Provisional Authorisation for COVID-19 Tests

Applicant	All Eights (Singapore) Pte Ltd
Name of test	Hologic Aptima® SARS-CoV-2 assay
Intended purpose (As per manufacturer's information for use)	*The Aptima® SARS-CoV-2 assay is a nucleic acid amplification in vitro diagnostic test intended for the qualitative detection of RNA from SARS-CoV-2 isolated and purified from nasopharyngeal (NP), nasal, mid-turbinate and oropharyngeal (OP) swab specimens, nasopharyngeal wash/aspirate or nasal aspirates obtained from individuals meeting COVID-19 clinical and/or epidemiological criteria.* *Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA, clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.* *Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.*
Date of Provisional Authorisation	22 Jun 2020