Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Abbott Rapid Diagnostics Pty Ltd

for approval to supply

Severe acute respiratory syndrome-associated coronavirus IVDs

ARTG Identifier	345192
ARTG Start Date	30/09/2020
Product Category	Medical Device Included - IVD Class 3
GMDN	CT772
GMDN Term	Severe acute respiratory syndrome-associated coronavirus IVDs
Intended Purpose	The Panbio™ COVID-19 Ag Rapid Test Devices are in vitro diagnostic rapid tests for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasopharyngeal or nasal swab specimens. The Panbio™ COVID-19 Ag Rapid Test Devices are for professional use only and are intended to be used as an aid in the diagnosis of SARS-CoV-2 infection.

Manufacturer Details	Address	Certificate number(s)
Abbott Rapid Diagnostics Jena GmbH	Orlaweg 1 Jena , Germany , 077 43 Germany	DV-2020-MC-04561-1

ARTG Standard Conditions

The above Medical Device Included - IVD Class 3 has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Severe acute respiratory syndrome-associated coronavirus IVDs

This entry: does not contain System(s)/Procedure Pack(s)

IVD Information

Name	Category Description
Panbio COVID-19 Ag Rapid Test Device (Nasal)	Point of care testing
Panbio COVID-19 Ag Rapid Test Device (Nasopharyngeal)	Point of care testing

Product Specific Conditions

· (1) The person in whose name the Device is included in the ARTG (the sponsor) may only supply the Device to one or more of the following
(a) a laboratory that is an accredited pathology laboratory within the meaning of the Health Insurance

Act 1973
(b) a medical practitioner, or an organisation, business or institution that employs or engages a medical practitioner, registered to practice under a law of a state or territory, where the practitioner is responsible for performing or supervising the performance of the test, and both the practitioner and a person acting under the practitioner's supervision to perform the test have received training in the correct use of the Device and interpretation of the test result
(c) a residential care or aged care facility that employs or engages a health practitioner, within the meaning of the Therapeutic Goods Act 1989, where the practitioner is responsible for performing or supervising the performance of the test, and both the practitioner and a person acting under the practitioner's supervision to perform the test have received training in the correct use of the Device and interpretation of the test result
(d) an organisation, business or institution that does not have the primary function of providing healthcare services but employs or engages a health practitioner within the meaning of the Therapeutic Goods Act 1989, where the practitioner is responsible for performing or supervising the performance of the test, where both the practitioner and a person acting under the practitioner's supervision to perform the test have received training in the correct use of the Device and interpretation of the test result
(e) a department of the Commonwealth, state or territory, with responsibility for health, or a department or other agency of the Commonwealth, state or territory acting on its behalf.

- (2) The Device must not be supplied for the purpose of self-testing.
- (3) The sponsor of the Device must provide training to a practitioner mentioned in paragraphs (1)(b) to (d) in the correct use of the Device and the interpretation of the test result, prior to that practitioner performing or supervising the performance of the test.
- (4) The sponsor must maintain records that demonstrate the Device has been supplied in compliance with these conditions.
- And within 12 months of an approval the following information will be required to be provided to the TGA.
- (5) A report of any adverse events, corrective and preventative actions, and customer complaints provided in the context of the number of devices supplied since the introduction of the Device(s) to market in Australia and Worldwide.
- (6) Information regarding any refusals by Regulatory Authorities for the supply of the Device(s) in any other regulatory jurisdictions.
- (7) Further analytical and clinical evidence to support
  (a) Analytical and clinical performance of the device
  (b) Device stability (e.g, shelf-life stability, transport stability)
- (8) Instructions for use that provide updated information on the analytical and clinical performance characteristics of the device.

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