

Rapid Testing and Sex Work Position Paper

POSITION STATEMENT

Scarlet Alliance supports the use of rapid testing under the following conditions only:

- Rapid testing is **not** targeted towards states in which sex workers working with HIV/STIs are criminalised. In those jurisdictions, rapid testing can mean instant criminalisation, making sex workers liable for prosecution. Rapid testing may put sex workers' confidentiality, careers, lives and income at risk;
- Rapid testing is not combined with contact tracing. Contact tracing has resulted in sex workers living with HIV being publicly vilified and their privacy and confidentiality breached;
- Rapid testing in community settings does not occur in sex industry workplaces. HIV testing in workplaces will have serious implications for sex workers' confidentiality. In other countries, health care providers have offered financial incentives to sex workers to undergo rapid testing in order to meet certain testing targets to receive funding, meaning testing may not be voluntary. Rapid testing in workplaces will result in privacy breaches where workers who decline testing are treated with suspicion and where workers receive reactive results during our shift whilst sharing space with peers, clients and employers;
- Rapid testing is always voluntary. No sex worker should ever be coerced into or compelled to have a rapid test. Sex workers already face mandatory testing in various jurisdictions around Australia, contrary to Australia's National Strategies. Voluntary, confidential, anonymous and patient-initiated testing remains the best-practice approach to STI and HIV testing;
- Rapid tests are not targeted towards sex workers. Sex workers are a low prevalence population and rapid testing is not recommended for low prevalence populations;
- Sex workers should have choice – rapid tests should always be offered in parallel with conventional testing. Rapid tests are only one testing option and do not replace conventional STI/HIV testing: testing accuracy is important for sex workers as we negotiate and manage risk;
- Clinical trial results on rapid testing efficacy and accessibility among gay male populations should not be applied to sex workers, who have a very different epidemiology and legal environment; and
- New HIV testing technologies are not used as a substitute for peer education, safer sex supplies, or community led health promotion; are not an alternative to human rights and an enabling legal environment; and do not detract funding from sex worker organisations.

BACKGROUND

Rapid test now approved for use in Australia

Australia is experiencing a changing legal and policy climate in relation to HIV and STI testing with the development of new testing technologies and new opportunities to use them in Australia.

In December 2012, the Therapeutic Goods Administration registered a 'point of care' test (also known as 'rapid test') to be used in Australia.¹ This particular test is called the Alere Determine HIV 1/2 Ag/Ab Combo. Rapid testing is also now supported by the 2011 National HIV Testing Policy, endorsed by BBVS (Blood Borne Viruses and Sexually Transmissible Infection Subcommittee) and the Ministerial Advisory Committee on Blood Borne Viruses (MACBBVS). The previous 2006 policy did not support it.²

Rapid testing has been used in Australia before, but only in laboratory or clinical settings as part of testing methodology. There will continue to be strict conditions on where, how, and by whom rapid tests can be conducted. These are detailed below.

What is rapid testing?

Conventional testing

Conventional HIV testing involves blood samples taken from patient's veins and tested in pathology laboratories using a process called enzyme-linked immunoassay (EIA). If a sample is reactive, a series of supplementary and confirmatory tests are performed. This means that test results may take a few days to a week to process. Patients can return to the test site to receive results in addition to post-test counseling, and the National HIV Testing Policy now provides scope for sites to provide HIV test results by phone at the discretion of the clinician. Some sexual health clinics now offer phone/SMS test results to clients who test frequently, rather than requiring the person to return to receive their results in person. Conventional testing then may take 1–2 weeks depending on batching and when a patient can make a return visit. Multiple appointments per test means that 'high risk' groups may need many clinic appointments per year.³ In jurisdictions where sex workers face mandatory STI/HIV testing, we are required by law to return to the site at periodic intervals (in Victoria legislation requires three-monthly testing, recently amended from monthly testing), regardless of the frequency we are working.

Rapid testing

Rapid testing may involve a finger prick test or oral swab test as opposed to a laboratory test, so the procedure is less invasive. Rapid tests provide a result within approximately 30 minutes and the results can be provided to the patient within the same visit. However, if the results are 'reactive' (or 'preliminary positive') a sample must be sent for confirmatory testing at a laboratory, and the person may need to return to the site for their results.⁴ Rapid tests can be used in community as well as clinical settings, although there are restrictions on where they can be used and who can administer them. Rapid tests have been used internationally, including in the United States, Europe and New Zealand.

¹ Australian Government Department of Health and Ageing, Therapeutic Goods Administration, 'The Use of Point of Care Tests for HIV in Australia', 17 December 2011 <http://www.tga.gov.au/consumers/information-devices-hiv-rapid-tests.htm>, accessed 13 February 2013.

² ASHM, National HIV Testing Policy, 2011 <http://testingportal.ashm.org.au/hiv>, 1.1 accessed 13 February 2013.

³ Alisa Pedrana and Mark Stoové, 'The Future of HIV Testing in Australia', *HIV Australia*, Volume 9, Number 3, November 2011, <http://www.afao.org.au/library/hiv-australia/volume-9/number-3/community-based-hiv-testing>, accessed 27 June 2014.

⁴ Ibid.

Who regulates rapid tests?

