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

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

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

**ARTG Start Date**
12/01/2015

**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 - HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid**

   **Product Type**
   IVD

   **GMN**
   48454 HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid

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

   **Intended purpose**
   The Determine HIV-1/2 is an In Vitro, visually read, qualitative immunoassay for the detection of antibodies to HIV-1 and HIV-2 in human serum, plasma or whole blood. The test is intended as an aid to detect antibodies to HIV-1/HIV-2 from infected individuals.

   **Variant information**

   **Specific Conditions**
   No Specific Conditions included on Record