

Participant Information Sheet

Title of Project: **RAPIDVend: HIVST Vending Machine Study**
Human Research Ethics Approval No: The University of Queensland HREC: 2020/HE002802
Study Protocol Number 1.0
Study Sponsor: Queensland Positive People

Research Team Contact Details - Principal Investigators

Co-ordinating Principal Investigator	Dr Judith Dean	University of Queensland
Principal Investigators	Mr Luke Coffey	RAPID Program, Queensland Positive People (QPP)
	A/Prof Amy Mullens	University of Southern Queensland
Co-Investigators	Prof. Charles Gilk	University of Queensland
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Description of the Study

The RAPIDVend study aims to explore the feasibility and acceptability of dispensing HIV Self-testing (HIVST) kits from the 'RAPIDVend' Vending Machine located at the following public spaces:

1. Clinic 29 - a sex on premises venue in Brisbane
2. The University of Southern Queensland Toowoomba campus.

The overall purpose of this study is to improve access to HIV testing among gay and other men who have sex with men and other key priority populations considered at risk of HIV.

Outcomes of this study will inform local and national level HIV testing models and health policy supporting the supply of HIV Self-testing (HIVST).

This project is being undertaken as part of Queensland Positive Peoples’ commitment to the United Nations 95-95-95 goals of eliminating HIV by 2030. In particular, the project attempts to meet the goals of the first '95', which is to have '95% of people living with HIV aware of their status'.

Study Partners

This project is being conducted by Queensland Positive People (QPP) PP RAPID Program, the University of Queensland, and the University of Southern Queensland.

QPP is a peer-based organisation that supports people living with HIV by offering innovative, community-based HIV testing using a respectful client-centered approach. As a peer-based organization, QPP aims to support the early identification and diagnosis of those living with HIV in the community and support them to:

- Consider early treatment
- Enhance connections with other PLHIV and
- Improve health outcomes
- Reduce the onward transmission of HIV

Your Part in the Study

Your participation commences with completing a **Pre-vend Consent Survey** to obtain a **ONE-OFF ACCESS CODE** that will give you access to **one ATOMO HIV-antibody HIV Self-test kit (HIVST)** from the **RAPIDVend (HIVST Vending Machine)**. Completing the **Pre-vend Consent Survey** implies that you voluntarily consented to participate in the study.



You can complete the Pre-vent Consent Survey via:

1. The RAPIDVend touchscreen or
2. Online by scanning the **QR Code** displayed on RAPIDVend or at [add hyperlink]

The steps in this study involve:

