
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Abbott Laboratories (S) Pte Ltd
<i>Name of test</i>	Abbott ARCHITECT SARS-CoV-2 IgM
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The SARS-CoV-2 IgM assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of IgM antibodies to SARS-CoV-2 in human serum and plasma on the ARCHITECT i System.</i></p> <p><i>The SARS-CoV-2 IgM 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 IgM assay should not be used as the sole basis for diagnosis.</i></p>
<i>Date of Provisional Authorisation</i>	3 September 2020
