Provisional Authorisation for COVID-19 Tests

Applicant	Restalyst Pte Ltd
Name of test	Restalyst COVID19N-REAAD™ Anti-SARS-CoV-2 Nucleocapsid Protein IgG ELISA
Intended purpose (As per manufacturer's information for use)	*COVID19N-REAAD™ Anti-SARS-CoV-2 Nucleocapsid Protein IgG ELISA (Coronavirus Disease 2019– REcombinant Antigen-Antibody Detection) is an enzyme–linked immunosorbent assay intended for qualitative detection of SARS-CoV-2 IgG antibodies in human serum and plasma (K2EDTA). COVID19N-REAAD™ is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. COVID19N-REAAD™ should not be used as the sole basis for diagnosis.* *COVID19N-REAAD™ is intended for professional use in detecting COVID-19 patients by detecting patient's anti-SARS-CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.* *The sensitivity of COVID19N-REAAD™ early after infection is unknown. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary. False positive results for IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.*
Date of Provisional Authorisation	7 August 2020