1. Complete **Pre-vent Consent Survey** to obtain a **ONE-OFF ACCESS CODE**.
2. On the **Pre-vent Consent Survey** you will be asked:
 - a. Are you 16 years old or older?
 - *To be eligible for this study you must be 16 years of age or older.*
 - b. Have you watched the ATOMO instruction video? [www.atomohivtest.com]
 - *Watching this Video is required as part of the Australian Therapeutic Goods Administration approval of the **ATOMO® HIV-Antibody test kit**.*
 - c. Do you consent to take part in the HIVST Vend Study?
 - d. Do you consent to be contacted by a RAPID Peer HIV Testing Facilitator in 7 days' after completing the Pre-Vend Consent Survey to check on how you went with the HIVST?
 - e. To enter your mobile phone number
 - *This is needed so a RAPID Peer HIV Testing Facilitator can contact you.*
 - *Your mobile phone number will be encrypted immediately on entering it into the RAPIDVend machine/Pre-Vend Consent Survey and only accessible to the RAPID Peer HIV Testing Facilitator.*
 - f. Enter your postcode
 - *This is optional but will help us understand where we may need to place other machines.*
 - g. When was your last HIV test?
 - *This is also optional but will help us understand who is using HIVST.*
3. Enter the **ONE-OFF ACCESS CODE** into the RAPIDVend to obtain a **ATOMO® HIV-Antibody test kit**. The kit will include:
 - a. 1 X ATOMO® HIV Self-test and 1 X bottle of test fluid
 - b. Easy to follow instructions on how to use the kit including the ATOMO instruction video
 - c. ATOMO Care Card with information on HIV Support Services
 - d. This participant information sheet
 - e. QPP Getting prepared to start your HIV home self-test with additional information on HIV, HIV-testing and local Queensland based HIV Support Services.
 - f. 5 condoms, 5 lubricant sachets
4. **7 days after you complete the Pre-Vend Survey**, you will be **contacted by a RAPID Peer HIV Testing Facilitator** to check on how you went with the HIV self-test
 - a. If you do not answer, the RAPID Peer HIV testing facilitator will attempt to ring you a further two times at this point as per Standard RAPID HIV testing Operating Procedures.
 - b. The RAPID Peer HIV Testing Facilitators are all trained in HIV pre-test informed consent processes and how to support people who return a positive HIV result to link to care.
5. **7 days after you complete the Pre-Vend Survey**, you will also **receive a text message (SMS)** with a link to a **POST-Vend SURVEY** on the mobile phone number you provided.
 - a. The **POST-Vend SURVEY** will ask you some questions about your experience using the HIVST kit, using the vending machine and the result of your HIV Self-test.
 - b. Once you have completed the Post-Vend survey, you will not receive any more SMS.
 - c. If you **DO NOT complete** the Post-Vend Survey following the initial 7-day SMS, you will receive a **reminder SMS at 14 and 21 days** after you complete the Pre-Vend Survey.
6. If you **enter a reactive, indeterminate or invalid result** on the POST-TEST Survey **you will be contacted** via the mobile phone number you provided by a RAPID Peer HIV Testing Facilitator for advice on linkage to care and support from QPP or other services you can go to for retesting.
 - a. This contact will be strictly confidential and is consistent with QPP-RAPID Program Standard post HIV testing Operating Procedures.
7. If you **do not complete the POST-TEST SURVEY within 28 days** of the HIVST kit a RAPID Peer HIV Testing Facilitator will try to contact you by phone to check that you have not had any problems using the HIV self-test.

Need support or information before or after testing?

You can **contact a RAPID peer HIV test facilitator at any stage** in the process for information about HIV or the HIVST test kit, or information about linkage to services and support on **3013 5566 or 1800 636 241** during RAPID service hours: **Tuesday-Friday 3pm-8pm, Saturdays 12pm-5pm.**

Your telephone number will be held securely and under strict confidence by RAPID Program at all points in the study. Your phone numbers will be removed from all study material once follow-up is completed. If you remain a client of QPP-RAPID program, the RAPID Peer HIV Testing Facilitator will follow QPP-RAPID Standard Operating Procedures in registering you as a client for future care through their service.

What is HIV Self-test Kit being used in this study?

The HIVST device in the kit is the **ATOMO® HIV-Antibody test**. This device looks for HIV **antibodies** in your blood by means of a simple finger prick. Completing the home ATOMO HIV self-test will allow you to know your HIV status in 15-minutes.

The ATOMO HIV Self-Test has been shown in laboratory testing to correctly identify 99.6% of HIV negative and HIV positive samples. Like other HIV tests, the ATOMO HIV Self-Test may not detect HIV that is recently acquired. For the ATOMO HIV Self-Test, the **window period is three months**. This means that the test may not detect HIV that has been acquired in the last three months. **If you think you have been exposed to HIV in the last three months**, it is important to speak to a doctor or visit a sexual health clinic. See ATOMO website for more information on the kit and instructions for use <https://www.atomohivtest.com/home.php#>

Participation is Voluntary

Your participation in this project is entirely voluntary. If you do not wish to take part, you are not obliged to. If you decide to access a kit and later change your mind, you are free to withdraw from the project at any stage without completing the survey or the test, without notifying QPP or the research team. Your decision as to whether you take part or not, or take part and then withdraw, will in no way impact your current or future relationship with the University of Queensland, the University of Southern Queensland, Queensland Positive People or the RAPID clinic.

