Provisional Authorisation for COVID-19 Tests

Applicant	Shimadzu (Asia Pacific) Pte. Ltd
Name of test	Shimadzu Ampdirect 2019-nCoV Detection Kit
Intended purpose (As per manufacturer's information for use)	*Ampdirect 2019-nCoV Detection Kit is a rapid sample preparation for real time Reverse Transcription -Polymerase Chain Reaction (RT-PCR) testing intended for the qualitative detection of the novel coronavirus SARS-CoV-2 RNA in upper respiratory specimens/oral secretion (such as nasopharyngeal swabs/saliva), collected from individuals suspected of COVID-19 by a healthcare provider. Additional testing and confirmation procedures should be performed in consultation with public health and/or other authorities.* *Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens/oral secretion during the acute phase of infection. While 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. The agent detected may not be the definite cause of disease.* *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 to make appropriate diagnosis.* *The Ampdirect 2019-nCoV Detection Kit is intended for use by qualified laboratories certified to perform high complexity testing and personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.*
Date of Provisional Authorisation	13 January 2021