Provisional Authorisation for COVID-19 Tests

Applicant	BGI Health (SG) Company Pte Ltd
Name of test	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV
Intended purpose (As per manufacturer's information for use)	*The Real-time fluorescent RT-PCR kit for detecting 2019-nCoV is a qualitative in vitro nucleic acid amplification assay to detect ORF1ab gene of 2019-nCoV using Reverse transcription in specimen of throat swab and Bronchoalveolar Lavage Fluid (BALF) for suspects, suspicious clustering cases and others for the purposes of diagnosis and differential diagnosis. Definition of suspects and suspicious clustering cases should be in line with relevant guidelines of COVID-19 diagnosis and treatment released by local authority.* *The kit was intended to use for assisting in COVID-19 diagnosis and epidemic control and the testing results should be used in practices in conjunction with epidemiology history, clinical manifestation, image examinations and other laboratory findings as well. It should be operated in line with relevant guidelines, such as diagnosis and treatment guideline of COVID-19 and guideline of COVID-19 prevention and control. Operations of detecting Nucleic Acid of 2019-nCoV should be manipulated in line with related laboratory guidelines for 2019-nCoV and biosafety.*
Date of Provisional Authorisation	24 April 2020