Provisional Authorisation for COVID-19 Tests

Applicant	Everest Links Pte Ltd
Name of test	VivaDiag™ SARS-CoV-2 IgM/IgG Rapid Test
Intended purpose (As per manufacturer's information for use)	*VivaDiag™ SARS-CoV-2 IgM/IgG Rapid Test (COVID-19 IgM/IgG Rapid Test) is for the qualitative detection of IgM and IgG antibodies to SARS-CoV-2 in human whole blood (fingertip/venous), serum or plasma. The test is for in vitro diagnostic use only. For professional use only. It is intended for clinical laboratories and healthcare professional use only for point-of-care testing. Not for at-home testing.* *The results from this test is not to be used for confirmatory testing or as a 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	20 March 2020