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.* *This test is also for the qualitative detection of nucleic acid from the SARS-CoV-2 in pooled samples containing up to 5 individual upper respiratory swab specimens (i.e. nasopharyngeal, nasal, mid-turbinate, or oropharyngeal swabs), where each specimen is collected under observation or by a healthcare provider using individual vials containing transport media. Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result and if results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing. For specific patients, whose specimen(s) were the subject of pooling, a notice that pooling was used during testing must be included when reporting the result to the healthcare provider.* *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. The Aptima SARS-CoV-2 assay on the Panther® and Panther Fusion® system is intended for use by clinical laboratory personnel specifically instructed and trained in the operation of the Panther and Panther Fusion systems and in vitro diagnostic procedures.*
Date of Provisional Authorisation	22 June 2020