
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Siemens Healthcare Pte Ltd
<i>Name of test</i>	Atellica® IM SARS-CoV-2 Antigen (CoV2Ag)
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The Atellica® IM SARS-CoV-2 Antigen (CoV2Ag) assay is for in vitro diagnostic use in the qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasopharyngeal (NP) swab and anterior nasal (AN) swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset, or from asymptomatic individuals, using an Atellica® immunoassay analyzer.</i></p> <p><i>This assay is intended as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection.</i></p>
<i>Date of Provisional Authorisation</i>	29 March 2021
