LICENCE CONDITIONS FOR

CLINICAL LABORATORY SERVICE LICENSEES PROVIDING OR INTENDING TO PROVIDE MALARIA PARASITE TESTING

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1 Application

1.1. These licence conditions ("**LCs**") apply to all persons which have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide a clinical laboratory service ("**CLS**") (such persons referred to as "**Licensee(s)**") and provide, or intend to provide, as part of the service, malaria parasite testing ("**MP testing**").

1.2. These LCs shall supersede and replace the LCs entitled 'Licence Conditions for Clinical Laboratory Service Licensees Providing or Intending to Provide Malaria Parasite Testing' issued on 10 August 2022.

1.3. For avoidance of doubt, the defined terms as used in these LCs shall have the meanings ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated.

1.4. A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:

(a) suspension or revocation of the Licensee's CLS licence;

(b) shortening the term of the Licensee's CLS licence;

(c) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or

(d) a direction requiring the Licensee to pay a financial penalty.

1.5 For avoidance of doubt, these LCs do not override a healthcare professional's duty to make clinical decisions that are in the best interests of each patient.

1.6 For avoidance of doubt, the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any

Regulations and other applicable licensing conditions, directions, and codes of practice made thereunder.

2 Practices

2.1. The Licensee shall ensure that its clinical laboratory service ("**Laboratory**") does not accept blood specimens of a patient directly from an employment agency or employer of that patient for MP testing.

2.2. The Licensee shall ensure that there are adequate measures in place in its Laboratory to prevent mix-up of blood specimens.

3 Quality Management System

3.1. The Licensee shall comply with the requirements in Section 3 (Quality Management System) of the Licensing Conditions for Clinical Laboratory Services, insofar as those requirements do not conflict with the requirements in paragraph 3.2 below.

3.2. Where the Licensee performs MP testing using the morphology-based method, the Licensee shall ensure that its Laboratory participates in the Malaria Parasite Proficiency Test conducted by the National Public Health Laboratory ("**NPHL**") at such frequency as may be determined by NPHL.

4 Records

4.1. The Licensee shall ensure that all records associated with MP testing conducted by its Laboratory are kept for a period of not less than three years.

5 Notification of Results for the Purposes of Compliance with the Infectious Diseases Act 1976 ("IDA")

5.1. Where the Licensee performs MP testing using the morphology-based method, the Licensee shall ensure that all positive blood films (thick and/or thin) from that MP testing are submitted to the National Malaria Reference Centre, National Public Health Laboratory of the National Centre for Infectious Diseases ("**NMRC**") at Block G, Level 13, 16 Jalan Tan Tock Seng, Singapore 308442 (or any other address that the NMRC may be located at in the future).

5.2 The Licensee shall ensure that its Laboratory notifies Director-General of Health in writing of any person who is diagnosed with malaria infection as a result of the MP testing conducted by its Laboratory, in accordance with the requirements set out under section 6 of the IDA and any other applicable laws, regulations or requirements.