Provisional Authorisation for COVID-19 Tests

Applicant	All Eights (Singapore) Pte Ltd
Name of test	EDI™ Novel Coronavirus COVID-19 IgM ELISA Kit
Intended purpose (As per manufacturer's information for use)	This kit is for in vitro diagnostics use only. The kit is detecting novel COVID-19 IgM antibody in human serum. It is for screening or to aid in the diagnosis of COVID-19. The results from this test should not be the sole basis for clinical diagnosis and treatment. The confirmation of infection with novel coronavirus (COVID-19) must be combined with the patient's clinical signs in conjunction to other tests.
Date of Provisional Authorisation	15 May 2020