Summary for ARTG Entry: 232594
Abbott Rapid Diagnostics Pty Ltd T/A Alere - Determine HIV-1/2 - HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid

ARTG entry for
Medical Device Included - IVD Class 4

Sponsor
Abbott Rapid Diagnostics Pty Ltd

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

Effective date
12/01/2015

GMND
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