Provisional Authorisation for COVID-19 Tests

Applicant	Abbott Laboratories (Singapore) Pte Ltd
Name of test	Abbott Alinity m SARS-CoV-2 AMP Kit
Intended purpose (As per manufacturer's information for use)	*The Alinity m SARS-CoV-2 assay is a real-time (rt) reverse transcriptase (RT) polymerase chain reaction (PCR) test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal (NP) and oropharyngeal (OP) swabs collected by a healthcare provider, from patients who are suspected of COVID-19 infection.* *Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasopharyngeal and oropharyngeal swabs during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.* *Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.* *The Alinity m SARS-CoV-2 assay is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.*
Date of Provisional Authorisation	14 September 2020