There are many different companies around the world manufacturing rapid tests. A distributor or manufacturer can apply to have their rapid test approved for use in Australia. Rapid tests are regulated by the Therapeutic Goods Association (TGA), who has authority to licence 'medical devices'. Each different 'kit' or device must be individually approved by the TGA. The TGA refers the test to the National Reference Laboratory, who will perform tests on the device using stored samples and may assess the manufacturing process and/or inspect the manufacturing facilities.⁵

Rapid testing is different to home testing

Rapid testing is distinct from home testing. The United States and the United Kingdom have approved certain kinds of home testing using an oral swab or finger prick test. Some tests can be read at home immediately, while others involve taking a sample and posting it to a laboratory for testing. Home testing is now being trialled in Australia as part of the Kirby Institute FORTH Study.⁶

The TGA has specifically stated that the Alere Determine HIV 1/2 Ag/Ab Combo is *not approved* for self-testing by individuals. They have stated that home testing kits have a different kind of 'risk profile', because they 'deprive patients of important pre-test discussion and post-test counselling and, if necessary, discussion of treatment options'. Self-tests for HIV are available over the Internet and can be imported into Australia for personal use. However, their reliability, performance and safety has not been evaluated by the TGA.⁷ Home testing with rapid tests is also not yet recommended by the HIV Testing Policy.⁸

Who can access rapid tests?

Rapid testing will not necessarily be free. If there is no Medicare subsidy provided, clinicians will bear the cost, or it will be passed on to patients. Cost will pose a barrier to people accessing testing and to clinicians offering testing. The cost of making an application to the TGA can be seen as a barrier for manufacturers to submit their test kits for approval, meaning there are fewer varieties of tests available.

Rapid tests have longer window periods

Rapid HIV tests (both finger prick and oral swabs) generally detect HIV antibodies, rather than antigens (the virus itself). This means that the window period for detection may be longer than conventional tests. The window period for conventional tests to detect HIV is up to 3 months, though most conventional tests use the latest generation tests which can detect HIV in shorter periods. Researchers have reported window periods for rapid tests of up to two weeks longer than conventional tests (using the latest or older generational tests). Window periods for rapid tests will vary from kit to kit, between different tests and manufacturers. There also may be a variation between the manufacturer's stated window period and the actual window period. AFAO states that these tests have not achieved equal or better performance to EIAs. The longer window period of a rapid test means that rapid tests may not be suitable for testing among people with a recent risk exposure.

⁵ Australian Federation of AIDS Organisations, Policy Briefing Paper on Rapid Testing, Linda Forbes and Phillip Keen, August 2010, http://www.afao.org.au/_data/assets/pdf_file/0014/4523/BP_0810_AFAO_rapid_hiv_testing_briefing_paper.pdf, accessed 27 June 2014.

⁶ Kirby Institute, The FOURTH Study, <http://www.nchechrsurveys.unsw.edu.au/forth/involved.htm>, 2012.

⁷ Australian Government Department of Health, Therapeutic Goods Administration, 'The Use of Point of Care Tests for HIV in Australia', 17 December 2011 <http://www.tga.gov.au/consumers/information-devices-hiv-rapid-tests.htm> accessed 30 November 2013.

⁸ ASHM, National HIV Testing Policy, 2011, 14.0, 'Home Based Testing in Australia', <http://testingportal.ashm.org.au/hiv/home-based-testing-in-australia>, accessed 27 June 2014.

The Alere Determine HIV 1/2 Ag/Ab Combo test recently approved by the TGA tests for *both* antibodies and antigens. Called the ‘fourth generation’ rapid HIV test, the addition of the antigen detection significantly reduces the window period. However, if someone has had recent HIV exposure, a conventional test would be recommended rather than a rapid test due to discrepancies in window periods. Rapid tests are designed as a screening tool rather than a diagnostic tool.

Rapid tests may be less accurate

Rapid tests may not be 100% accurate. Rapid tests may have lower performance than conventional tests in terms of sensitivity (that a true antibody positive sample will give a positive result) and specificity (that a positive result on the rapid test will be a true positive: lower specificity will mean more false positive results). Although AFAO states that some newer rapid HIV tests now have 100% sensitivity in established HIV infection,⁹ if a rapid test has a ‘reactive’ result, it cannot be conveyed as a ‘positive’ – the health professional administering the test should do confirmative testing.¹⁰

While finger prick tests may be more accurate, clusters of false positive results have occurred with oral fluid rapid tests. In the United States, the New York City Department of Health and Mental Hygiene have reported a cluster of false positive results among STI clinics using the OraQuick Advance Rapid HIV-1/2 Antibody Test. Clinics using the oral fluid rapid test reported two episodic increases in false positive test results.¹¹ In Uganda, trials using EIA tests, Western blot tests and rapid tests have revealed critical inaccuracies in rapid testing results. In the study, 129 of the 295 people that received reactive rapid test results were actually HIV-negative.¹² Another study performed in the Eastern Democratic Republic of Congo found that ‘two consecutive positive results from two separate rapid tests have a 10.5% chance of producing false-positive results.’¹³

Some studies have also reported false negative results: ‘A study conducted by the South African government revealed rapid HIV testing sensitivities that averaged 68.7% in Cape Town’s local clinics. Thus, the tests are failing to detect HIV in nearly one third of patients who have the virus. In Cameroon, the same rapid testing algorithm that produces a specificity of 98.8% has a sensitivity of 94.7%, resulting in 6 out of every 100 people receiving a negative diagnosis when they are in fact HIV-positive.’¹⁴

In Australia, the Alere Determine packaging describes the test as an ‘aid’ to detect antigens and antibodies and states that it is ‘for professional use only.’ The company states that ‘No test provides assurance’ that a specimen does not contain HIV antigens or antibodies present at very early stage of infection. It states that a negative result ‘does not preclude the possibility of exposure to or infection

⁹ Australian Federation of AIDS Organisations, Policy Briefing Paper on Rapid Testing, August 2010, 2, 5 http://www.afao.org.au/_data/assets/pdf_file/0014/4523/BP_0810_AFAO_rapid_hiv_testing_briefing_paper.pdf, accessed 27 June 2014.

