
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Trans Sahara Corporation Pte Ltd
<i>Name of test</i>	Xiamen Boson Rapid 2019-nCoV IgG/IgM Combo Test Card
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>Rapid 2019-nCoV IgG/IgM Combo Test Card is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of IgG and IgM antibodies to 2019 novel coronavirus (2019- nCoV, SARS-CoV-2) in human serum, plasma, or whole blood. Rapid 2019-nCoV IgG/IgM Combo Test Card is a supplement detection for COVID-19 suspected infected patients besides nucleic acid test, which could greatly raise the accuracy of the detection for COVID-19. This test detects the presence of COVID-19 antibodies (IgG/IgM) 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 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>	14 May 2020
