

# PERFORMANCE OF THE GEENIUS HIV 1/2 CONFIRMATORY ASSAY FOR DIAGNOSIS OF HIV IN THE AUSTRALIAN SETTING

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## Background

Timely and accurate diagnosis plays a critical role in clinical management and prevention of HIV. The Geenius HIV 1/2 confirmatory assay is an immunochromatographic test (ICT) with a 20-minute turnaround time that is recommended by national peak bodies for HIV confirmatory testing internationally. In 2025, the Australian HIV case definition introduced the Geenius ICT as an alternative method to western blot (WB) for HIV confirmatory testing. Here we describe the performance of the Geenius ICT and automated reader for confirmation of HIV in an Australian state reference laboratory.

## Methods

A single site retrospective laboratory evaluation of the Geenius ICT was performed. Sera comprising a range of HIV results, collected from individuals  $\geq 18$  years between 1<sup>st</sup> January 2022 and 31<sup>st</sup> December, 2023 were included, supplemented with two historical HIV-2 samples. Standard of care clinical testing included HIV Ag/Ab and WB; plus HIV p24 antigen and HIV proviral DNA testing when indicated. Available metadata including age, sex, HIV-1 subtype and antiretroviral therapy were collected from the laboratory information system.

## Results

Two hundred specimens (100 HIV positive, 100 HIV negative) were included. Median age was 35; 72.5% were male. Compared to the standard of care composite laboratory HIV definition, Geenius ICT correctly identified 91% HIV positive and 95% HIV negative specimens; compared with 80% and 67% correctly identified by WB, respectively. Indeterminate results were observed more frequently with WB (23.5%) than Geenius ICT (3%). Geenius ICT result concordance between the independent laboratory scientists and automated reader was high (99.5%).

## Conclusion

The Geenius ICT demonstrated improved accuracy for the diagnosis of HIV compared with WB. Incorporation of the Geenius ICT into HIV diagnostic workflows may be enhanced through use of the automated reader. The rapid turnaround time of the Geenius ICT facilitates improved laboratory efficiency and reduced time to HIV diagnosis in Australia.

Disclosure of interest: None