Specimen Requirements for *Plasmodium spp.* Detection and Identification by Real-Time (RTi) Polymerase Chain Reaction (PCR) on clinical specimens.

Methodology:	*Plasmodium spp. (vivax, falciparum, malariae, and ovale)* RTi-PCR
Performed:	*Plasmodium spp.* RTi-PCR is performed only on specimens approved by the Disease Investigation Branch (DIB) of the Disease Outbreak and Control Division (DOCD), Department of Health (DOH).
Criteria for testing:	Clinical signs and symptoms compatible with *Plasmodium spp.* infection and/or specimens meeting the case definition set by the DIB of the DOCD of the DOH.
Turn-Around-Time:	Results are reported 2-3 business days from receipt of specimen(s).
Specimen type required:	Blood. A minimum of 200uL sample is required, 500uL is the ideal sample quantity. Formalin fixed specimens are not suitable for molecular studies.
Specimen storage/transport:	Collect a 1-5mL blood samples in Vacutainer® EDTA tubes prior to anti-parasitic therapy and ship at 4°C. Samples will be stored at temperature it was received.
Specimen submission:	Specimens are submitted from requesting laboratories with 81.3 submission form(s). Test is subject to CLIA regulation which require two patient identifiers on the specimen container and the test requisition(s). The Epidemiology Specialist of the DIB must notify Rebecca H. Sciulli of the Biological Response Section at 453-5993 or Precilia Calimlim at 453-5984 prior to the submission of specimens.
Criteria for rejection:	Rejection criteria are an accreditation requirement, and are intended to ensure specimen integrity prior to testing and minimize exposure hazards. Resubmit if possible. Testing requires Lab Director's approval. 1. Specimen leaked in transit. 2. Specimen is not collected in a proper container or special handling instructions are not followed.

3. Specimen not received on cold packs (i.e. 4°C)
4. Specimen quantity is insufficient to perform the tests.
5. Unlabeled specimens prior to testing-submitters must identify the specimen in person or submit a written documentation by fax or e-mail.
6. Incomplete requisition form (e.g., travel history, medical history, previous lab results, if appropriate, etc.). Submitter must complete requisition form.
7. Specimen label does not match the requisition. Submitters must correct the discrepancy.

Stability: If specimen cannot be transported to the State Laboratories Division within 24 hours after collection, keep refrigerated then ship at 4°C.

Requisition Form: Each specimen submitted must have a completed Form 81.3. Submitter is responsible for completing SLD Form 81.3 (including but not limited to the following information: two patient's unique identifier, submitter, specimen site/specimen type, date of onset, date of collection, date shipped/sent to the SLD, test(s) requested name and address of submitter and other pertinent information.

Requisition forms shall be placed in a separate bag and shall not be packed with the specimen(s).

Normal Value: No *Plasmodium spp. (vivax, falciparum ,malariae,* and/or *ovale)* nucleic acid detected.

Result Notification: Laboratory reports are reported to the submitters via fax. Laboratory reports to DIB will be posted to the DOCD Sharepoint and notified by email.

Test performed at: Biological Response Section (BRS)
Laboratory Preparedness and Response Program (LPRP)
State Laboratories Division
Department of Health
2725 Waimano Home Road
Pearl City, Hawaii 96782

Contact: Rebecca Sciulli M.Sc. MT at (808) 453-5993 or (808) 368-3373
Precilia Calimlim at (808) 453-5984

Approved By:

A.Christian Whelen, Ph.D.
Administrator, State Laboratories Division

9/22/2014
Date