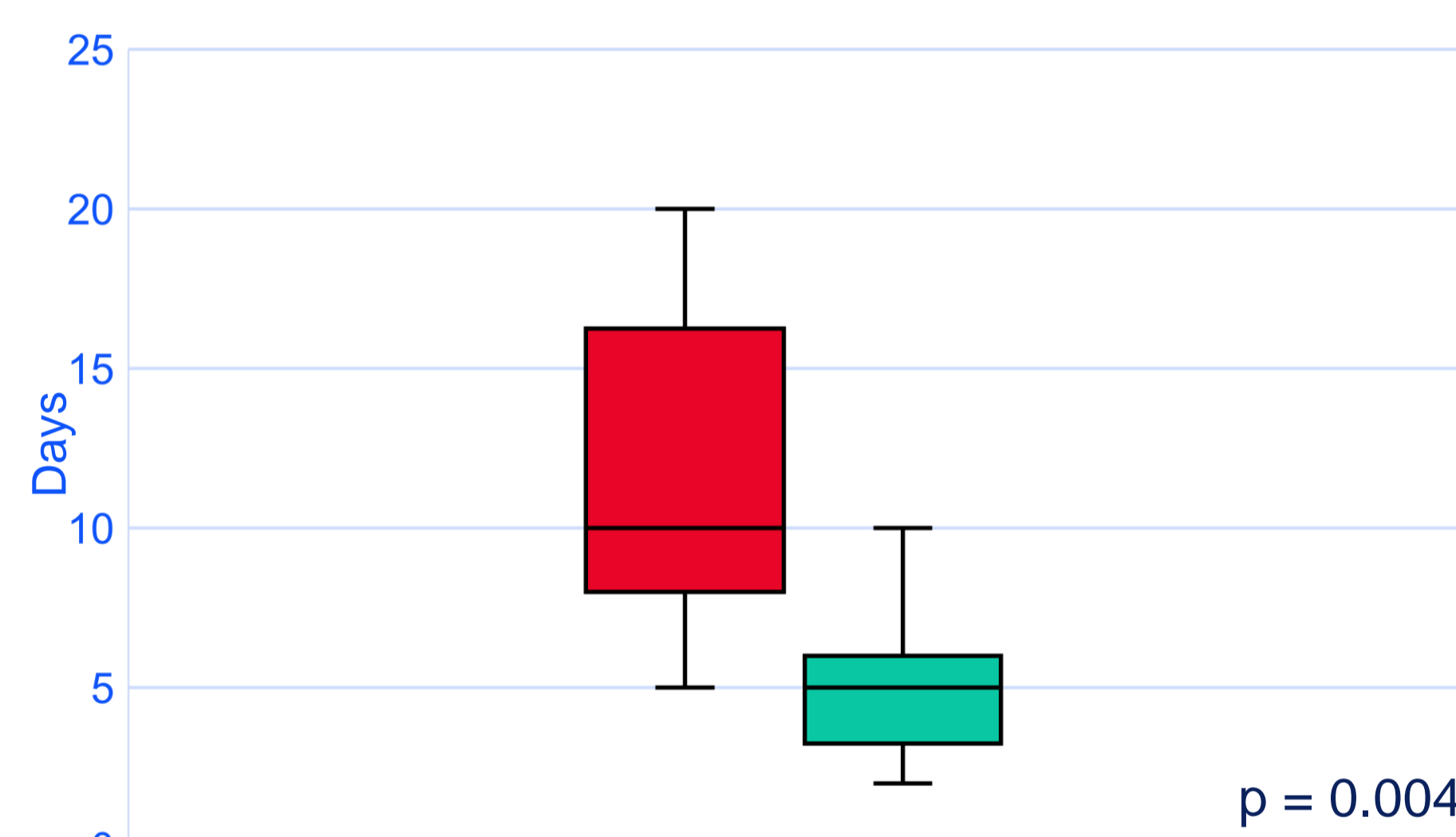


Figure 2. Time to new laboratory confirmed HIV diagnosis by western blot (red) or p24 assay (green)

Data on ART commencement were available for 21 individuals. There was no difference in time to ART commencement, with median time of 10 days for individuals diagnosed either through WB or p24 assay

