Provisional Authorisation for COVID-19 Tests

Applicant	Andaman Medical Pte Ltd
Name of test	GENEDIA W COVID-19 Ag
Intended purpose (As per manufacturer's information for use)	*The GENEDIA W COVID-19 Ag is an in vitro diagnostic single-use test and qualitative immunoassay to detect SARS-CoV-2 antigen in nasopharyngeal swab and sputum specimen from human. This assay is designed for professional personnel in laboratory and at point-of-care as an aid in screening patients suspected of being infected.* *A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly. A negative test result does not eliminate the possibility of SARS-CoV-2 infection.*
Date of Provisional Authorisation	18 November 2020