Provisional Authorisation for COVID-19 Tests

Applicant	Xentific Labs Pte Ltd
Name of test	CLUNGENE® COVID-19 Antigen Rapid Test Cassette
Intended purpose (As per manufacturer's information for use)	*The COVID-19 Antigen Rapid Test Cassette is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider.* *Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in nasopharyngeal swab and oropharyngeal swab 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. The agent detected may not be the definite cause of disease.* *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, and confirmed with a molecular assay, if necessary for patient management.* *The COVID-19 Antigen Rapid Test Cassette is intended for use by trained clinical laboratory personnel specifically instructed and trained in vitro diagnostic procedures.*
Date of Provisional Authorisation	8 January 2021