Provisional Authorisation for COVID-19 Tests

Applicant	Siemens Healthcare Pte Ltd
Name of test	Siemens Atellica® IM SARS-CoV-2 IgG (sCOVG)
Intended purpose (As per manufacturer's information for use)	*The Atellica® IM SARS-CoV-2 IgG (sCOVG) assay is for in vitro diagnostic use in the qualitative and quantitative detection of IgG antibodies, including neutralizing antibodies, to SARS-CoV-2 in human serum and plasma (lithium heparin) obtained by venipuncture or capillary puncture using the Atellica® IM Analyzer.* *This assay is intended as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection and as an aid in identifying patients with an adaptive immune response to SARS-CoV- 2, indicating recent or prior infection.*
Date of Provisional Authorisation	5 February 2021