



Therapeutic Goods (Prohibited and Restricted Representations—Atomo HIV Self Test) Permission (No. 2) 2019

I, Nicole McLay, as delegate of the Secretary of the Department of Health, make the following permission.

Dated 10 April 2019

Nicole McLay
Assistant Secretary
Regulatory Education and Compliance Branch
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Prohibited and Restricted Representations—Atomo HIV Self Test) Permission (No. 2) 2019*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date and Details
1. The whole of this instrument	The day after this instrument is made.	

Note: This table relates only to the provisions of this instrument originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column for information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 42 of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:

- (a) device number;
- (b) included in the Register;
- (c) label;
- (d) medical device;
- (e) Register; and
- (f) Therapeutic Goods Advertising Code.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

Atomo HIV Self Test means the Class 4 IVD medical device, *Atomo HIV self test – HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid* (device number 311989), included in the Register with the commencement date 28 November 2018.

care card, in relation to the Atomo HIV Self Test, means the document in Schedule 6 to this instrument.

Class 4 IVD medical device has the same meaning as in the Regulations.

fact sheet, in relation to the Atomo HIV Self Test, means the document in Schedule 3 to this instrument.

instructions for use, in relation to the Atomo HIV Self Test, means the document in Schedule 4 to this instrument.

instructional video, in relation to the Atomo HIV Self Test, means the on-line instructional video referenced in the specific conditions in the entry on the Register for the Atomo HIV Self Test.

label, in relation to the Atomo HIV Self Test, means the document, or part of the document, in Schedule 5 to this instrument.

prohibited representation has the same meaning as in subsection 42DJ(1) of the Act.

restricted representation has the same meaning as in subsection 42DD of the Act.

Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

serious form, in relation to a disease, condition, ailment or defect, has the same meaning as in subsection 28(1) of the Therapeutic Goods Advertising Code.

website means the website at www.atomohivselftest.com.

5 Permission—prohibited representation

For subsections 42DK(2) and 42DL of the Act, in relation to each item, the prohibited representations specified in column 2 of the table in Schedule 1 to this instrument are permitted to be used:

- (a) on the label; or
- (b) on the package; or
- (c) on other material included with the package; or
- (d) in the advertisement.

specified in column 3 of the table, in relation to the therapeutic goods specified in column 4 of the table, subject to the conditions (if any) specified in column 5 of the table of that Schedule.

6 Permission—restricted representation

For subsection 42DK(1) of the Act, in relation to each item, the restricted representations specified in column 2 of the table in Schedule 2 to this instrument are permitted to be used in an advertisement specified in column 3 of the table, about the therapeutic goods specified in column 4 of the table, subject to the conditions (if any) specified in column 5 of the table of that Schedule.

7 Repeals

Each instrument that is specified in Schedule 7 to this instrument is repealed as set out in the applicable items in that Schedule.

Schedule 1—Permission: prohibited representation

Note: See section 5.

Permitted use of prohibited representation				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Prohibited representation	Advertisement	Therapeutic goods	Condition
1	a representation regarding the treatment, cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to: (a) sexually transmitted diseases; and (b) human immunodeficiency virus and acquired immune deficiency syndrome (HIV AIDS)	fact sheet	Atomo HIV Self Test	
2	a representation regarding the treatment, cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to: (a) sexually transmitted diseases; and (b) human immunodeficiency virus and acquired immune deficiency syndrome (HIV AIDS)	each of the following: (a) instructions for use; (b) label; (c) care card	Atomo HIV Self Test	the advertisements specified in column 3 must only be: (a) published or disseminated by means of the website; or (b) distributed with the goods specified in column 4
	a representation regarding the treatment, cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to: (a) sexually transmitted diseases; and (b) human immunodeficiency virus and acquired immune deficiency syndrome (HIV AIDS)	each of the following: (a) instructional video; (b) other online content	Atomo HIV Self Test	the advertisement specified in column 3 must only be published or disseminated by means of the website

Schedule 2—Permission: restricted representation

Note: See section 6.

Permitted use of restricted representation

Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representation	Advertisement	Therapeutic goods	Condition
1	a representation that refers to one or more serious forms of bleeding disorders, including haemophilia	instructions for use	Atomo HIV Self Test	the advertisement specified in column 3 must only be: <ul style="list-style-type: none"> (a) published or disseminated by means of a website (b) distributed with the product specified in column 4

Schedule 3—Fact sheet

Note: See section 4, definition of *fact sheet*.

afao AUSTRALIAN FEDERATION OF AIDS ORGANISATIONS Leading the community response to HIV

HIV SELF-TEST FACT SHEET

On 28 November 2018, an HIV self-test was approved for sale in Australia for the first time. The HIV self-test was made available for sale on 4 April 2019.

