Provisional Authorisation for COVID-19 Tests

Applicant	Unison Collaborative Pte Ltd
Name of test	Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal)
Intended purpose (As per manufacturer's information for use)	*Panbio™ COVID-19 Ag Rapid Test Device is an in vitro diagnostic rapid test for the qualitative detection of SAR-CoV-2 antigen (Ag) in human nasopharyngeal swab specimens from individuals who meet COVID-19 clinical and / or epidemiological criteria. Panbio™ COVID-19 Ag Rapid Test Device is for professional use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection.* *The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation. The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The test is not intended to be used as a donor screening test for SARS-CoV-2.*
Date of Provisional Authorisation	15 October 2020