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## Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	bioMérieux Singapore Pte Ltd
<i>Name of test</i>	VIDAS® SARS-COV-2 IgM
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>VIDAS® SARS-COV-2 IgM (9COM) is an automated qualitative assay for use on the VIDAS® family of instruments, for the detection of immunoglobulin M (IgM) specific for SARS-CoV-2 in human serum or plasma (lithium heparin) using the ELFA (Enzyme Linked Fluorescent Assay) technique.</i></p> <p><i>This assay is intended for use as an aid to determine if individuals may have been exposed and infected by this virus and if they have mounted a specific anti-SARS-CoV-2 IgM immune response.</i></p>
<i>Date of Provisional Authorisation</i>	14 October 2020

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