



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 513625 Aceso Diagnostics Pty Ltd - Multiple-viruses IVDs

ARTG entry for Medical Device Included - IVD Class 3
Sponsor Aceso Diagnostics Pty Ltd
Postal Address Level 25 100 Mount Street, North Sydney, NSW, 2060
Australia
ARTG Start Date 29/09/2025
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	Location Id
Hangzhou Alltest Biotech Co Ltd	550# Yinhai Street Hangzhou Economic & Technological Development Area, Hangzhou, 310018 China	107117

Products

1 . Multiple-viruses IVDs

Product Type	IVD	Effective Date	13/02/2026
GMDN	CT702 Multiple-viruses IVDs		
Intended Purpose	Intended to detect SARS-CoV-2, Influenza A/B and RSV virus with nasal swab specimen from symptomatic individuals for self-testing by lay persons.		

Specific Conditions

No Specific Conditions included on Record

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