¹⁰ Ibid, 5.

¹¹ Centre for Disease Control and Prevention, ‘False Positive Oral Fluid Rapid HIV Tests’, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm57e618a1.htm?s_cid=mm57e618a1_e, accessed on 27 June 2014.

¹² Statistics from Gray, R., et al. “Limitations of rapid HIV-1 tests during screening for trials in Uganda: diagnostic test accuracy study.” *BMJ* 335 7612 (2007): 335, accessed on 2 November 2010, <http://www.bmj.com/content/335/7612/188.full>, cited in Unite for Sight, ‘Challenges and Failures of HIV Screening with Rapid Tests’, <http://www.uniteforsight.org/health-screenings/hiv> accessed on 13 February 2013.

¹³ Klarkowski, D., et. al. “The Evaluation of Rapid *In Situ* HIV Confirmation Test in a Programme with a High Failure Rate of the WHO HIV Two-Test Diagnostic Algorithm.” *PLoS One*. 4.2 (2009). Accessed on 2 November 2010. <http://www.biomedsearch.com/attachments/00/19/19/73/19197370/pone.0004351.pdf>, cited in Unite for Sight, ‘Challenges and Failures of HIV Screening with Rapid Tests’, <http://www.uniteforsight.org/health-screenings/hiv> accessed on 13 February 2013

¹⁴ Aghokeng, A., et. al. “Inaccurate Diagnosis of HIV-1 Groupe M and O is a Key Challenge for Ongoing Universal Access to Antiretroviral Treatment and HIV Prevention in Cameroon.” *PLoS One*. 4.11 (2009). Accessed on 2 November 2010. <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0007702> cited in Unite for Sight, ‘Challenges and Failures of HIV Screening with Rapid Tests’, <http://www.uniteforsight.org/health-screenings/hiv> accessed on 13 February 2013.

with HIV' and that a positive result 'should be confirmed using another method and the results should be evaluated in light of the overall clinical evaluation before a diagnosis is made.'

LIMITATIONS OF THE PROCEDURE

- **Alere** Determine™ HIV-1/2 Ag/Ab Combo is designed to simultaneously detect antibodies to HIV-1 and/or HIV-2 and free non immunocomplexed HIV-1 p24 antigen (Ag), in human serum, plasma and whole blood. Other body fluids or pooled specimens may not give accurate results and should not be used.
- The intensity of the Ab and Ag bars does not correlate to the titer of antibody and antigen in the specimen.
- No test provides absolute assurance that a specimen does not contain low levels of HIV-1 p24 antigen and/or antibodies to HIV-1 and HIV-2 such as those present at a very early stage of infection.
- A negative result for both antibodies to HIV and p24 antigen does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2 viruses.
- A positive result for antibodies to HIV with a negative result for p24 antigen does not preclude the possibility of acute infection.
- Positive results should be confirmed using another method and the results should be evaluated in light of the overall clinical evaluation before a diagnosis is made.

The Alere Determine packaging includes tables that records its specificity at 99.66%:

SPECIFICITY

A total of 2343 confirmed negative serum, plasma or whole blood specimens were tested by **Alere** Determine™ HIV-1/2 Ag/Ab Combo and specificity was determined for the Antibody Test line and for the Antigen Test line (Table IV). In both tests the specificity is more than 99 %.

Table IV
Specificity of **Alere** Determine™ HIV-1/2 Ag/Ab Combo

Population	Number of Specimens Tested	Negative by Alere Determine™ HIV 1/2 Ag/Ab Combo Ab Test line	Specificity (%) of the Antibody Test line	Negative by Alere Determine™ HIV 1/2 Ag/Ab Combo Ag Test line	Specificity (%) of the Antigen Test line
Seronegative specimens	1783	1769	99.21 %	1776	99.61 %
Pregnant women	200	200	100.00 %	199	99.50 %
Disease States Other than HIV and Potentially Interfering Substances*	360	356	98.89 %	360	100.00 %
Total	2343	2325	99.23 %	2335	99.66 %

*IV drug users, rheumatoid factor, cancer, alcoholic cirrhosis, autoimmune (ANA), high cholesterol, lipemic, high bilirubin, hemolyzed, anti mouse IgG and other viral or bacterial infections, multiparous, (HBV, HCV, HTLV, CMV, Toxo IgG, Syphilis, HSV 1/2, EBV, Flu vaccinated patients and Chlamydia IgG/IgM).

A total of 1783 negative specimens (included in table IV) were tested in nine different clinical sites from four major geographic areas and specificity was determined for the Antibody Test line and for the Antigen Test line (Table V).

Similarly, the packaging for the Trinity Biotech Uni-Gold HIV test, being trialed in Australia, notes under 'precautions' that the test is a 'screening' device, and that 'any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.' It lists its specificity at 99.6%.

A negative result with Uni-Gold™ HIV does not exclude the possibility of infection with HIV. A false negative result can occur in the following circumstances:

- low levels of antibody (e.g., early seroconversion specimens) are below the detection limit of the test
- infection with a variant of the virus that is less detectable by the Uni-Gold™ HIV assay configuration
- HIV antibodies in the patient that do not react with specific antigens utilized in the assay configuration
- specimen handling conditions which result in the loss of HIV antibody multivalency.

Failure to allow kits to come to room temperature prior to use may impact results.

