Provisional Authorisation for COVID-19 Tests

Applicant	Genomax Technologies Pte Ltd
Name of test	Hangzhou Lysun 2019-nCoV IgG/IgM Rapid Test Device
Intended purpose (As per manufacturer's information for use)	*The 2019-nCoV IgG/IgM Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG anti–2019-nCoV virus and IgM anti-2019-nCoV virus in human whole blood, serum or plasma. It is intended to be used by the professionals as an aid in the diagnosis of infection with 2019-nCoV viruses. Any reactive specimen with the 2019-nCoV IgG/IgM Rapid Test must be confirmed with alternative testing method(s).*
Date of Provisional Authorisation	7 July 2020