Provisional Authorisation for COVID-19 Tests

Applicant	Hermes-Epitek Corporation Pte Ltd
Name of test	Vstrip COVID-19 Antigen Rapid Test
Intended purpose (As per manufacturer's information for use)	*Vstrip COVID-19 Antigen Rapid Test is a rapid in vitro immunochromatographic assay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.* *Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.* *Negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.* *The Vstrip COVID-19 Antigen Rapid Test is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel in healthcare setting.*
Date of Provisional Authorisation	23 December 2020