As technologies develop, rapid tests will become more accurate. In the mean time, these risks pose dangers for sex workers. Because of the longer window periods and the need for lab confirmation of reactive results, rapid tests are less reliable to confirm HIV negative status. If a sex worker receives a reactive result when at work, we may face discrimination, be prevented from working, and potentially be criminalised until our HIV status is confirmed negative by laboratory testing. Sex workers rely on testing accuracy for our safer sex decisions, negotiations and legal status.

False positives and negatives

Inaccurate tests bring serious implications for sex workers – for our work, our legal status, and our negotiation of risk.

Even where rapid tests have high specificity and sensitivity, without 100% accuracy there will still be false positives and false negatives. AFAO writes:¹⁵

The manufacturer of the Determine HIV-1/2 Ag/Ab Combination Rapid test estimates that the test has a specificity of between 99.23 (for antibodies) and 99.66% (for antigens). For the purpose of the illustration below the assumed specificity is 99.5%.

If this test were used to test 1,000 people... where the prevalence of HIV in the population was just 0.5% then the results would be:

- 1,000 tests
- 990 negatives
- 10 'reactive' results, of which:
 - 5 would be true positive results
 - 5 would be false positive results

Five of the 10 initially 'reactive' results would be true positives, and 5 would be false positives.

Thus, 50% of the reactive results would be false positive results.

The Kirby Institute examined more closely what it means when rapid tests are used in low prevalence populations. The research questions the application of data relating to one population to another. The table 'Ratio of False Reactives to True Positives Using a Rapid HIV Test' below compares rapid testing data for MSM populations with rapid testing data for female sex worker populations. It

¹⁵ Australian Federation of AIDS Organisations, Policy Briefing Paper on Rapid Testing, August 2010, 5, http://www.afao.org.au/_data/assets/pdf_file/0014/4523/BP_0810_AFAO_rapid_hiv_testing_briefing_paper.pdf, accessed 27 June 2014.

illustrates how the HIV prevalence in the population being tested will affect the outcomes in terms of the ratio of false positives to true positives in tests with different specificity characteristics. The table is based on data from the only rapid HIV test that has been licensed to date in Australia, the Alere Determine Combo rapid HIV test. The calculations in this slide use a specificity of 99.4%, which was the observed specificity using this test in an Australian Study by Dr Damian Conway and colleagues. A specificity value of 99.4% means that 6 out of every 1,000 tests will theoretically be a false reactive (or false positive) result.

This test used in a high HIV prevalence population, such as MSM testing at sexual health clinics in Australia, would produce 1 false positive for every 2.3 true positives (6 false positives for every 14 true positives). The same test used in a low prevalence population, such as female sex workers tested at sexual health clinics in Australia, would produce many more false positives than true positives. There would be 15 false positives for every one true positive result.¹⁶

Ratio of False Reactives to True Positives using a Rapid HIV Test

	Specificity & Results Ratios
Positive Yield (proportion of tests that will be true positives)	99.4%* (i.e. 6 false reactives per 1,000 tests)
1.4% (MSM tested at selected sexual health clinics 2008-2012)**	1:2.3
0.04% (Female sex workers tested at selected sexual health clinics 2008-2012)***	15:1

Concerns about the accuracy of rapid testing raises implications in terms of who rapid testing is made available to and to which populations it is targeted.

Rapid tests must not be compulsory for sex workers

Sex workers have a low prevalence of HIV and STIs

Sex workers already consistently demonstrate low rates of STIs and high rates of testing. Both Australia’s *Sixth National HIV Strategy 2010-2013* and *the Second National STI Strategy 2010-2013* note that ‘the incidence of HIV/STIs in sex workers in Australia is among the lowest in the world. This is largely because of the establishment of safe-sex as a norm, the availability of safe-sex equipment, and community-driven health promotion and peer-based interventions.’¹⁷ Research clearly and consistently illustrates that sex workers enjoy lower rates of STIs than the general population, and

¹⁶ P Keen, Kirby Institute, 2014, *Overall specificity of the TGA-licensed Determine HIV-1/2 Ag/Ab Combo rapid HIV test, as observed in an Australian study of MSM: Conway, D., Holt, M., McNulty, A., Couldwell, D., Smith, D., Davies, S, Cunningham, P, Keen, P, Guy, R. (2013). *Field performance of the Alere Determine HIV Combo assay in a large Australian multicentre study in a sexual health clinic setting*. STI & AIDS World Congress 2013, Vienna; *** **The Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2013. The Kirby Institute, The University of New South Wales, Sydney.
¹⁷ Australian Government Department of Health and Ageing, *Sixth National HIV Strategy 2010-2013*, Commonwealth of Australia, Canberra, 2010, 16; Australian Government Department of Health and Ageing, *Second National STI Strategy 2010-2013*, Commonwealth of Australia, Canberra, 2010, 16.

have very high rates of prophylactic use.¹⁸ The LASH (Law and Sex worker Health) report to the NSW Health Department in 2012 found that condom use at work approaches 100% in Sydney brothels.¹⁹ The LASH Report on the Sex Industry in Western Australia in 2005 also found close to 100% rate of condom use at work in Perth brothels.²⁰ The Kirby Institute Annual Surveillance Report for 2011 shows that the Chlamydia rate was the lowest among female sex workers, that testing rates were highest among female sex workers, and that HIV prevalence remained low among women self-identifying as sex workers.²¹ HIV among sex workers has remained consistently low – less than 1%.²²

These statistics raise questions about how beneficial rapid testing will be for sex workers.