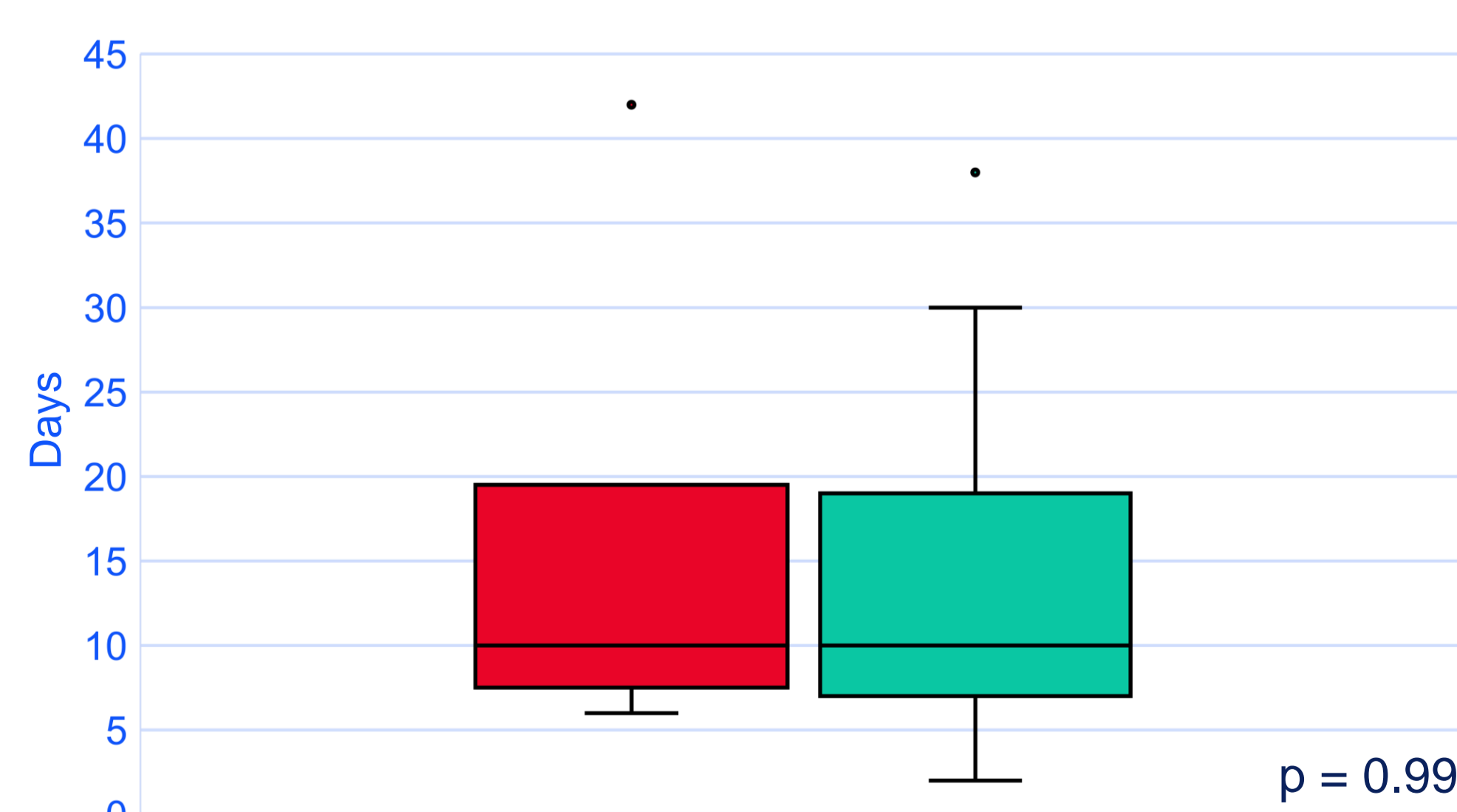


Figure 3. Time to antiretroviral commencement in individuals diagnosed through western blot (red) or p24 assay (green)

Individuals diagnosed through WB had lower median CD4 count, consistent with established infection. Conversely, median HIV viral load in individuals diagnosed through p24 was higher, consistent with acute infection (Table 1)

Time to ART commencement was dependent on CD4 count at diagnosis. Median time to ART initiation for individuals diagnosed through WB with CD4 count <0.05 x10<sup>9</sup>/L, <0.20 x10<sup>9</sup>/L and ≥0.20 x10<sup>9</sup>/L was 15, 12 and nine days, respectively.

Table 1. Time to new HIV diagnosis and baseline tests

	All new HIV diagnoses (n=31)	New HIV by positive WB (n=25)	New HIV by p24 assay (n=6)	P value
Days to HIV diagnosis <sup>a</sup>	5 (4 – 8)	5 (4 – 6)	10 (9 – 14)	0.004
HIV VL copies/mL	183,888 (101,766 – 822,415)	119,002 (85,704 – 512,466)	1,273,358 (436,986 – 4,139,515)	0.008
HIV VL Log <sub>10</sub>	5.26 (5.01 – 5.92)	5.08 (4.93 – 5.71)	6.10 (5.64 – 6.62)	0.001
CD4 T cell count x10 <sup>9</sup> /L	0.27 (0.06 – 0.51)	0.16 (0.04 – 0.34)	0.54 (0.51 – 0.64)	0.001
CD4 T cell %	16.9 (6.4 – 24.3)	16.0 (4.2 – 21.5)	21.9 (13.8 – 28.3)	0.19
Days to ART	10 (7 – 18)	10 (7 – 19)	10 (8 – 12)	0.99

Data are shown as median and interquartile range. <sup>a</sup>Diagnosis as per Australian Public Health Laboratory Network 2015<sup>2</sup>. ART, antiretroviral therapy; VL, viral load; WB, western blot.

## Conclusions

- Median time to laboratory confirmed diagnosis of acute HIV was double that of established infection (10 vs 5 days) using the current diagnostic algorithm
- Newer approaches to confirmatory HIV testing, such as NATs, have become available that may streamline the diagnostic process. Qualitative NATs for HIV diagnosis are now TGA approved
- The updated PHLN case definition for HIV provides opportunity for NATs to be incorporated into the HIV diagnostic algorithm, which could significantly reduce time to HIV diagnosis while retaining high test specificity

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### References

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