Provisional Authorisation for COVID-19 Tests

Applicant	Siemens Healthcare Pte Ltd
Name of test	CLINITEST Rapid COVID-19 Antigen Test
Intended purpose (As per manufacturer's information for use)	*The CLINITEST® Rapid COVID-19 Antigen Test is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal (NP) swab or nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections and can be used by healthcare professionals up to ten days post symptom onset, or to screen asymptomatic individuals. Negative results from patients with symptom onset beyond ten days should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.* *The CLINITEST Rapid COVID-19 Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2. The test also provides individuals with the option to self-collect their nasal sample under the supervision of a healthcare professional.*
Date of Provisional Authorisation	20 May 2021