Provisional Authorisation for COVID-19 Tests

Applicant	Unison Collaborative Pte Ltd
Name of test	Panbio™ COVID-19 IgG/IgM Rapid Test Device
Intended purpose (As per manufacturer's information for use)	*The Panbio™ COVID-19 IgG/IgM Rapid Test Device (Fingerstick Whole Blood/ Venous Whole Blood/ Serum/ Plasma) is an in vitro diagnostic rapid test for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human serum, plasma, venous and fingerstick whole blood. The Panbio™ COVID-19 IgG/IgM Rapid Test Device (Fingerstick Whole Blood/ Venous Whole Blood/ Serum/ Plasma) 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 results. Negative results will not preclude SARS-CoV-2 infection and they cannot be used as a sole basis for treatment or other management decision.* *The test is not intended to be used as a donor screening test for SARS-CoV-2.* *The results from this test is not to be used for confirmatory testing or as sole basis for diagnosis. The results will have to be interpreted together with clinical presentation and are to be confirmed with supplemental testing (e.g. RT-PCR).*
Date of Provisional Authorisation	23 Jun 2020