Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	333342 AM Diagnostics - Severe acute respiratory syndrome-associated coronavirus IVDs
ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	AM Diagnostics
Postal Address	PO Box 2698, ELLENBROOK, WA, 6069 Australia
ARTG Start Date	5/04/2020
Product Category	Medical Device Class 3
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	Address
Hangzhou Alltest Biotech Co Ltd	550# Yinhai Street Hangzhou Economic & Technological Development Area , Hangzhou, 310018 China

Products

1 . Severe acute respiratory syndrome-associated coronavirus IVDs

Product Type	IVD	**Effective Date**	5/04/2020
GMDN	CT772 Severe acute respiratory syndrome-associated coronavirus IVDs		
Intended Purpose	the 2019-n-CoV IgG/IgM Rapid Test Cassette is a lateral flow Chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to 2019-nCoV in human whole blood , serum or plasma specimens		

Specific Conditions

1. The person (the sponsor) in relation to whom the Device is included in the ARTG may only supply the Device to
a.laboratories that are accredited pathology laboratories and/or
b. medical practitioners who are registered under a law of a State or Territory and/or
c. health care professionals in residential and aged care facilities and/or d.Commonwealth, State or Territory department of health and/or
e. an agency of the Commonwealth, State or Territory acting on behalf of Commonwealth, State or Territory department of health.

And within 12 months of an approval the following information will be required to be provided to the TGA.

2. 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.

3. Information regarding any refusals by Regulatory Authorities for the supply of the Device(s) in any other regulatory jurisdictions

4. 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)

5. Instructions for use that provide updated information on the analytical and clinical performance characteristics of the device.

6. Evidence of how the user may verify, at the time of use that the device will perform as intended by the manufacturer through the use of controls.