WHO SHOULD BE TESTING FOR HIV?

HIV testing is appropriate for anyone who may have been exposed to HIV. HIV exposure can occur through sexual contact without the use of an effective HIV prevention strategy (such as treatment as prevention, PrEP or condoms), sharing of needles or exposure to bodily fluids such as blood. HIV cannot be transmitted through casual contact such as hugging, kissing, or other skin to skin contact.

People who should consider routine, regular HIV testing include:

- gay and bisexual men and other men who have sex with men
- trans and gender diverse people
- people who inject drugs
- people who have multiple partners or recent partner change
- sexual and injecting partners of people living with HIV
- people who are from, have travelled to, or have partners from high prevalence countries

For gay and bisexual men, it is recommended to get tested up to four times per year.

WHAT IS AN HIV SELF-TEST?

An HIV self-test is an HIV test that you can perform yourself in the privacy of your own home or wherever you feel comfortable. The HIV self-test available in Australia is designed to be accurate and easy to use. After you have completed the test, you will be able to read the result in fifteen minutes.

The HIV self-test is a small cartridge containing a pre-filled test strip. It is similar in size and shape to a USB drive. Included in the HIV self-test pack will be an HIV self-test cartridge, a set of instructions, a bottle of test fluid (which is used along with a blood sample), a disposable lancet, and a Care Card with contact information. If you have questions or concerns about the test or your result:

There is currently only one HIV self-test approved for sale in Australia, the Atomo HIV Self-Test. It is important to only buy devices approved for self-testing so you can be sure the result is accurate and that the device is

HOW DOES IT WORK?

The self-test is a finger-prick blood test. The result is provided within fifteen minutes after performing the test.

HOW ACCURATE IS THE TEST?

The 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 self-test may not detect HIV that is recently acquired. For the 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. If the potential exposure occurred within the last 72 hours, you may be eligible for post exposure prophylaxis (PEP), which can prevent HIV acquisition occurring.

HOW MUCH DOES IT COST?

The HIV self-test will retail for \$49, plus shipping and handling.

WHERE DO I GET ONE?

HIV self-tests are available for purchase online at the following page: [Atomo HIV Self-Test](#). You will be required to watch an instructional video on the proper use of the test prior to completing your order.

HIV self-tests may also be distributed or sold by organisations such as AIDS Councils. You can find a list of relevant local organisations to contact regarding a HIV self-test [here](#).

WHAT HAPPENS IF I GET A POSITIVE RESULT?

While the self-test is very accurate, it is still a screening test. Because it is a screening test, getting a positive result does not necessarily mean you have HIV. If you have received a positive result on the self-test, it will still need to be confirmed with further testing by a doctor. You can refer to the enclosed Care Card for more information about accessing follow-up testing.

If you receive a positive result with the follow-up testing, it is important that you speak to a doctor about starting treatment. HIV is a manageable condition, treatment today is very effective and those living with HIV are able to live long and healthy lives.

For more information on HIV self-testing please contact AFAO on (02) 9557 9399.

LAST UPDATED: 2 APRIL 2019

Schedule 4—Instructions for use

Note: See section 4, definition of *instructions for use*.

1 Watch the video: www.atomohivtest.com

2 Wash and dry hands. Check expiry date before you open the test pack.

3 Massage your finger to warm it up.

4 Gently pierce and take out the green tube, then discard it.

5 Push grey button to prick finger.

6 Place test on instructions next to results.

7 Squeeze firmly behind skin to get blood.

8 Hold test on tube, fill blood tube with blood.

9 Hold test on tube, now fill blood tube over to the wall.

10 Add 4 drops in the wall.

11 Wait 10 minutes before the result. Do not wash the test.

Results

- HIV negative:** A blue arrow at the top of the window, the test is negative. This is a reassuring test. Test again after 3 months.
- Test did not work:** The test is not working. Try a new test.
- HIV positive:** A red arrow at the top of the window, the test is positive. This is a reassuring test. Test again after 3 months.

Leave test here, this helps with filling the blood tube

atomo HIV SELF TEST

Need Help with the Test?

Before You Start

Finger Prick

Filling the Blood Tube

What if I don't see a result after 10 minutes?

