
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	SK BIOTECH PTE. LTD.
<i>Name of test</i>	Liming Bio StrongStep® System Device for SARS-CoV-2 Antigen Rapid Test
<i>Intended purpose (As per manufacturer's information for use)</i>	<i>The StrongStep@System Device for SARS-CoV-2 Antigen Rapid Test is a rapid immunochromatographic assay for the detection of SARS-CoV-2 virus Nucleocapsid Protein antigen in human Nasal/Oropharyngeal swab collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms. The assay is used as an aid in the diagnosis of COVID-19.</i>
<i>Date of Provisional Authorisation</i>	25 February 2021