Sex workers are likely to receive false positive results from rapid tests

Because sex workers have low prevalence of HIV, the chance of a false positive from rapid testing is higher than for other population groups. For populations with a higher prevalence of HIV, the chance of the results being a false positive is lower.

This means that sex workers using rapid tests are more likely to receive false positive than actual positive results.

Rapid testing is recommended for high prevalence populations; rapid testing is not appropriate for sex workers as a low prevalence population

Rapid HIV tests are recommended for use in populations with relatively high HIV prevalence. The National HIV Strategy 2010-2013 says ‘Priority will be given to assessing approaches to the implementation of rapid HIV testing for use in communities that have high HIV prevalence’.²³

The HIV Testing Policy 2011 states that testing may be considered for community-based testing interventions *for high-risk or hard-to-reach populations and individuals (who are resistant to conventional testing)*. It may also be appropriate for people who might be otherwise reticent to access conventional testing and/or return for test results.²⁴

The lower the HIV prevalence in a population, the higher the chance of false positives. Sex workers have low prevalence of STIs. Clinicians believe that rapid HIV testing is not appropriate for HIV testing in low prevalence populations.²⁵

¹⁸ Roberta Perkins and Francis Lovejoy, *Call Girls*, University of Western Australia Press, 2007. High rates of condom use also relate to oral services: *Health Needs Assessment of Parlour Workers in South Western Sydney Area Health Service*, SWSAHS 2002.

¹⁹ Basil Donovan, C Harcourt, S Egger, L Watchirs Smith, K Schneider, JM Kaldor, MY Chen, CK Fairley, S Tabrizi, *The Sex Industry in New South Wales: A Report to the NSW Government*, Kirby Institute, University of New South Wales, Sydney, 2012, <http://www.kirby.unsw.edu.au/sites/default/files/hiv/attachment/NSWSexIndustryReportV4.pdf> accessed 27 June 2014

²⁰ Basil Donovan, C Harcourt, S Egger, K Schneider, J O’Connor, L Marshall, MY Chen, CK Fairley, (2010). *The Sex Industry in Western Australia: a Report to the Western Australian Government*. Sydney: National Centre in HIV Epidemiology and Clinical Research, University of New South Wales, vii, accessed <http://www.kirby.unsw.edu.au/sites/default/files/hiv/attachment/WASexReport.pdf> 27 June 2014.

²¹ Kirby Institute, HIV, Viral Hepatitis and Sexually Transmissible Infections in Australia Annual Surveillance Report, University of New South Wales, 2011, p8, Figure 46, Figure 34.

²² National Centre in HIV Epidemiology and Clinical Research, *HIV/AIDS, Viral Hepatitis and Sexually Transmissible Infections in Australia, Annual Surveillance Report 2010*. University of New South Wales, Sydney, NSW at 26 and Figure 36.

²³ Australian Government, Department of Health and Ageing, *Sixth National HIV Strategy, 2010-2013* at 6.2.

²⁴ ASHM, National HIV Testing Policy, 2011, 12.4, <http://testingportal.ashm.org.au/hiv> accessed 27 June 2014.

²⁵ Australian Federation of AIDS Organisations, Policy Briefing Paper on Rapid Testing, August 2010, 5, http://www.afao.org.au/data/assets/pdf_file/0014/4523/BP_0810_AFAO_rapid_hiv_testing_briefing_paper.pdf, accessed 27 June 2014.

Australian trials – conflating results across populations

There are rapid tests currently being trialled in Australia through sexual health clinics in Sydney, Melbourne and Brisbane. The health sector is strongly promoting and campaigning for rapid HIV testing, which presents tensions where sex worker funding is linked through an AIDS council. These trials are assessing patients' satisfaction with pre-test discussion, result delivery and process, whether patients would recommend rapid testing, and re-presenting for tests. Rapid tests are being trialled on populations of gay men,²⁶ so results (about increased testing volumes and proportion of people being tested for the first time) are not necessarily applicable to sex worker populations. Sex workers have a variety of genders and sexual orientations that include, but are not limited to, gay men. Gay male populations historically have a different epidemiology to sex worker populations and results from rapid testing trials among gay men should not be applied to sex workers.

Rapid testing means instant criminalisation

In some states, working as a sex worker living with HIV or an STI is criminalised. Where this is the case, rapid testing could mean that sex workers become immediately criminalised upon receiving a positive or 'reactive' result. Although a reactive result is not a diagnosis and should not mean instant criminalisation, a reactive result could foreseeably lead to presumptions about the HIV status of the sex worker, with a number of ramifications. The process of waiting for confirmatory testing, especially if the rapid test is administered in a workplace environment, where the health professional is aware the person is a sex worker, or in a remote or rural environment where we may not be anonymous, raises issues around the person's legal work status, confidentiality, prosecution, discrimination and stigma. In a workplace environment, a reactive or indeterminate result will immediately place a person's occupation, career and income at stake. This is regardless of whether individual workers practice safer sex, cater to specifically HIV positive clients, or offer non-penetrative services. This risk is compounded because sex workers as a population are more likely to receive false reactive results. There are serious ramifications of rapid testing for sex workers in jurisdictions where working with HIV/STIs is criminalised.

