Provisional Authorisation for COVID-19 Tests

Applicant	BioMedix Singapore Pte Ltd
Name of test	CerTest SARS-CoV-2
Intended purpose (As per manufacturer's information for use)	CerTest SARS-CoV-2 one step card test is a coloured chromatographic immunoassay for the qualitative detection of nucleoprotein antigen of SARS-CoV-2 from nasopharyngeal swab samples from patients suspected of COVID-19 infection. CerTest SARS-CoV-2 card test offers a simple and a highly sensitive screening assay as an aid in the diagnosis of SARS-CoV-2 infection. Please take note that a negative result cannot completely exclude an active COVID-19 infection, repeat testing or preferably confirmatory testing should be performed (NAAT) whenever possible, particularly in symptomatic patients.
Date of Provisional Authorisation	8 January 2021