



Repealed - Therapeutic Goods (Prohibited and Restricted Representations—Atomo HIV Self Test) Permission 2019

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

Dated 2 April 2019

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

REPEALED

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1 Name

This instrument is the *Therapeutic Goods (Prohibited and Restricted Representations—Atomo HIV Self Test) Permission 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/Details
1. The whole of this instrument	The day after this instrument is made.	3 April 2019

Note: This table relates only to the provisions of this instrument as originally made.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, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 42DK 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, of 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 section 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.atomohivtest.com.

5 Permission—prohibited representation

For subsections 42DK(2) and (3) 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 in 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
3	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: (a) published or disseminated by means of the website; or (b) distributed with the goods specified in column 4

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Schedule 3—Fact sheet

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



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 26 March 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
- sexual and injecting partners of people living with
- people who are from, have travelled to, or have lived in high HIV prevalence countries

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

WHAT IS AN HIV SELF-TEST?

An HIV self-test is a rapid test that you can use in the privacy of your home. It is a simple, quick blood test that you can use. After using the self-test, you will receive a result within 20 minutes.

The self-test is a simple, quick blood test that you can use in the privacy of your home. It is a simple, quick blood test that you can use. After using the self-test, you will receive a result within 20 minutes.

When you buy a self-test in Australia, the packaging will tell you how to use it. You should buy devices approved for sale in Australia, the packaging will tell you how to use it. You should buy devices approved for sale in Australia, the packaging will tell you how to use it.

HOW DOES IT WORK?

The self-test is a simple, quick blood test. The result is provided within 20 minutes. You will receive a result within 20 minutes after performing the test.

HOW ACCURATE IS THE TEST?

The HIV self-test has been shown in laboratory tests to correctly identify 99.6% of HIV negative and 99.9% of HIV positive people.

Like other HIV tests, the self-test is most accurate when used on a recently acquired infection. For the best results, you should use the self-test on a sample of blood acquired in the last 3 months.

If you think you may have been exposed to HIV, it is important to get tested. The self-test can help you to be eligible for HIV treatment.

You can find more information about the self-test on the AFAO website.

You can find more information about the self-test online at the following link: [www.afao.org.au](#). You will be required to watch an instructional video before use of the test prior to completing the test.

The self-test is available to be distributed or sold by organisations such as community health centres. You can find a list of relevant local organisations to purchase 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.

Schedule 4—Instructions for use

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

Watch the video: www.atomohivtest.com

You need these four items:

- Test device
- Grey Station
- Green Tab
- Blood Tube
- Test Fluid Bottle
- Timer
- Phone or watch

Need more help? Tap over page.

- Wash and dry hands. Check expiry date before you open the foil pouch.
- Massage your finger for 1 to 10 seconds.
- Gently lift and take out the green tab, then discard it.
- Push grey button in to prick finger.
- Place test on instructions next to results.
- Squeeze firmly behind prick site to get blood.
- Fill blood tube with blood. If blood tube isn't full, squeeze finger and add more blood.
- Hold test on table. Now flip blood tube over to the wall.
- Hold 4 minutes before reading the results. Do not wait more than 20 minutes.

Results

HIV negative
If you see the symbol at the C, you have not been infected with HIV. This is a screening test. Test again after 3 months. If your finger is still bleeding use a tissue or wipe. Carefully match your result with the red, orange and green options. For more information on HIV, tap over page.

Test did not work
If you see the symbol at the C, you did not get a result. This is a screening test. Test again after 3 months. Use correct technique for additional information.

Need Help with the Test?

Finger Prick
Having trouble removing the green tab?
• Did you use the tab HOT, then pull it out.
Scared it will hurt?
• Don't worry, it feels like a rubber band snap against your finger.
• You will not see the results.
Pushed the grey button but can't see blood?
• Is the button HOT?
• No, you just push it.
Note: If you see blood, you have been pricked.

What happens if my test is NEGATIVE?
It is important to know whether it has been 3 months since your last risk event. If it has been less than 3 months, you should test again. If it has been more than 3 months since a risk event, you need to repeat the test in 3 months. Remember this is a screening test. If you are unsure, see advice, refer to the CareCard.
Important! Repeat after 3 months.

What happens if my test does not work?
If you are unsure whether you've done the test correctly, go to atomohivtest.com for more information. If you are unsure whether you've done the test correctly, go to atomohivtest.com for more information. If you are unsure whether you've done the test correctly, go to atomohivtest.com for more information.

