
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	SPD Scientific 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. This product is strictly for medical professional use only and not intended for personal use. The administration of the test and the interpretation of the results should be done by a trained health professional. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required.</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>	24 July 2020
