
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Healthgroup Medical Pte Ltd
<i>Name of test</i>	HealthGroup Medical V-CODE Sars-CoV-2 (COVID-19) IgG/IgM Rapid Test
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The SARS-CoV-2 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) is a lateral flow immunoassay for the qualitative detection and differentiation of IgG and IgM of Novel Coronavirus (SARS-CoV-2) in human whole blood, serum or plasma.</i></p> <p><i>This test detects the presence of COVID-19 antibodies (IgM/IgG) in blood samples. As there may be a few days' delay between the viral infection and development of antibodies in an individual, any negative result from this test should not be used as a sole basis to rule out COVID-19 infection. The negative results have to be carefully considered together with clinical presentations. Any positive result from this test should be confirmed with supplemental laboratory testing (e.g. RT-PCR).</i></p>
<i>Date of Provisional Authorisation</i>	18 May 2020
