Provisional Authorisation for COVID-19 Tests

Applicant	Genomax Technologies Pte Ltd
Name of test	Allplex 2019-nCoV Assay
Intended purpose (As per manufacturer's information for use)	*The Allplex™ 2019-nCoV Assay is an in vitro diagnostic (IVD) real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens e.g. nasopharyngeal, oropharyngeal swab, and lower respiratory specimens, e.g. sputum, from individuals with signs and symptoms of COVID-19. For the swab specimen, eSWAB, eNAT and UTM are validated.*
Date of Provisional Authorisation	30 April 2020