
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	MP Biomedicals Asia Pacific Pte Ltd
<i>Name of test</i>	MP Diagnostics ASSURE® SARS-CoV-2 IgG/IgM Rapid Test
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The MP Diagnostics ASSURE® SARS-CoV-2 IgG/IgM Rapid Test is a qualitative in vitro immunochromatographic test to detect and differentiate IgG/IgM antibodies against SARS-CoV-2 in human plasma, serum, finger pricked whole blood or whole blood with anti-coagulants. It is intended for professional use.</i></p> <p><i>The results from this test is not to be used for confirmatory testing or as a sole basis for diagnosis. The results will have to be interpreted together with clinical presentation and are to be confirmed with supplemental testing (e.g. RT-PCR).</i></p>
<i>Date of Provisional Authorisation</i>	8 May 2020
