

Rapid HIV testing increases the rate of HIV detection in men who have sex with men: using rapid HIV testing in a primary care clinic

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Abstract. Rapid HIV testing was approved in Australia in December 2012. Data was collected to describe the early experience of using rapid testing in Australia but as the information was collected, the authors noted that there appeared to be a high rate of HIV diagnoses amongst rapid testers. Further analysis confirmed this impression, when the rate was compared to a baseline rate of HIV diagnoses over the 32 months before the rapid testing started (4.1% vs 1.3%).

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Australia is classified as a low HIV prevalence country with the epidemic highly concentrated in men who have sex with men (MSM).¹ We have universal access to health care with free and anonymous HIV testing. Despite this and high self-reported HIV testing rates among MSM in Australia, test records from high HIV caseload clinics in Melbourne suggest few MSM test at recommended frequencies². Until recently, diagnosis of HIV in Australia has been through conventional enzyme immunoassay and western blot tests, which may act as a barrier to testing due to the waiting period and the need to return to the clinic for results, with some MSM expressing a preference for more convenient and immediate forms of HIV testing.³

The first rapid HIV point-of-care test (RPOCT), the Alere Determine Combo HIV Ab/Ag test (Alere, Sinnamon Park, QLD, Australia) was approved by the Australian Therapeutic Goods Administration in December 2012. In March 2013, Prahran Market Clinic started using this kit commercially and we report on our experience. Prahran Market Clinic is a primary care clinic (general practice) with an interest in HIV medicine, which undertakes ~2500 HIV tests annually. In the context of an established high HIV caseload primary care clinic, we assessed the following:

- (1) The performance of the RPOCT against standard serology,^{1,4}
- (2) The acceptability of the RPOCT,
- (3) The HIV positivity rate of MSM opting for RPOCT compared with positivity among MSM receiving conventional testing over the previous 32 months.

The Alere HIV RPOCT was made available to all patients of consenting age requesting it. Patients having the RPOCT also had a serum test done. We also collected data about patient satisfaction.

Between 15 March 2013 and 31 August 2013, we conducted 302 RPOCT, 219 among MSM. Amongst MSMs, 219 out of 1527 patients chose to have the RPOCT (14.3%, 95% confidence interval (CI): 12.5–16.1%). The results for the RPOCT and for serum HIV testing using a fourth-generation enzyme immunoassay HIV antibody test are described in Fig. 1. These preliminary data indicate that the RPOCT performed well compared with serological testing, yielding a sensitivity of 90% (95% CI: 83.2–96.8%), a positive predictive value of 90% (95% CI: 83.2–96.8%), a specificity of 99.7% (95% CI: 99.1–100%) and a negative predictive value of 99.7% (95% CI: 99.1–100%). All fully positive HIV results and seroconverters where the western blot result was not fully positive were considered positive results for these calculations. There were nine patients diagnosed with HIV in this period – three of these were seroconverting at the time and were confirmed on further testing. The RPOCT detected two out of three seroconverters. This is consistent with reported experience.^{5–9} The one false positive result was in a MSM. There were no positive HIV antigen results in the sample.

Among 270 discrete patients requesting RPOCT, 146 patient satisfaction questionnaires were completed. One in five patients (20%, 95% CI: 14–26%) indicated they would not have had a HIV test if the RPOCT was not available and most (57%, 95% CI: 49–65%) said they would test more often because RPOCTs were offered. Satisfaction with the test was high (98.6%, 95% CI:

