

Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Quantum Technologies Global Pte Ltd
<i>Name of test</i>	Sofia SARS Antigen FIA
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The Sofia SARS Antigen FIA is a lateral flow immunofluorescent sandwich assay that is used with the Sofia and Sofia 2 instrument intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and nasal (NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.</i></p> <p><i>Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. 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. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.</i></p> <p><i>Negative results, from patients with symptom onset beyond five days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.</i></p> <p><i>The Sofia SARS Antigen FIA is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings, and</i></p>

proficient in performing tests using the Sofia and Sofia 2 instruments. The Sofia SARS Antigen FIA should be used with Sofia or Sofia 2. The Sofia SARS Antigen FIA does not differentiate between SARS-CoV and SARS-CoV-2.

Date of Provisional Authorisation

5 August 2020
