Provisional Authorisation for COVID-19 Tests

Applicant	SG Diagnostics Pte Ltd
Name of test	SG Diagnostics COVID-19 Antigen Rapid Test Kit (Colloidal Gold-Based)
Intended purpose (As per manufacturer's information for use)	*The SG Diagnostics COVID-19 Antigen Rapid Test Kit (Colloidal Gold-Based) is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct swabs from individuals suspected of COVID-19 by their healthcare provider.* *Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in swabs 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 from patients with symptom onset beyond seven days, should be treated as 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 SG Diagnostics COVID-19 Antigen Rapid Test Kit is intended for use by medical professionals or trained operators who are proficient in performing rapid lateral flow tests.*
Date of Provisional Authorisation	8 January 2021