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## Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	BioAcumen Global Pte Ltd
<i>Name of test</i>	BioA SARS-CoV-2 Real-Time RT-PCR Kit v1.0
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The BioA SARS-CoV-2 Real-Time RT-PCR Kit v1.0 is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider.</i></p> <p><i>Results are for the identification of SARS-CoV-2 viral RNA. SARS-CoV-2 viral RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 viral RNA. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.</i></p> <p><i>Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.</i></p> <p><i>Testing with BioA SARS-CoV-2 Real-Time RT-PCR Kit v1.0 is intended for use by qualified and trained laboratory personnel specifically instructed and trained in the techniques of real-time PCR assays.</i></p>
<i>Date of Provisional Authorisation</i>	14 September 2020