
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	INEX Innovate Pte Ltd
<i>Name of test</i>	GenoAmp Real-Time RT-PCR SARS-CoV-2
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>GenoAmp Real-Time RT-PCR SARS-CoV-2 kit is a real-time molecular test for the screening of SARS-CoV-2 extracted from nasopharyngeal swab. The kit is an in vitro diagnostic real-time reverse transcription-PCR assay for the qualitative detection of SARS-CoV-2 nucleic acids from individuals suspected of COVID-19.</i></p> <p><i>The RT-PCR Kit is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of RT-PCR and in vitro diagnostic procedures.</i></p>
<i>Date of Provisional Authorisation</i>	3 September 2020
