
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Xentific Labs Pte Ltd
<i>Name of test</i>	Standard Q COVID-19 Ag Test
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>STANDARD Q COVID-19 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 present in human nasopharynx. This test is for administration by healthcare workers and labs only, as an aid to early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms with SARS-CoV-2 infection. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of SARS-CoV-2 infection.</i></p> <p><i>A negative result may occur if the concentration of antigen in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or molecular assay or ELISA.</i></p>
<i>Date of Provisional Authorisation</i>	3 June 2020
