

Changes to the sale and promotion of HIV self-testing devices in Australia



20 December 2021

This briefing paper has been developed by AFAO to update the HIV community workforce on changes to the availability of HIV Self-Tests (HIVST) in Australia.

Key Points

- In October 2021, the Therapeutic Goods Administration (TGA) eased conditions on the registration of Australia's only approved HIVST, the Atomo HIVST, allowing individuals to buy the device over-the-counter in pharmacies.
- Access through online channels will be easier as consumers no longer need to watch an instructional video to purchase an HIVST.
- HIV testing must be convenient and accessible for all priority populations if Australia is to meet its goal of ending HIV transmission by 2025 and achieve its obligation to diagnose 95% of people with HIV in Australia by 2030.
- Tests can be supplied through relevant businesses and specialist HIV organisations.
- New advertising permissions allow health promotion of the approved device by retailers and civil society organisations.
- The HIVST may not detect HIV acquired in the three months before using the test. Community members should be advised to consult a medical practitioner if there was an episode of exposure during this time period.
- The test is a screen for HIV, and a reactive test result requires confirmatory testing in a clinical facility. A care card is included with the device and provides information if an individual returns a reactive result.

Policy Context

The World Health Organisation recommends HIV self-testing as a core element of comprehensive HIV programming.¹ This recommendation is incorporated domestically in the *Eighth National HIV Strategy 2018 – 2022*, which includes improving the frequency, regularity and targeting of access to testing for priority populations and decreasing the rate of late diagnosis as a target.²

Australia's *National HIV Testing Policy* advises that self-testing minimises the barriers associated with conventional testing, including lack of access and feelings of stigma and the risk of discrimination. Self-testing can also support autonomy and provides added confidentiality, privacy and convenience for people who do not engage in HIV testing.³ Australian research confirms that the proportion of people with HIV undiagnosed is higher among people born overseas than the Australian-born population.⁴

¹ World Health Organization, *WHO Recommends HIV Self-Testing – Evidence Update and Considerations for Success* (Policy Brief, 2019) <<https://www.who.int/publications/i/item/WHO-CDS-HIV-19.36>>.

² Commonwealth Department of Health, *Eighth National HIV Strategy 2018 – 2022* (National Strategy, 2018) 17 <[https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1/\\$File/HIV-Eight-Nat-Strategy-2018-22.pdf](https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1/$File/HIV-Eight-Nat-Strategy-2018-22.pdf)>.

³ ASHM, *National HIV Testing Policy* (Policy, 2020) 10 <<https://testingportal.ashm.org.au/national-hiv-testing-policy/>>.

⁴ 'HIV Surveillance Data', Kirby Institute, UNSW Sydney (HIV Data, 2020) <<https://data.kirby.unsw.edu.au/hiv/>>.

Summary

COVID-19: Impact on HIV testing in Australia

COVID-19 restrictions on movement disrupted consumer engagement with healthcare settings, leading to reduced face-to-face contact with health services. This led to a one-third decline in the number of HIV tests in Australia in the fourth quarter of 2020 compared to the fourth quarter of 2019.⁵ The Atomo HIVST is an alternative HIV testing method that will help to restore testing rates to pre-pandemic levels.

Evidence base

AFAO successfully relied on an evidence base that demonstrated gay and bisexual men can validly test themselves and correctly interpret test results. The research showed:

- HIV self-testing increased the frequency of testing in gay and bisexual men. There was a four-fold increase in non-recent testers.⁶
- Most gay and bisexual men (90%) are satisfied with the usability of the Atomo HIVST. Increasing the options for gay and bisexual men to access HIV self-testing will drive up testing rates.⁷
- A United States study found 91% of participants correctly interpreted sample HIV self-testing results when presented with images depicting positive, negative, weak positive and invalid results.⁸

Promoting the Atomo HIVST: Conditions

The Atomo HIVST became available in selected Australian pharmacies in December 2021 and will be progressively supplied to pharmacies across Australia in 2022. An advertising permission enables broader promotion of the device while keeping with the following communications required to be displayed in promotion materials:

- Community members should be advised to consult a medical practitioner if there was an episode of exposure during this time period.
- The test is a screen for HIV. A reactive test result requires confirmatory testing in a clinical facility.

In addition, AFAO jointly developed a care card with Atomo that comes with the device and includes information if an individual returns a reactive result.

AFAO is hopeful the easing of advertising and supply conditions will incentivise other HIVST manufacturers to seek TGA approval to enter the Australian market.

⁵ Skye McGregor, 'National Update on HIV: HIV in Australia, 2011-2020' (Conference Paper, 2021 Joint Australasian HIV&AIDS and Sexual Health Conferences', 6 - 9 September 2021 online).

⁶ Jamil S Muhammad et al, 'Effect of availability of HIV self-testing on HIV testing frequency in gay and bisexual men at high risk of infection (FORTH): a waiting-list randomised controlled trial' (2017) 4(6) *The Lancet HIV* e241.

⁷ Shaun Powyer et al, 'Australian First Virtual HIV Testing Service: Innovation in Response to COVID-19' (Conference Paper, 2021 Joint Australasian HIV&AIDS and Sexual Health Conferences', 6 - 9 September 2020 online)

[<https://az659834.vo.msecnd.net/eventsairaeuprod/production-ashm-public/02586ccd49da4db0a87faaf01d042047>](https://az659834.vo.msecnd.net/eventsairaeuprod/production-ashm-public/02586ccd49da4db0a87faaf01d042047>).

⁸ Robin J MacGowan et al, 'Pilot Evaluation of the Ability of Men Who Have Sex with Men to Self-Administer Rapid HIV Tests, Prepare Dried Blood Spot Cards, and Interpret Test Results' (2018) 22 *AIDS and Behaviour* 117.