Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	334505 ONSITE DIAGNOSTICS PTY LTD - Severe acute respiratory syndrome-associated coronavirus IVDs
ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	ONSITE DIAGNOSTICS PTY LTD
Postal Address	PO Box 164, Burleigh Heads, QLD, 4220 Australia
ARTG Start Date	17/04/2020
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
Zhejiang Orient Gene Biotech Co Ltd	3787 East Yangguang Avenue Dipu Street Anji, Huzhou, 313300 China

Products

1 . Severe acute respiratory syndrome-associated coronavirus IVDs

Product Type	IVD	**Effective Date**	24/01/2023 1:11:01 PM
GMDN	CT772 Severe acute respiratory syndrome-associated coronavirus IVDs		
Intended Purpose	The purpose of the device is for rapid, presumptive, initial qualitative simultaneous detection and differentiation of anti-SARS-CoV-2 IgG and IgM antibodies in either human serum, plasma or whole blood within just 10 minutes. It is a lateral flow immunoassay test cassette. Results are qualitative only and should be confirmed using alternative test methods. To be used by health care practitioners only.		

Specific Conditions

The following conditions apply to COVID-19 POCT serology tests

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 ages 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.

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