Inverness Medical Innovations Australia Pty Ltd T/A Alere - Determine HIV-1/2 Ag/Ab Combo - HIV1/HIV2 antigen/antibody IVD, kit, immunochromatographic test (ICT), rapid

**ARTG entry for** Medical Device Included - IVD Class 4

**Sponsor** Inverness Medical Innovations Australia Pty Ltd T/A Alere

**Postal Address** PO Box 7063, East Brisbane, QLD, 4169 Australia

**ARTG Start Date** 20/01/2015

**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** Alere Medical Co Ltd

**Address** 357 Matsuhidai Matsudo-shi, Chiba-ken, 270-2214 Japan

**Products**

1. Determine HIV-1/2 Ag/Ab Combo - HIV1/HIV2 antigen/antibody IVD, kit, immunochromatographic test (ICT), rapid

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**GMND**

48447 HIV1/HIV2 antigen/antibody IVD, kit, immunochromatographic test (ICT), rapid

**Functional description**
The Determine HIV-1/2 Ag/Ab Combo is an immunochromatographic test for the qualitative detection of p24 antigen and antibodies to HIV-1 and HIV-2.

**Intended purpose**
The Determine HIV-1/2 Ag/Ab Combo is an In Vitro, visually read, qualitative immunoassay for the simultaneous detection of free non immunocomplexed HIV-1 p24 antigen (Ag) and antibodies (Ab) to HIV-1 and HIV-2 in human blood. The test specimen can be serum, plasma, fingerstick or venous whole blood. The test is intended as an aid to detect HIV-1 p24 antigen and antibodies to HIV-1/HIV-2 from infected individuals.

**Variant information**

**Specific Conditions**
1. The person (the sponsor) in relation to whom the Alere Determine HIV 1/2 Ag/Ab Combo (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 health professionals who will perform, or supervise the performance of, HIV testing using the device, 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, and
   iv) provide a declaration to the sponsor every 12 months that all personnel using the Device have received training in the delivery and administration of HIV point of care devices in accordance with the requirements of the National HIV Testing Policy.
2. The sponsor of the Device (Alere Determine HIV 1/2 Ag/Ab Combo) 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 Post Market Surveillance Branch (PMSB) of the Therapeutic Goods Administration, a post market surveillance report for each period of six (6) months commencing on the date of inclusion of the Device in the ARTG identifying any adverse events, problems or complaints relating to the use or application of the Device. The first report must be provided at the end of eight (8) months from the date of inclusion of the Device in the ARTG and each six (6) months thereafter, for a period of three years.
5. The sponsor must provide to the TGA a report and documents for each period of twelve (12) months commencing on the date of inclusion of the Device in the ARTG. The first report must be provided at the end of fourteen (14) months from the date of inclusion of the Device on the ARTG and each twelve (12) months thereafter. Information about the distribution of the Device and evidence of compliance with the conditions of ARTG inclusion for that twelve months (the period) must be provided, including
a) copies of the current NATA accreditation certificate for each laboratory to which the Device has been supplied during the period and documented evidence of participation of the laboratory in an HIV point of care quality assurance program

b) in relation to each organisation that is not an accredited medical testing laboratory
   i) documented evidence of a relationship of the kind referred to in condition 1b. above with a NATA accredited laboratory, and
   ii) documented evidence of the participation by the organisation in an HIV point of care quality assurance program, and

c) documented evidence that condition 2 has been complied with by the sponsor during the period, and

d) documented evidence that each person using the Device during the period has satisfactorily completed training in the correct use of the Device and interpretation of results being evidence that
   i) identifies the name and qualifications of health professionals who use or supervise the use of the Device, the date of their training and provider of the training,
   ii) identifies the names of all other users of the Device, the date of their training and provider of the training,
   iii) lists the specific skills and knowledge evaluated in the training, and

e) declarations, including certificates or other evidence, that each person using the Device has received training in the delivery and administration of HIV point of care devices in accordance with the requirements of the National HIV Testing Policy.

6. Post-market reports must be sent to the PMSB at the following email address, postmarketdevices@tga.gov.au.

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