What happens if my test is NEGATIVE?
It is important to know whether it has been 3 months since your last risk event. If it has been less than 3 months, you should test again. If it has been more than 3 months since a risk event, you need to repeat the test in 3 months. Remember this is a screening test. If you are unsure, see advice, refer to the CareCard.
Important! Repeat after 3 months.

About HIV

What is HIV?
"HIV" stands for human immunodeficiency virus. It is a virus that targets the immune system and over time reduces the body's ability to fight infections. HIV reproduces in the body and if not controlled, weakens the immune system and can lead to the AIDS (Acquired Immune Deficiency Syndrome) stage. Although there is no cure for HIV or AIDS, with the correct medical treatment and medication it can be managed as a chronic, but not life-threatening condition. Life expectancy for someone diagnosed with HIV tends to be similar to someone who does not have HIV, if they start treatment as soon as possible and remain on regular treatment.

What are the signs and symptoms of HIV?
The only way to know if you have HIV is to have an HIV test. It is very important to get tested to prevent passing on the virus to others without knowing.

How is HIV acquired or passed on?
HIV is passed in bodily fluids such as blood, breast milk, semen, and rectal and vaginal fluids. Person to person transmission of HIV occurs when there is direct blood-to-blood contact with another person's blood, semen, and rectal or vaginal fluids who has HIV. The risk for passing on and acquiring HIV is increased in the presence of an untreated sexually transmitted infection (STI), e.g. chlamydia, gonorrhoea, syphilis and/or herpes sores such as genital ulcers. HIV can also be transmitted to a newborn baby from an HIV positive mother during childbirth and when breastfeeding. Participants in this study were provided screening for HIV & STI offered.

What are Risk Events?
A "Risk event" is an activity which may heighten your chance of exposure to HIV, such as:
• Unprotected sex with someone who has HIV or whose HIV status is unknown.
• Unprotected sex (vaginal or anal intercourse) with a number of partners.
• Using shared needles or injecting equipment.
• Having sex with someone who has HIV or whose HIV status is unknown.
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HIV is NOT transmitted by:
• Casual contact (shaking hands, sharing a cup or drinking, etc.)
• Kissing
• Saliva or spitting
• Tears
• Sweat
• Urine
• Air or water

HIV Infection can be prevented by:
• Having a condom during vaginal or anal sex.
• Talking to sexual partners about their testing history and their current HIV test status.
• Encouraging sexual partners to get tested.
• Using sterile needles or syringes.
• Using the Exposure Prophylaxis (PrEP), a medication used to treat HIV positive people, taken by HIV negative people to reduce the risk of acquiring HIV (not yet available in all states or countries).
• Using the Exposure Prophylaxis (PEP), a short course of medication which, if taken within 72 hours after a risk event, is believed to significantly reduce the chance of becoming infected (may not be available in all states or countries).

Storage
• The test must be stored between 2°C to 8°C.
• Do not freeze or overheat.
• Do not open the foil pouch until you are ready to use the test.
• Do not use the test after the expiry date on the packaging.
• Do not use the test if the pouch is damaged or you see any liquid inside the test.
• Do not use the test if you see any liquid inside the test.
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Warnings and Precautions
• The test is not for use in children.
• Do not use the test if you are pregnant or breastfeeding.
• Do not use the test if you are taking any medication that may affect the test results.
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Disposal
• Dispose of the Atomohiv test in a bin. Do not put it in the recycling bin.
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Test Performance
• Sensitivity: 99.9%
• Specificity: 99.9%
• Accuracy: 99.9%
• Precision: 99.9%
• Reliability: 99.9%

atomohivtest.com

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, 321-323 The Arcade Bldg,
Harris Street, North Sydney NSW 2060, Australia

atomo

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 ___/___/___

A follow-up confirmatory blood test 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
NSW	Sexual Health Infolink	www.shi.nsw.gov.au
NT	Clinic 34	www.nt.gov.au
QLD	Sexual Health and HIV Service at Metro North	www.health.qld.gov.au
SA	SHINE SA	www.shine.org.au
TAS	Sexual Health Service Tas	www.health.tas.gov.au
VIC	Thorne Harbour Her	www.health.vic.gov.au
WA	SHQ (Sexual H	www.health.wa.gov.au

08 - Darwin
(other locations)
03 75611
00 794 584
(03) 6166 2572 - Hobart
(see website for other locations)
(03) 9865 6700
1800 198 205

Schedule 7—Repeals

Note: See section 7.

Therapeutic Goods (Prohibited Representations—HIV Self-Test Fact Sheet) Permission 2019

1 The whole of the instrument

Repeal the instrument.

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