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## Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	MiRXES Pte. Ltd.
<i>Name of test</i>	MiRXES Fortitude Kit 2.1
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The MiRXES Fortitude Kit 2.1 contains the assays and controls, based on real-time Reverse Transcriptase-Polymerase Chain Reaction workflow, for the qualitative detection of SARS-CoV-2 specific RNA in nasopharyngeal swab samples. MiRXES Fortitude Kit 2.1 is intended for use by qualified clinical laboratory personnel trained in the techniques of molecular biology, real-time RT-PCR and in vitro diagnostic procedures.</i></p> <p><i>A positive result from the test indicates the presence of SARS-CoV-2 specific RNA in the test sample; correlation with patient history, clinical symptoms and other diagnostic or epidemiological information may be necessary to determine the infection status.</i></p> <p><i>A negative result does not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.</i></p>
<i>Date of Provisional Authorisation</i>	8 May 2020

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