
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Everest Links Pte Ltd
<i>Name of test</i>	VivaDiag™ SARS-CoV-2 Ag Rapid Test
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>VivaDiag™ SARS-CoV-2 Ag Rapid Test is for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab, oropharyngeal swab or nasopharyngeal swab specimen. The test is for in vitro diagnostic use only. For professional use only.</i></p> <p><i>It is intended for clinical laboratories and healthcare professional use only for point-of-care testing. Not for at-home testing. Negative results do not rule out SARS-CoV-2 infection, particularly for those who have been in contact with the virus. Follow-up testing with a molecular diagnostic and/or CT should be considered to rule out infection in these individuals.</i></p>
<i>Date of Provisional Authorisation</i>	29 October 2020
