



Australian Government

Department of Health  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

## Atomo Diagnostics Limited

for approval to supply

### Atomo HIV self test - HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid

<b>ARTG Identifier</b>	311989
<b>ARTG Start Date</b>	28/11/2018
<b>Product Category</b>	Medical Device Included - IVD Class 4
<b>GMDN</b>	48454
<b>GMDN Term</b>	HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid
<b>Intended Purpose</b>	The Atomo HIV Self Test is a single-use, immunochromatographic, rapid in-vitro diagnostic test for the detection of antibodies to Human Immunodeficiency Virus (HIV) Type 1 and Type 2 in whole blood. The device is intended to be used by untrained lay users as a self test to aid in the diagnosis of infection with HIV-1 and HIV-2 from samples of fresh, whole blood obtained through a finger stick blood collection technique. The test result is qualitative and not for screening blood donors.

Manufacturer Details	Address	Certificate number(s)
Atomo Diagnostics Limited	Level 1 3-5 George Street Leichhardt , NSW , 2 040 Australia	DV-2018-MC-21422-1

#### ARTG Standard Conditions

The above Medical Device Included - IVD Class 4 has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

#### Products Covered by This Entry

##### 1. Atomo HIV self test - HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid

**This entry:** does not contain System(s)/Procedure Pack(s)  
does not contain In-house IVD(s)

**Functional Description** The Atomo HIV Self Test is a single-use, rapid in-vitro diagnostic test for the detection of antibodies to Human Immunodeficiency Virus (HIV) Type 1 and Type 2 in whole blood.

#### Variant Information

Description	Range
-------------	-------

#### IVD Information

Name	Category Description
------	----------------------

Name	Category Description
Atomo HIV self test	Self Testing

### Product Specific Conditions

- Supply
  - (1) The person in relation to whom the Atomo HIV Self Test (the device) is included in the Australian Register of Therapeutic Goods (the sponsor) must ensure that the device is only supplied to one or more of the following
    - (a) a business, organisation or institution (including a pharmacy) that employs or engages individuals who have received appropriate training (in any form) in relation to the correct use and performance of the device, and the interpretation of the test result
    - (b) a person directly through the website of the sponsor or a pharmacy
- Customer support services
  - (2) The sponsor must publish on its website a simple, clear and effective instructional video, demonstrating the correct use and performance of the device, and the interpretation of the test result
- (3) The sponsor must
  - (a) provide information about relevant support services and confirmatory testing available in each state and territory with the supply of each device and
  - (b) publish the information mentioned in paragraph (a) on its website
- (4) The sponsor must take steps to ensure that a business, organisation or institution (including a pharmacy) mentioned in condition (1)(a), or a pharmacy mentioned in condition (1)(b), has access to, and encourages the dissemination of, the following by any means
  - (a) information about the correct use and performance of the device, and the interpretation of the test result, consistent with the information provided in the instructional video mentioned in condition (2) and
  - (b) information about the support services and confirmatory testing mentioned in condition (3)
- (5) The sponsor must provide a telephone helpline that
  - (a) provides customer support about the correct use and performance of the device, and the interpretation of the test result and
  - (b) operates (as a minimum) between 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), 7 days per week
- (6) The sponsor must ensure that the operators providing customer support services mentioned in condition (5) have received training in the delivery and administration of HIV testing, in accordance with the requirements of the National HIV Testing Policy (which may be accessed via the ASHM website at [www.ashm.org.au](http://www.ashm.org.au))
- Post market surveillance reports
  - (7) The sponsor must provide a post market surveillance report, containing the following information, to the Therapeutic Goods Administration (at the email address [postmarketdevices@health.gov.au](mailto:postmarketdevices@health.gov.au)) for each reporting period specified in condition (8), before 1 October after that reporting period
    - (a) the numbers of tests sold both in Australia and overseas
    - (b) any adverse events, including numbers of any reported false positive or false negative results, both in Australia and overseas
    - (c) reported problems, issues or complaints associated with the use or interpretation of the device, both in Australia and overseas
- (8) Each of the following is a reporting period
  - (a) the period beginning on the day when this condition is imposed, and ending at the end of the next 30 June
  - (b) each of the next five financial years.
- Record keeping
  - (9) The sponsor must maintain records that demonstrate that the sponsor has complied with each of the conditions mentioned above (relating to supply, customer support services and post market surveillance reports) and provide those records to the Secretary on request.