Public Summary

Summary for ARTG Entry:	400342 Q Plus Access - Severe acute respiratory syndrome-associated coronavirus IVDs
ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	Q Plus Access
Postal Address	27 Mcwilliams Crescent, Point Cook, VIC, 3030 Australia
ARTG Start Date	29/11/2022
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
Sanwa BioTech Limited	Unit 1-3 & 12 5/F Wah Lai Industrial Centre 10 Kwei Tei Street New Territories, Fo Tan, Hong Kong - SAR of China

Products

1 . Severe acute respiratory syndrome-associated coronavirus IVDs

Product Type	IVD	**Effective Date**	29/11/2022
GMDN	CT772 Severe acute respiratory syndrome-associated coronavirus IVDs		
Intended Purpose	ALiA SARS-CoV-2 Antigen FIA Test is a fluorescent immunoassay intended for the qualitative detection of nucleocapsid antigen from SARS-CoV-2 in nasopharyngeal swab from individuals who are suspected of COVID-19 infection by their healthcare provider. Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in nasopharyngeal swab during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not rule out SARS-CoV-2 infection and should not be used as a sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management. The ALiA SARS-CoV-2 Antigent FIA Test is intended for use with ALiA FIA Analyser by medical professionals, trained operators, and clinical laboratory technicians. The COVID-19 Test Kit also includes an External Control Pack. ALiA SARS-CoV-2 Antigen FIA Test External Control Pack contains 1 vial of Positive Control (SARS-CoV-2 recombinant nucleocapsid in stabliser) and 1 vial Negative control (stabliser). Each control pack contains 0.5mL of ALiA SARS-CoV-2 Positive and Negative Control. These controls are to be used with the ALiA FIA Analyser and ALiA SARS-CoV-2 Antigen FIA Test only and are intended to verify that the test kits are working and that the test is performed correctly. The test is intended for us by medical professionals, trained operators, and clinical laboratory technicians.		

Specific Conditions

The following non-standard conditions apply to the point of care device:

The following conditions are imposed on the supply of COVID-19 rapid antigen tests included in the Register:
1. The person in whose name the device is included in the Register (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 person who is registered under a law of a state or territory to practice pharmacy (a pharmacist), where:
i. the pharmacist is responsible for performing or supervising the performance of the test; and
ii. the person mentioned in subparagraph (i) and any other person acting under their supervision to perform the test have received training in the correct use of the device and the interpretation of the test result;
c. a health practitioner within the meaning of the Therapeutic Goods Act 1989 (other than a pharmacist) or a person registered under a law of a state or territory to practice paramedicine (a paramedic), where:
i. the health practitioner or the paramedic is responsible for performing or supervising the performance of the test; and
ii. the person mentioned in subparagraph (i) and any other person acting under their supervision to perform the test have received training in the correct use of the device and the interpretation of the test result; and
iii. the device is only used to test employees or contractors of, or a patient under the direct care of, the health practitioner or the paramedic;
d. a residential care or aged care facility, or a home care service provider, that employs or engages a health practitioner within the meaning of the Therapeutic Goods Act 1989 or a paramedic, where:
i. the health practitioner or the paramedic is responsible for performing or supervising the performance of the test; and

ii. the person mentioned in subparagraph (i) and any other person acting under their supervision to perform the test have received training in the correct use of the device and the interpretation of the test result; and
iii. the device is only used to test residents, employees or contractors of, or visitors to, the residential care or aged care facility, or clients, employees, or contractors of the home care service provider;
e. an organisation, business or institution that employs or engages a health practitioner within the meaning of the Therapeutic Goods Act 1989 or a paramedic, where:
i. the health practitioner or the paramedic is responsible for performing or supervising the performance of the test; and
ii. the person mentioned in subparagraph (i) and any other person acting under their supervision to perform the test have received training in the correct use of the device and the interpretation of the test result; and
iii. the device is only used to test employees, contractors or students of the organisation, business or institution.
f. 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 person mentioned in subparagraphs (1)(b)(ii), (1)(c)(ii), (1)(d)(ii) or (1)(e)(ii) in the correct use of the device and the interpretation of the test result, prior to that person 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, including any kits supplied by distributors and on-sellers.

Post market surveillance report
5. The sponsor must provide a post market surveillance report, which includes the following information:
a. the numbers of tests supplied in Australia and overseas
b. any adverse events, reported problems, issues or complaints associated with the use or interpretation of the device, including numbers of any reported false positive or false negative results for tests supplied in Australia and overseas
c. for each type of problem, issue or complaint, provide the manufacturer's analysis of the issue and its risks, as well as any emerging trends.

6. The report is to be sent to the TGA (at the email address postmarketdevices@health.gov.au) for:
a. the period beginning on the day when this condition is imposed, and ending on the next 30 June
b. each of the next three financial years
c. before 1 October after that reporting period