Provisional Authorisation for COVID-19 Tests

Applicant	Roche Diagnostics Asia Pacific Pte Ltd
Name of test	Roche Elecsys SARS-CoV-2 Antigen
Intended purpose (As per manufacturer's information for use)	*Elecsys SARS-CoV-2 Antigen is an immunoassay for the in vitro qualitative detection of the nucleocapsid antigen of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in nasopharyngeal and oropharyngeal swab samples from patients with signs and symptoms suggestive of COVID-19. The test is intended as an aid in the diagnosis of SARS-CoV-2 infection. The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.* *A negative test result does not rule out the possibility of an infection with SARS-CoV-2. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history or presence of clinical signs and symptoms suggestive for COVID-19.*
Date of Provisional Authorisation	30 March 2021