Provisional Authorisation for COVID-19 Tests

Applicant	Roche Diagnostics Asia Pacific Pte Ltd
Name of test	SARS-CoV-2 Rapid Antigen Test Nasal
Intended purpose (As per manufacturer's information for use)	*The SARS CoV 2 Rapid Antigen Test Nasal is a rapid chromatographic immunoassay for the qualitative detection of SARS CoV 2 nucleocapsid antigen present in human nasal samples. This test is intended to detect antigen from SARS CoV 2 in individuals suspected of COVID 19 or with known or suspected exposure to SARS CoV 2. This product is intended for professional use in laboratory and Point of Care environments, or self-collection under the supervision of a healthcare worker.* *In addition, the test is intended for patients for whom days post symptom onset is 0-5 days.* *A negative result may occur if the concentration of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly. Therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or a molecular assay.*
Date of Provisional Authorisation	31 May 2021