Provisional Authorisation for COVID-19 Tests

Applicant	Roche Diagnostics Asia Pacific Pte Ltd
Name of test	cobas® Liat SARS-CoV-2 & Influenza A/B
Intended purpose (As per manufacturer's information for use)	*The cobas® SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas® Liat® System (cobas® SARS-CoV-2 & Influenza A/B) is an automated multiplex real-time RT-PCR assay intended for the simultaneous rapid in vitro qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B virus RNA in healthcare provider-collected nasopharyngeal and nasal swabs and self-collected nasal swabs (collected in a healthcare setting with instruction by a healthcare provider) from individuals suspected of a viral respiratory infection.* *cobas® SARS-CoV-2 & Influenza A/B is intended for use in the simultaneous rapid in vitro detection and differentiation of SARS-CoV-2, influenza A virus, and influenza B virus nucleic acid in clinical specimens and is not intended to detect influenza C virus. SARS-CoV-2, influenza A and influenza B viral RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of active infection but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definite cause of disease.* *Negative results do not preclude infection from SARS-CoV-2, influenza A, and/or influenza B and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.*
Date of Provisional Authorisation	11 February 2021