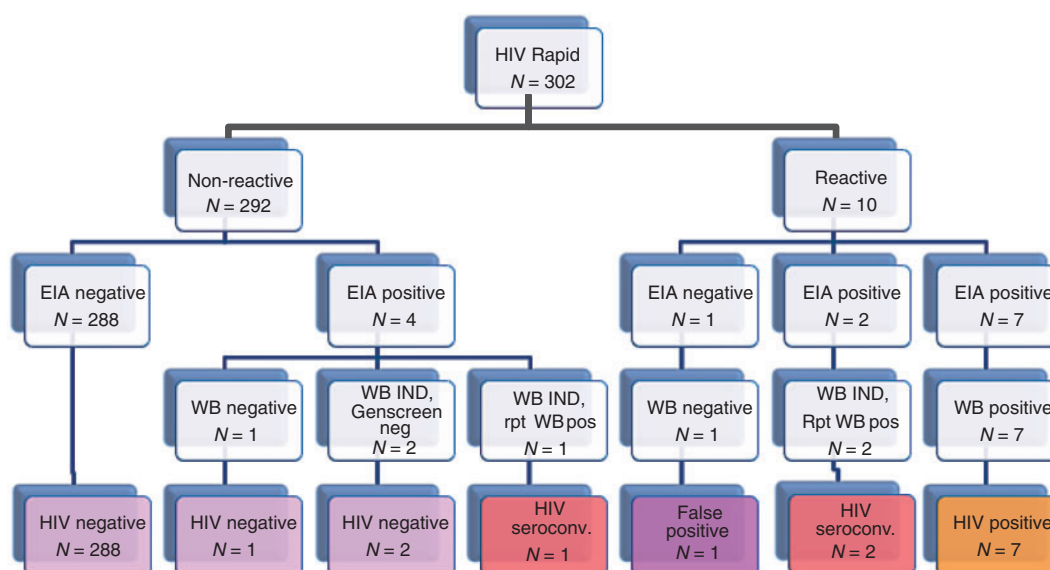


Fig. 1. Summary of all rapid point-of-care test results: all tests done and final results. Trials were performed from 15 March 2013 to 31 August 2013. EIA, enzyme immunoassay; WB, western blot.

96.7–100%) based on whether the patient would use the test again.

The HIV positivity rate among MSM having the RPOCT was 4.1% (95% CI: 1.9–7.7) compared with 1.3% (99 out of 7403 MSM) (95% CI: 1.1–1.5; $P < 0.05$) for the 32-month retrospective HIV positivity rate for MSM using serum testing.

Despite the need for parallel testing and an additional patient cost of AU\$20 for each test, the HIV RPOCT was well accepted, demonstrating that RPOCTs can be integrated effectively and reliably in an Australian primary care clinic. Survey data also suggests that the RPOCT was successful in increasing the uptake of HIV testing (77 new files for MSM patients). Comparative HIV positivity rates among MSM indicated that patients at high risk of undiagnosed HIV opted for a RPOCT, either because these MSM did not test frequently, were test naïve or were engaging in high-risk sexual behaviours.

Our experience demonstrates that RPOCTs can be effectively incorporated into primary care practice in Australia and potentially reduce some of the barriers associated with conventional HIV testing. Our preliminary findings show that MSM at a higher risk of undiagnosed HIV were attracted to RPOCT, supporting the role of this testing model in enhancing individual patient care and in preventing HIV transmissions in Australia.

References

- Kirby Institute. HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia annual surveillance report. Sydney: University of New South Wales; 2012.
- Guy R, Goller JL, Spelman T, El-Hayek C, Gold J, Leslie D, *et al.* Does the frequency of HIV and STI testing among men who have sex with men in primary care adhere with Australian guidelines? *Sex Transm Infect* 2010; 86(5): 371–6. doi:10.1136/sti.2009.040972
- Conway D, Guy R, Davies S, Couldwell D, McNulty A, Smith D, *et al.* Rapid testing is acceptable and preferred among gay men attending sexual health clinics: findings from the Sydney rapid test study. ASHM Conference 17–19 October 2012, Melbourne, Australia. 2012.
- Beelaert G, Fransen K. Evaluation of rapid and simple fourth-generation HIV screening assay for qualitative detection of HIV p24 antigen and/or antibodies to HIV-1 and HIV-2. *J Virol Methods* 2010; 168(1–2): 218–22. doi:10.1016/j.jviromet.2010.06.002
- Smit E, Atherton C, Osman H. Determine HIV-1/2 Ag/Ab Combo lacks sensitivity in detecting early HIV infections. The European Society for Clinical Virology Winter Meeting; 2011 January 13–15; London, UK.
- Gürtler L, Mühlbacher A, Michl U, Hofmann H, Paggi GG, Bossi V, *et al.* Reduction of the diagnostic window with a new combined p24 antigen and human immunodeficiency virus antibody screen assay. *J Virol Methods* 1998; 75(1): 27–38. doi:10.1016/S0166-0934(98)00094-9
- Burst S, Duttman H, Feldner J, Gürtler L, Thorstensson R, Simon F. Shortening of the diagnostic window with a new combined HIV p24 antigen and antibody HIV1/2/O screening test. *J Virol Methods* 2000; 90(2): 153–65. doi:10.1016/S0166-0934(00)00229-9
- Masciotra S, Luo W, Youngpairoj AS, Kennedy MS, Wells S, Ambrose K, *et al.* Performance of the Alere Determine HIV-1/2 Ag/Ab combo rapid test with specimens from HIV-1 seroconverters from the US and HIV-2 infected individuals from Ivory Coast. *J Clin Virol* 2013. doi:10.1016/j.jcv.2013.07.002
- Chetty V, Moodley D, Chuturgoon A. Evaluation of a 4th generation rapid HIV test for earlier and reliable detection of HIV infection in pregnancy. *J Clin Virol* 2012; 54(2): 180–4. doi:10.1016/j.jcv.2012.02.021