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## Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Hi-Beau Group
<i>Name of test</i>	SAVANT™ New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunochromatography)
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The kit is used for qualitative detection of new coronavirus nucleocapsid (N) antigen from the SARS-CoV-2 in oropharyngeal swab aspirate specimens collected from individuals suspected of COVID-19 by their healthcare providers.</i></p> <p><i>Results are for the detection of new coronavirus (SARS-CoV-2) N Protein, which is generally detectable in oropharyngeal swab specimens during the acute phase of infection. Positive results are indicative of active infection with SARS-CoV-2; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.</i></p> <p><i>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. All the agencies within Singapore and its territories are required to report all positive results to the appropriate public health authorities.</i></p> <p><i>Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.</i></p>
<i>Date of Provisional Authorisation</i>	13 July 2020

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