
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Alcotech Pte Ltd
<i>Name of test</i>	FaStep COVID-19 IgG/IgM Rapid Test Device
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The COVID-19 IgG/IgM Rapid Test Device is an in vitro immunoassay for the direct and qualitative detection of anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG in human whole blood, serum or plasma. The test is for professional use only.</i></p> <p><i>The results from this test is not to be used for confirmatory testing or as 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>	28 August 2020