In 2008 an Australian sex worker living with HIV was prosecuted and jailed in the Australian Capital Territory for providing a sexual service while knowingly HIV positive even though no evidence of unsafe behaviour was presented.²⁷ In 2012 a sex worker in Victoria was charged for being a positive worker despite maintaining that they always provided safe services. As a result of the first case there was a dramatic drop in sex worker attendance at a outreach medical services: 'In the four-week period following the court case, the numbers attending the service dropped from an average of 40 per night to three.'²⁸

Criminalisation means that HIV positive sex workers, or sex workers who suspect we may have contracted HIV or STIs, may be reluctant to disclose our status or undergo HIV testing for fear of discrimination from our workplaces, communities and health providers. The National Needs Assessment of Sex Workers who Live with HIV in 2008 found that many health organisations 'are judgmental and critical of the involvement of HIV positive people in sex work and often attempt to dissuade them from continuing.'²⁹ Participants in the study reported that '[i]nstances of disclosure of both HIV status and sex work generally lead to very poor treatment and harassment, and in one reported case included physical violence by a health care worker.'³⁰ Others reported 'misinformation'

²⁶ Philip Keen, 'Rapid HIV Testing in Australia', *HIV Australia*, Vol. 9, No. 3, November 2011, <http://www.afao.org.au/library/hiv-australia/volume-9/number-3/rapid-hiv-testing-in-australia> accessed 27 June 2014.

²⁷ Elena Jeffreys, Kane Matthews and Alina Thomas, 'HIV Criminalisation and Sex Work in Australia', *Reproductive Health Matters*, 2010, 18:35, 129 – 136 at 130.

²⁸ Ibid.

²⁹ Kane Matthews, *The National Needs Assessment of Sex Workers who Live with HIV*, Scarlet Alliance, Sydney 2008, at 24.

³⁰ Ibid at 32.

being provided to them about the legality of participating in commercial sex, or felt health services were ‘taking on more of a law enforcement role.’³¹

During consultation with sex workers, one sex worker noted that the ability to alter a person’s occupational future within thirty minutes may be as much a barrier to sex workers opting for rapid tests as for gay men waiting ten days for a conventional test. Rapid testing can lead to rapid criminalisation for sex workers.

Rapid testing must not be targeted towards sex workers in jurisdictions where sex workers living with HIV/STIs are criminalised.

Rapid testing should not lead to contact tracing

Scarlet Alliance does not support contact tracing as an effective approach in relation to sex workers. Contact tracing has proven to be ineffective in relation to sex workers. Sex workers are not usually aware of our client’s legal name or contact details and the approach has proven to result in the criminalisation of sex workers.

Rapid tests should be voluntary, patient-initiated, anonymous and confidential. In the ACT and Victorian cases in which sex workers have been prosecuted for working with HIV, their name, HIV status and unrelated personal details were released to the media.³² The Chief Public Health Officer in the ACT released these details as a contact tracing strategy, against the advice of Scarlet Alliance. Articles appeared across Australia, New Zealand, Germany, Vietnam, Belgium and Hong Kong, contributing to their public stigma.³³ News sources published a photograph of the Victorian sex worker leaving court.

Rapid testing results should be privy to the individual patient and health professional only. It should be up to the individual to choose whether to engage in partner notification if we feel there has been risk of exposure. A reactive result in a criminalised or workplace environment, if misinterpreted as a positive diagnosis, could trigger mandatory reporting and contact tracing. This is one of the reasons Scarlet Alliance believes rapid testing is not appropriate in states or territories where sex workers are criminalised for having a STI or living with HIV.

Who can perform rapid tests?

Rapid HIV tests are subject to the parts of the *Therapeutic Goods (Medical Devices) Regulations 2002*, under which testing may only be performed by a ‘health professional.’

‘Health professional’ includes a person who is:

- a medical practitioner, a dentist or any other kind of health care worker registered under a law of a State or Territory; or
- a biomedical engineer, chiropractor, optometrist, orthodontist, osteopath, pharmacist, physiotherapist, podiatrist, prosthetist or rehabilitation engineer.

This definition is very wide and could include outreach workers performing rapid testing of sex workers in brothels or other sex industry workplaces. HIV testing in workplaces will have serious implications for sex workers confidentiality.

³¹ Kane Matthews, *The National Needs Assessment of Sex Workers who Live with HIV*, Scarlet Alliance, Sydney 2008, at 32.

³² Elena Jeffreys, Kane Matthews and Alina Thomas, ‘HIV Criminalisation and Sex Work in Australia’, *Reproductive Health Matters*, 2010, 18:35, 129 – 136 at 130.

³³ *Ibid.*

The HIV Testing Policy further stipulates who can perform rapid testing:³⁴

Individuals working in organisations which are endorsed by the State or Territory in which the service is offered and/or privately employed medical practitioners who:

- have been certified in performing PoC and who have completed appropriate, accredited training;
- have access to clinical support and the infrastructure to perform venous testing and arrange immediate referral for ongoing medical and/or emotional support;
- are able to be appropriately indemnified and compliant with relevant NATA and Medicare arrangements; and
- have access to and apply strict protocols which describe and define the application of this Policy.

The test can be used outside the laboratory by appropriately trained health professionals however all positive results must be confirmed through referral to a laboratory.³⁵

Rapid tests are limited to accredited testing sites with certified staff, not individuals. The National HIV Testing Policy specifies that every prospective PoC testing site must meet a number of criteria in order to perform PoC tests. The criteria include that there must be a trained phlebotomist on site, minimum numbers of staff accredited in PoC testing, procedures in place for confirmatory testing, relationships with testing laboratories that comply with National Pathology Accreditation Advisory Council standards and accreditation with National Association of Testing Authorities.³⁶

Where can rapid testing happen?

Rapid testing has been approved for use in both clinical and community settings. This is one of the key aspects of rapid testing affecting sex workers. Where rapid testing happens is of significance to sex workers - there may be different implications for sex workers, depending on whether rapid testing is occurring in a clinical or community environment.

