
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Beckman Coulter Singapore Pte Ltd
<i>Name of test</i>	ACCESS SARS-CoV-2 IgG
<i>Intended purpose (As per manufacturer's information for use)</i>	<i>The Access SARS-CoV-2 IgG assay is a paramagnetic particle, chemiluminescent immunoassay intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum, serum separator tubes and plasma (lithium heparin, dipotassium EDTA, tripotassium EDTA, and sodium citrate). The Access SARS-CoV-2 IgG assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.</i>
<i>Date of Provisional Authorisation</i>	22 Jun 2020
