Provisional Authorisation for COVID-19 Tests

Applicant	Biomed Diagnostics Pte Ltd
Name of test	Luminex ARIES® SARS-CoV-2 Assay
Intended purpose (As per manufacturer's information for use)	*ARIES® SARS-CoV-2 Assay is a Real-Time reverse-transcriptase polymerase chain reaction (RT-PCR) based qualitative in vitro diagnostic test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal swab specimens collected 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 nasopharyngeal swab specimens 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 ARIES SARS-CoV-2 Assay is intended for use by trained clinical laboratory personnel specifically instructed and trained on Luminex® ARIES Systems and in vitro diagnostic procedures.* *The ARIES SARS-CoV-2 Assay is indicated for use with the ARIES Systems.*
Date of Provisional Authorisation	16 Jun 2020