
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Abbott Laboratories (S) Pte Ltd
<i>Name of test</i>	Abbott SARS-CoV-2 IgG – ARCHITECT assay
<i>Intended purpose (As per manufacturer's information for use)</i>	<i>The SARS-CoV-2 IgG assay is a chemiluminescent micro particle immunoassay (CMIA) used for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma on the ARCHITECT i System. The SARS-CoV-2 IgG assay is to be used as an aid in the diagnosis of SARS-CoV-2 infection in conjunction with clinical presentation and other laboratory tests. Results from the SARS-CoV-2 IgG assay should not be used as the sole basis for diagnosis.</i>
<i>Date of Provisional Authorisation</i>	30 April 2020
