Provisional Authorisation for COVID-19 Tests

Applicant	HealthGroup Medical Pte Ltd
Name of test	V-CODE ENCODE SARS-COV-2 Antigen Rapid Test Device
Intended purpose (As per manufacturer's information for use)	*The SARS-COV-2 Antigen Rapid Test Device is a rapid visual immunoassay for the qualitative, presumptive detection of COVID-19 antigens from throat swabs and nasal swab specimens. It is intended to be used by professionals as a test and provides a preliminary test result to aid in the diagnosis of infection with novel Coronavirus.* *Any interpretation or use of this preliminary test result must also rely on other clinical findings as well as on the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this test.* *If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of COVID-19 viral antigens in specimen, as they may be present below the minimum detection level of the test. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.*
Date of Provisional Authorisation	10 December 2020