Provisional Authorisation for COVID-19 Tests

Applicant	Cell ID Pte Ltd
Name of test	Smart COVID-19 IgM-IgG Rapid Diagnostic Test
Intended purpose (As per manufacturer's information for use)	*The Smart COVID-19 IgM/IgG Rapid Diagnostic Test (RDT) is a single use and rapid lateral flow chromatographic immunoassay, for the qualitative test for the detection of antibodies to SARS-CoV-2 (COVID-19 virus) in human serum, plasma or whole blood. This test detects the presence of COVID-19 antibodies (IgM/IgG) in blood samples. As there may be a few days' delay between the viral infection and development of antibodies in an individual, any negative result from this test should not be used as sole basis to rule out COVID-19 infection. The negative results have to be carefully considered together with clinical presentations. Any positive result from this test should be confirmed with supplemental laboratory testing (e.g. RT-PCR). Users are the professionals in hospitals and clinics. A non-reactive result does not preclude the possibility of exposure to COVID-19. Clinical correlation is indicated with appropriate medical evaluation and possibly additional testing to decide whether a diagnosis of COVID-19 is accurate.*
Date of Provisional Authorisation	25 Jun 2020