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## Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Roche Diagnostics Asia Pacific Pte Ltd
<i>Name of test</i>	Roche Elecsys Anti-SARS-CoV-2 S
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>Immunoassay for the in vitro quantitative determination of antibodies (including IgG) to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) spike (S) protein receptor binding domain (RBD) in human serum and plasma. The test is intended as an aid to assess the adaptive humoral immune response to the SARS-CoV-2 S protein.</i></p> <p><i>The electrochemiluminescence Immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.</i></p>
<i>Date of Provisional Authorisation</i>	14 October 2020

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