Provisional Authorisation for COVID-19 Tests

Applicant	Alliance BioMed Pte Ltd
Name of test	Alliance Resolute 2.0
Intended purpose (As per manufacturer's information for use)	*RESOLUTE 2.0 is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 virus in nasopharyngeal (NP), oropharyngeal (OP), anterior nasal, mid-turbinate (MT) nasal swabs and deep throat saliva (DTS) specimen from individuals with signs and symptoms of infection who are suspected of COVID-19.* *RESOLUTE 2.0 is intended for the direct amplification of Coronavirus SARS-CoV-2 RNA from NP, OP, OP-MT swab in Universal Transport Medium (UTM) or DTS specimen. RNA extraction is not required for the use of this kit.* *Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens, during the acute phase of infection. A positive result is indicative of the presence of SARS-CoV-2 RNA. Correlation with clinical presentation and other clinical investigations is necessary to determine the patient's infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.* *A negative result does not exclude SARS-CoV-2 infection. Clinical correlation is required and if indicated, repeat sampling and use of other clinical and laboratory investigations may be warranted.* *The test results from the RESOLUTE 2.0 SARS-CoV-2 detection assay should not be used as the sole basis for patient management decisions.*
Date of Provisional Authorisation	7 July 2020