
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	SkyQuest Pte Ltd
<i>Name of test</i>	Wondfo 2019-nCoV Antibody Test (Lateral Flow Method)
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>Wondfo 2019-nCoV Antibody Test (Lateral Flow Method) is an immunochromatographic assay for rapid, qualitative detection of the novel coronaviruses (2019-nCoV) IgG/IgM antibodies in human whole blood, serum or plasma specimen. The test is only to be used in conjunction with nucleic acid method in the diagnosis of suspected cases.</i></p> <p><i>The test is not intended to be used for general population screening and only provides preliminary test results. Positive results need further confirmation and negative results cannot exclude the possibility of 2019-nCoV infection and they cannot be used as the sole basis for treatment or other management decision.</i></p>
<i>Date of Provisional Authorisation</i>	9 April 2020