What if I see a result after 10 minutes?

What if I see a result after 10 minutes?

What to do after your Result

What happens if my test result is POSITIVE?

What happens if my test result is NEGATIVE?

What if I see a result after 10 minutes?

About HIV

What is HIV?

What are the signs and symptoms of HIV?

How is HIV spread or passed on?

What if I see a result after 10 minutes?

Watch an instructional video. If you have any specific questions, feedback or suggestions email feedback@atomodiagnostics.com

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Materials included:

- 1. Instructions for use (IFI)
- 2. Atomo HIV Self Test (in its pack with desiccant)
- 3. Dropper or test tube (included)
- 4. Dropper bag
- 5. Care Card

Items NOT included but required:

- 1. A clean surface for opening test donors.
- 2. A clean surface for opening test donors.
- 3. A clean surface for opening test donors.
- 4. A clean surface for opening test donors.
- 5. A clean surface for opening test donors.

Warnings and Precautions:

- 1. Do not use a test tube that has been opened or reused.
- 2. Do not use a test tube that has been opened or reused.
- 3. Do not use a test tube that has been opened or reused.
- 4. Do not use a test tube that has been opened or reused.
- 5. Do not use a test tube that has been opened or reused.

Limitations of the Test:

- 1. The test is not intended to be used for the diagnosis of HIV infection in individuals who are already known to be HIV positive.
- 2. The test is not intended to be used for the diagnosis of HIV infection in individuals who are already known to be HIV positive.
- 3. The test is not intended to be used for the diagnosis of HIV infection in individuals who are already known to be HIV positive.

Storage:

- 1. The test must be stored between 2°C to 8°C.
- 2. Do not store in direct sunlight.
- 3. Do not open the test pack until you are ready to use the test.

Disposal:

- 1. The test must be disposed of in a sharps container.
- 2. The test must be disposed of in a sharps container.
- 3. The test must be disposed of in a sharps container.

Test Performance:

The Atomo HIV Self Test has been shown to have a sensitivity of 99.9% and a specificity of 99.9% for the detection of HIV-1 and HIV-2 antibodies in individuals who are already known to be HIV positive.

Conducted in Kenya, a country identified by the WHO as a high burden of HIV infection.

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Schedule 5—Label

Note: See section 4, definition of *label*.



Schedule 6—Care card

Note: See section 4, definition of *care card*.

CARE CARD

INFORMATION & HELP

For guidance on using Atomo HIV Self Test, visit www.atomohivtest.com or call 1300 235 035

For HIV support services and further information, visit www.afao.org.au

Turn over for a list of some of the HIV support services available across Australia that can assist with arranging follow up testing.

Atomo Diagnostic Pty Ltd
Level 2, 155-161 (Hornebush Rd)
Lonsdale Park NSW 2100 Australia

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REFERRAL REQUEST

Dear Healthcare Practitioner,

HIV SELF TEST USER REQUIRING FURTHER CONFIRMATORY TESTING.

The **Atomo HIV Self Test** gave a positive or inconclusive result for HIV (1&2) antibodies.

The test was performed on ___/___/20__.

A follow-up confirmatory blood test for HIV is requested.

HIV SUPPORT SERVICES

General health advice is available 24 hours a day with Health Direct
24 hour crisis support is available at Lifeline

ACT	Canberra Sexual Health Centre	www.health.act.gov.au/cshc	1800 000 000
NSW	Sexual Health Intblink	www.shi.nsw.gov.au	13 11 11
NT	Clinic 54	www.nt.gov.au/wellbeing/hospitals-health-services/sexual-health-centre-clinic-54	08 8948 1111 - Darwin (see website for other locations)
QLD	Sexual Health and HIV Service at Metro North	www.metro.north.health.qld.gov.au/hospitals-services/sexual-health-hiv-services	(07) 3837 5611
SA	SHINE SA	www.shinesa.org.au	1300 794 584
TAS	Sexual Health Service Tasmania	www.dhhs.tas.gov.au/sexualhealth	(03) 6166 2672 - Hobart (see website for other locations)
VIC	Thorne Harbour Health	www.thorneharbour.org.au	(03) 9865 6700
WA	SHQ (Sexual Health Quarters)	www.shq.org.au	1800 198 205

Schedule 7—Repeals

Note: See section 7.

Therapeutic Goods (Prohibited and Restricted Representations—Atomo HIV Self Test) Permission 2019

1 The whole of the instrument

Repeal the instrument.

Repealed