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## Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	All Eights (Singapore) Pte Ltd
<i>Name of test</i>	ESPLINE® SARS-CoV-2
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>ESPLINE SARS-CoV-2 is for the in vitro diagnostic use with immunochromatographic assay for the detection of SARS-CoV-2 antigen directly from nasopharyngeal swab fluid and is intended for use as an aid in the diagnosis of SARS-CoV-2 infection. This product is for professional use only.</i></p> <p><i>A negative result may occur if the level of antigen in a sample is below the detection limit of the test. Test results must be evaluated in conjunction with clinical symptoms and other test results to make an accurate diagnosis.</i></p> <p><i>Negative results do not preclude SARS-CoV-2 and other virus infection.</i></p>
<i>Date of Provisional Authorisation</i>	25 September 2020

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