
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Jian Yuan Holdings Pte Ltd
<i>Name of test</i>	COVID-19 Antigen Rapid Test Kit
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>This kit enables screening for both symptomatic and asymptomatic carriers of the COVID-19 virus (named as SARS-CoV-2 or 2019-nCoV). It qualitatively tests the virus nucleocapsid antigen in human respiratory specimens during the acute phase of infection. The test needs no instrument, and results can be observed after 10 minutes with the naked eye. This test is for use at the Point of Care (POC).</i></p> <p><i>This kit is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures, and proper infection control procedures and individuals similarly trained in point of care settings.</i></p> <p><i>A negative result for an individual subject indicates absence of detectable antigen of the COVID-19 virus, but not preclude the possibility of exposure to or infection with this virus.</i></p>
<i>Date of Provisional Authorisation</i>	28 August 2020
