
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Bio-Rad Laboratories (Singapore) Pte Ltd
<i>Name of test</i>	Biorad Platelia SARS-CoV-2 Total Ab
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The Platelia SARS-CoV-2 Total Ab assay is a semi-quantitative in vitro diagnostic test, in a one-step antigen capture format, for the detection of IgM/IgA/IgG antibodies to the SARS-CoV-2 in human serum and plasma (EDTA, heparin, ACD or citrate) specimens.</i></p> <p><i>This assay is an aid for the diagnosis of patients with symptoms suggestive of infection caused by SARS-CoV-2. In conjunction with clinical presentation and testing with other methods (RT-PCR, CT-Scan, specific detection for anti-SARS-CoV-2 IgM/IgA/IgG antibodies), Platelia SARS-CoV-2 Total Ab can be used to help diagnose COVID-19 disease.</i></p> <p><i>Platelia SARS-CoV-2 Total Ab can be used manually or on automated systems.</i></p>
<i>Date of Provisional Authorisation</i>	22 Jun 2020
