Public Summary

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

<table>
<thead>
<tr>
<th>Product Type</th>
<th>IVD</th>
<th>Effective date</th>
<th>12/01/2015</th>
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<tbody>
<tr>
<td>GMDN</td>
<td></td>
<td>48454 HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid</td>
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<td>Functional description</td>
<td>The Determine HIV-1/2 is an immunochromatographic test for the qualitative detection of antibodies to HIV-1 and HIV-2.</td>
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<td>Intended purpose</td>
<td>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.</td>
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Variant information
Specific Conditions
No Specific Conditions included on Record

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