
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Abbott Laboratories (S) Pte Ltd
<i>Name of test</i>	Abbott ARCHITECT SARS-CoV-2 IgG II Quant
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The SARS-CoV-2 IgG II Quant assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative and quantitative determination of IgG antibodies to SARS-CoV-2 in human serum and plasma on the ARCHITECT i System.</i></p> <p><i>The SARS-CoV-2 IgG II Quant 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. The assay is also to be used as an aid in evaluating immune status of infected individuals and to monitor antibody response in individuals that have received the COVID-19 vaccine, by quantitatively measuring IgG antibodies against the spike receptor-binding domain (RBD) of SARS-CoV-2. Results from the SARS-CoV-2 IgG II Quant assay should not be used as the sole basis for diagnosis of SARS-CoV-2 infection.</i></p>
<i>Date of Provisional Authorisation</i>	12 March 2021
