# Public Summary

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| **Summary for ARTG Entry:** | 347510 | Atomo Diagnostics Limited - AtomoRapid HIV 1&2 - HIV1/HIV2 antigen IVD, kit, immunochromatographic test (ICT), rapid |

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| **ARTG entry for** | Medical Device Included - IVD Class 4 |
| **Sponsor** | Atomo Diagnostics Limited |
| **Postal Address** | Level 1 3-5 George Street, Leichhardt, NSW, 2040<br>Australia |
| **ARTG Start Date** | 6/11/2020 |
| **Product Category** | Medical Device Class 4 |
| **Status** | Active |
| **Approval Area** | IVD |

## 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.

## Manufacturers

| Name | Address |
|---|---|
| Atomo Diagnostics Limited | Level 1 3-5 George Street<br>Leichhardt, NSW, 2040<br>Australia |

## Products

### 1 . AtomoRapid HIV 1&2 - HIV1/HIV2 antigen IVD, kit, immunochromatographic test (ICT), rapid

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| **Product Type** | IVD | **Effective Date** | 6/11/2020 |

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| **GMDN** | 48432 HIV1/HIV2 antigen IVD, kit, immunochromatographic test (ICT), rapid |
| **Functional Description** | The AtomoRapid HIV (1&2) test is a colloidal gold enhanced, rapid immunochromatographic assay for the qualitative detection of antibodies to HIV in human whole blood, serum or plasma. This test is a screening test, and all positives must be confirmed using an alternate test. The test is single-use and intended for healthcare professional use only. Not for screening blood donors. |
| **Intended Purpose** | The AtomoRapid HIV (1&2) test is a colloidal gold enhanced, rapid immunochromatographic assay for the qualitative detection of antibodies to human immunodeficiency virus (HIV) in human whole blood, serum or plasma. This test is a screening test, and all positives must be confirmed using an alternate test. The test is single-use and intended for healthcare professional use only. Not for screening blood donors. |

**Variant information**

#### Specific Conditions

1) The person (the sponsor) in relation to whom the AtomoRapid HIV 1&2 Test (the Device) is included in the Australian Register of Therapeutic Goods (the ARTG) must ensure that the Device is only supplied for use by
a) laboratories that are accredited by the National Association of Testing Authorities (NATA) as medical testing laboratories and that participate in an HIV point of care quality assurance program or
b) organisations that
i) employ healthcare workers who will perform, or supervise the performance of, HIV testing using the device and have received training in the delivery and administration of HIV testing in accordance with the requirements of the National HIV Testing Policy and
ii) have an established relationship (in relation to the referral and testing of specimens) with a NATA accredited medical testing laboratory and
iii) participate in an HIV point of care quality assurance program.

2) The sponsor of the AtomoRapid HIV 1&2 Test must make available training in the correct use of the Device and interpretation of results.

3) The sponsor must maintain records that demonstrate that the device has been supplied in compliance with condition 1 and that it has complied with condition 2.

4) The sponsor must provide to the Therapeutic Goods Administration (TGA) a post market surveillance report for each reporting period commencing on the date of inclusion of the device in the ARTG and ending at the end of the next 30 June and each twelve (12) months thereafter for the next five (5) financial years. Reports must be provided to the TGA before 1 October after each reporting period and must include the following
a) Numbers of tests sold in Australia and Worldwide.
b) Any adverse events including numbers of any reported false positive or false negative results in Australia and Worldwide.
c) Reported problems or complaints associated with the use/interpretation of the device in Australia and Worldwide.

5) Post-market reports must be sent to the TGA at the following email address
postmarketdevices@health.gov.au.

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