Provisional Authorisation for COVID-19 Tests

Applicant	Becton Dickinson Holding Ptd Ltd
Name of test	BD SARS-CoV-2 Reagents for BD MAX™ System
Intended purpose (As per manufacturer's information for use)	*The BD SARS-CoV-2 Reagents for BD MAX™ System is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasal, nasopharyngeal and oropharyngeal swab samples from individuals suspected of COVID-19 by their healthcare provider.* *Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory samples 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. 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.* *The BD SARS-CoV-2 Reagents for BD MAX System is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR, in vitro diagnostic procedures, and use of the BD MAX System.*
Date of Provisional Authorisation	6 May 2020