Expected Benefits to You

It is expected that this project will directly benefit you by letting you know your HIV status. Early diagnosis of HIV leads to better health outcomes for people living with HIV. You will also be contributing to a wider field of research that will help shape future policy towards HIV prevention efforts in Queensland.

Risks Associated with the Participating in the Study

Risk associated with HIV Self-testing

Completing an HIV self-test at home or in another private setting may have some foreseeable risk of stress and anxiety due to the nature of receiving a result without a peer, nurse, or doctor present. If you feel distressed and need to talk to someone immediately, please call Lifeline on 13 11 14. Support is also available through the peer health workers at QPP who can be reached on 3013 5566 or 1800 636 241 or the numbers provided in the Kit such as on the ATOMO Care Card.

For those people who are not aware of their HIV status, it is important to know that the ATOMO HIV self-test is a **screening test**, and that in the event of a **positive self-test result** it is essential to get a confirmatory test done, this can with your doctor (GP), or a local sexual health clinic. You can also ring 13 HEALTH (13 43 25 84) to find a local service.

You should also practice safe sex at all times (E.g. use condoms) until you get your confirmatory HIV test result. QPP remains at your disposal at any time to assist with information on a reactive result, where you can obtain a confirmatory test from, and can provide someone for you to speak with who has also experienced being diagnosed with HIV.



Privacy and Confidentiality

- QPP complies with both the Commonwealth Privacy Act (2000) and the Public Health Act 2005
- QPP's own Privacy Policy can be found at www.qpp.org.au/privacy-policy
- The evaluation research component of this program adheres to the Guidelines of the Ethical Review Process of The University of Queensland

Strict procedures are in place to ensure your anonymity and confidentiality. Your anonymity is maintained with regards to the online survey and follow up SMS (and potential follow up phone contact). Your phone number is only obtained for the purposes of:

- The phone call and SMS at 7-days post completion of the Pre-Vend Consent Survey.
- The follow-up at 28 days if you do not complete the Post-Vend Survey
- Up to 2 follow-up phone calls if you have not replied to the above phone calls or SMS.

Your phone number will not be used in any research component of the study or in any other manner without your express permission. At no point do you have to disclose your name. Your phone and survey data will be stored in a secure password protected Research Data Management system that is only accessible by the project investigators.

The data collected in this research may be used in future research projects such as a comparison of HIV self-test experiences and testing rates and client experiences of other services provided at QPP-RAPID Program and other peer-based, community testing sites and Sexual Health Clinics or a cost effectiveness analysis of HIV home testing. Data would remain non-identifiable. Any reports or articles published from this study will only include de-identified data and no personal information will be ever disclosed.

Consent to Participate

Completing and submitting the Pre-Vend Consent Survey indicates acknowledgement of having read this Information Sheet and indicates consent to participate in the project.

Questions or Further Information about the Project

Please refer to the Research Team Contact Details at the top of the form if you have any questions about the project or to request further information.

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Concerns or Complaints Regarding the Conduct of the Project

This study adheres to the Guidelines of the ethical review process of The University of Queensland. Whilst you are free to discuss your participation in this study with project staff (contactable on the phone numbers above), you can also speak to an officer of the University Ethics committee not involved in the study if you have any concerns or complaints about any aspect of the project, such as the way it is being conducted or any questions about being a research participant. You can contact the Ethics Officer of the University of Queensland Human Research Ethics Committee directly on:

Research & Training Division, Cumbrae-Stewart Building, University of Queensland, St Lucia, 4072, AUSTRALIA. Phone: 0061 7 3365 3924

Thank you for taking the time to help with this research project. Please download or print a copy of this sheet for your information.