There are restrictions on what must be in place if rapid testing is being offered. The National HIV Testing Policy outlines these requirements, including:³⁷

- formal supervisory relationship with approved HIV testing laboratory to NATA and NPAAC standards;
- capacity to perform both finger prick test and venepuncture;
- procedures in place with high quality laboratories for rapid dispatch and processing of venous blood samples for confirmatory testing of reactive/inconclusive results;
- testing conducted under the auspice of a NATA/Royal College of Pathologists of Australasia (RCPA) Medical Testing accredited laboratory;
- tests that are suitable for use at point of care have been included in the ARTG;
- high-quality information on the tests and their use is available and provided;
- the health worker performing the test is suitably trained; and

³⁴ ASHM, National HIV Testing Policy 2011, Who Can Perform PoC Testing? 12.1
http://testingportal.ashm.org.au/resources/Australian_National_HIV_Testing_Policy_v1-1.pdf accessed 27 June 2014.

³⁵ ASHM, National HIV Testing Policy 2011, Accreditation, 12.2,
http://www.testingportal.ashm.org.au/resources/2011_National_HIV_Testing_Policy_v1.3.pdf, accessed 27 June 2014.

³⁶ Ibid.

³⁷ ASHM, National HIV Testing Policy 2011, Where to Test?, 13.3,
http://www.testingportal.ashm.org.au/resources/2011_National_HIV_Testing_Policy_v1.3.pdf, accessed 27 June 2014.

- quality assurance programmes are available to assure ongoing competency of health workers performing the tests and ongoing compliance of any facility.

The TGA has also stipulated specific conditions for the Alere Determine HIV Combo Point Of Care Test that the person (the sponsor) in relation to whom the device is registered on the Australian Register of Therapeutic Goods (the ARTG) must abide by. These include regular periodic reporting commitments demonstrating compliance with testing policies, accreditation and training.³⁸ It will be the responsibility of the sponsor, Alere, to distribute the kit to organisations, including laboratories, who meet the requirement of being able to provide appropriate services including care and counseling.

Some sex workers may prefer to access testing in a peer or community environment. Culturally or linguistically diverse or migrant sex workers may prefer to access testing in an environment with multilingual peers. However, a sex industry workplace is not a community space and testing should not be offered there.

Rapid testing should not occur in sex industry workplaces

Rapid testing could be offered in community settings outside clinics. Testing in community settings is in place in other countries. For example, the New Zealand AIDS Foundation have their own clinic in which they perform rapid testing for HIV, syphilis and hepatitis C. In Australia, sexual health services are already offering HIV/STI testing in brothels and on outreach via conventional testing, often with staff who are overly enthusiastic about their testing role without an awareness of the repercussions on sex workers privacy.

There are serious implications for sex workers when HIV/STI testing is offered in sex industry workplaces. Reports from sex workers at the Empower Foundation in Thailand state that sex workers are being offered financial incentives (up to a day's wage) to undergo a rapid test. Health care providers may be required to meet certain targets for testing those perceived to be in high risk groups in order to receive funding. In these cases 'voluntary' testing may not always be voluntary in practice: sex workers report sexual health clinic staff arriving spontaneously at their workplace to conduct blood tests on the premises, and those workers who declined testing were treated with suspicion. In Australia, in jurisdictions with mandatory testing in place, sex workers have reported brothel operators requiring them to see a doctor of the operator's choice, following which the results are handed directly back to the operator rather than the worker, without regard for that worker's right to privacy. Sex workers fear clients demanding rapid tests if they are offered in a workplace, making it more difficult to negotiate safer sex practices. Issues around confidentiality are compounded in jurisdictions where working with HIV/STIs is criminalised.

Sex workers do not usually use our legal names in sex industry businesses, and yet a reactive test could result in increased workplace scrutiny and a process that includes mandatory reporting and potentially visa and migration investigation and review.

Despite a proven track record of exemplary sexual health, in some jurisdictions in Australia, depending on our section of the industry, sex workers are required to have regular mandatory tests for STIs and HIV. Laws and policies which promote or enforce mandatory testing are contrary to best-practice models of sexual health and are not evidenced by current epidemiology in Australia. Compulsory testing has been shown to create an unnecessary, expensive burden on public health

³⁸ Department of Health, Therapeutic Goods Administration, Product specific conditions for the Alere Determine HIV Combo POCT, <http://www.tga.gov.au/consumers/information-devices-hiv-rapid-tests-alere-determine.htm>, accessed 27 June 2014.

funds, has led to sex workers hiding our profession from medical experts, has jeopardised sex worker privacy and has consumed resources that could be better spent on peer education. Further, mandatory testing fails to confirm a sex worker's actual sexual health status due to window periods, and can create a false sense of security among clients leading to increased requests for unsafe practices.³⁹ Studies indicate that testing rates are 'excessive',⁴⁰ and recommend that 'screening intervals for sex workers should be based on local STI epidemiology and not locked by legislation.'⁴¹ In their study, Samaranayake et al. found that the use of resources in screening and providing certificates to sex workers could be better spent.⁴² Sex workers do not support mandatory testing.⁴³

Rapid testing poses unique issues because the results are available within 30 minutes. Workers would receive results during our shifts, whilst sharing space with peers, clients and employers. Sex workers already have sexual health services arriving in our workplaces during working hours because they believe testing in those environments are 'more convenient' for sex workers.

