Provisional Authorisation for COVID-19 Tests

Applicant	SG Diagnostics Pte Ltd
Name of test	COVID-19 Antigen Test
Intended purpose (As per manufacturer's information for use)	*Artron COVID-19 Antigen Test is a rapid and convenient immuno-chromatographic assay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab specimens directly collected from individuals who are suspected of COVID-19 infection. The device is designed to aid in the rapid differential diagnosis of COVID-19 virus infection.* *Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in nasopharyngeal swab specimens 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. Laboratories are required to report all positive results to the appropriate public health authorities.* *Negative results should be treated as presumptive, and 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.* *Artron COVID-19 Antigen Test is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel.*
Date of Provisional Authorisation	7 December 2020