

Repealed - Therapeutic Goods (Prohibited and Restricted Representations—Atomo HIV Self Test) Permission 2019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

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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Note:	This table relates only to the provisions of this ir	nstrument as originally made.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
- 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.

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:	fact sheet	Atomo HIV Self Test	
	(a) sexually transmitted diseases; and			
	 (b) human immunodeficiency virus and acquired immune deficiency syndrome (HIV AIDS) 	4	\mathbf{N}	
2	a representation regarding the treatment, cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to:	each of the following: (a) instructions for use: (b) label;	Atomo HIV Sell Test	 the advertisements specified in column 3 must only be: (a) published or disseminated by means of the
	 (a) sexually transmitted diseases; and (b) human immunodeficiency virus and acquired immune deficiency syndrome (HIV AIDS) 	(c) care card		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	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
	 (b) human immunodeficiency virus and acquired immune deficiency syndrome (HIV AIDS) 			

Schedule 2—Permission: restricted representation

Note: See section 6.

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; on (b) distributed with the goods specified in column 4
			$\mathbf{\mathbf{A}}$	
			X	

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 r
- sexual and injecting partners of people living with '
- people who are from, have travelled to, or h² prevalence countries

For gay and bisexual men, it is recorfour times per year.

WHAT IS AN P

An HIV self-test is an privacy of your r' HIV self-test r' use. After result

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WORK?

, ∠rick blood test. The result is provided within ∠riter performing the test. HOW ACCURATE IS THE TEST? The HIV self-test has been shown in lab

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months. This means that acquired in the last th

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, oe distributed or sold by organisations such , ou can find a list of relevant local organisations to , ig a HIV self-test <u>here.</u>

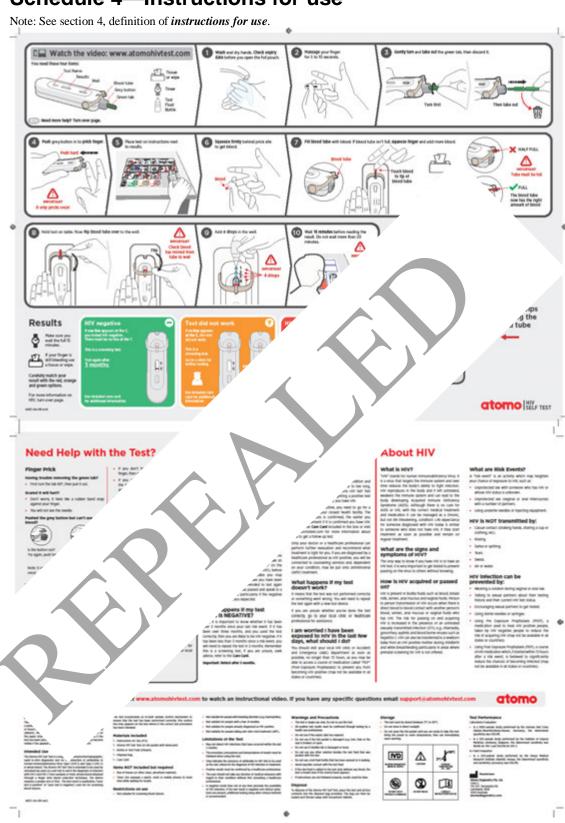
WHAT HAPPENS IF I GET A POSITIVE RESULT?

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 selftest, 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: 22 MARCH 2019

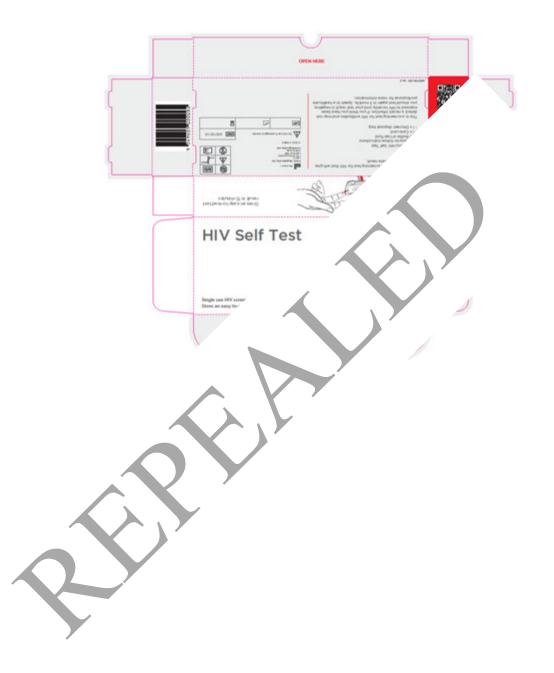


Schedule 4—Instructions for use

Therapeutic Goods (Prohibited and Restricted Representations—Atomo HIV Self Test) Permission 2019Error! No text of specified style in document.

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.

Alexen Dependin Ply Lid Level 2, 707-701 Research Rd, Hammacharter Labelbard, MIN 2040, Anische

REFERRAL REQUEST

Dear Healthcare Practioner,

HIV SELF TEST USER REQUIRING FURTHER CONFIRMATORY TESTING.

The Atomo HIV Self Test gave a positive or Inconclusive result for HIV (182) antibodies.

The test was performed on ____/__ A follow-up confirmatory blood ' requested.

HIV SUPPORT SERVICES

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

ACT	Canberra Sexual Health Centre	www.health.act.gov.av
NSW	Sexual Health Infolink	www.shiLnsw.gov
NT	Clinic 34	www.nl.gz
	Council Line 8th and LUV Country	

QLD at Metro North SA SHINE SA

TAS Sexual Health Service Tay

Thome Harbour He SHQ (Serual P

/8 - Darw

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atomo

400 794 584 (03) 6166 2672 - Hobart site for other locations) (03) 9865 6700 1800 198 205

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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.