Rapid testing should never be used as part of mandatory testing. Rapid testing would not be considered for other industry workplaces, and it is not appropriate in sex industry workplaces, where the implications are grave. Scarlet Alliance does not support the use of rapid HIV/STI tests for sex workers in workplace environments.

Rapid testing must be voluntary

Voluntary testing remains the optimal approach to STI and HIV testing in Australia as outlined in the *National Strategies*. The *National STI Strategy* recommends voluntary patient-initiated testing as a successful approach to detecting STIs, and warns that mandatory testing has 'potential to limit access to services for higher risk groups'.⁴⁴ The National HIV Strategy states that 'principles for informed consent and confidentiality underpin high rates of voluntary testing', and aims to increase the number of people voluntarily seeking testing.⁴⁵ Importantly, research illustrates that despite more frequent testing in Victoria, STI prevalence is uniformly low among sex workers in Sydney and Perth where screening is voluntary and negotiated between the worker and our clinician on an individual basis.⁴⁶

³⁹ Scarlet Alliance, *Mandatory or Compulsory Testing of Sex Workers for HIV and/or Sexually Transmissible Infections in the Australian Context*, Briefing Paper for HASTI Committee of MACASHH, 1st August 2007, 1, citing: Australian Government, *National HIV/AIDS Strategy – Revitalising Australia's response 2005-2008*, Australian Government, Canberra, 2005; National Centre in HIV Epidemiology and Clinical Research, *HIV/AIDS, Viral Hepatitis and Sexually Transmissible Infections in Australia, Annual Surveillance Report, 2006*; Brisbane Sexual Health Clinic (BIALA) staff and individual sex workers raised access problems as a result of mandatory testing, Scarlet Alliance Community Forum, Brisbane, March 2005; Basil Donovan and Christine Harcourt, 'Sex Workers', *Sexual Health Medicine*, (Fairley, Russell, Bradford (ed), IP Communications, Melbourne, 2005.

⁴⁰ D Wilson, K Heymer, J Anderson, J O'Connor, C Harcourt and B Donovan (2009), 'Sex workers can be screened too often: a cost-effective analysis in Victoria, Australia', *Sexually Transmitted Infections*, October 2009, 117.

⁴¹ Ibid.

⁴² A Samaranayake, M Chen, J Hocking, C Bradshaw, R Cumming and C Fairley (2009) 'Legislation requiring monthly testing of sex workers with low rates of sexually transmitted infections restricts access to services for higher risk individual' *Sexually Transmitted Infections*, 85:7, 540 – 542.

⁴³ Elena Jeffreys, Janelle Fawkes, Zahra Stardust, 'Mandatory Testing for HIV and Sexually Transmissible Infections among Sex Workers in Australia: A Barrier to HIV and STI Prevention', *World Journal of AIDS*, 2012, 2, 203-211, accessed at <http://www.scirp.org/journal/PaperInformation.aspx?paperID=22595> on 17 January 2013, abstract and 208.

⁴⁴ Australian Government, Department of Health and Ageing, *Second National Sexually Transmissible Infections Strategy 2010-2013*, Commonwealth of Australia, 2010, 6.2.

⁴⁵ Australian Government, Department of Health and Ageing, *Sixth National HIV Strategy 2010-2013*, Commonwealth of Australia, 2010, 6.2.

⁴⁶ D Wilson, K Heymer, J Anderson, J O'Connor, C Harcourt and D Donovan (2009), 'Sex workers can be screened too often: a cost-effective analysis in Victoria, Australia', *Sexually Transmitted Infections*, October 2009.

Rapid testing should not replace conventional testing, peer education and community led health promotion

The current focus in Australia is on rapid testing for HIV. There are no applications awaiting approval from the TGA in Australia for rapid tests for other STIs at the time of writing.

However rapid tests can also test for other STIs including syphilis, chlamydia, and hepatitis. International manufacturers also make rapid tests for other STIs and the New Zealand AIDS Foundation perform rapid testing for HIV, hepatitis C and syphilis together. For sex workers, HIV prevention, peer education and testing cannot be separated from other STIs. It is best practice to test for HIV in combination with other STIs.

The low rates of STIs/HIV among sex workers are because of a long history of peer education and community engagement. Funding must continue for sex worker organisations to maintain this success. A focus on rapid HIV testing should not lead to a reduction in STI screening or detract resources from peer education around safer sex.

Rapids tests are only one testing option and should not be used as a substitute for conventional testing. In the UK, a company offering home testing kits for a virus causing cervical cancer have been found to have misleading advertising by the Advertising Standards Authority because the company implied the test was a substitute for a pap smear test, and that the test could reduce the need for women to have regular smear tests.⁴⁷

Sex workers should have choice over the kinds and frequency of HIV/STI testing we access and in what context. Testing efficacy is important for sex workers as we negotiate risk. Rapid testing should always be offered in parallel with conventional testing.

Australia is a world leader in our HIV response, with strong and longstanding partnerships between government and affected communities. The success of HIV prevention initiatives among sex workers can be attributed to the establishment of safer sex as a norm, community driven health promotion and peer education. Sex worker organisations face systemic underfunding, noted by the Fifth National HIV Strategy, and require enhanced investment and increased resourcing to maintain low rates of HIV and STIs among our communities. Fervor about new testing technologies should not come at the expense of evidence-based strategies that have proven successful for sex workers over many decades.

⁴⁷ Ian Sample, Watchdog Criticises Maker of Home HPV Test for Misleading Advertising, 17 October 2012, <http://www.guardian.co.uk/science/2012/oct/17/watchdog-criticises-hpv-test-advertising>, accessed on 13 February 2013.