
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
<i>Intended purpose (As per manufacturer's information for use)</i>	<i>Elecsys Anti-SARS-CoV-2 is an immunoassay for the in vitro qualitative detection of antibodies (including IgG) to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in human serum and plasma. The test is intended as an aid in the determination of the immune reaction to SARS-CoV-2. The electrochemiluminescence Immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.</i>
<i>Date of Provisional Authorisation</i>	5 May 2020
