Laboratory Preparedness and Response Branch
Biological Response Section

Specimen Requirements for Real-Time (rti) Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR) for Chikungunya Virus in Clinical Samples

Methodology:	CDC Chikungunya (CHIK) Virus Real-Time RT-PCR Assay
Performed:	The CDC CHIK real-time (rti) Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR) Assay is a **non-FDA** approved assay developed by the CDC which detects both Asian and East/Central/South African (ECSA) genotypes. The assay requires the use of at least one of the two (2) broadly reactive detection probes and an Asian-specific detection probe. Confirmatory testing of an equivocal result is performed at the CDC.
Criteria for testing:	Clinical signs and symptoms compatible with chikungunya virus infection and/or specimens meeting the case definition set by the Disease Investigation Branch (DIB) of the Disease Outbreak Control Division (DOCD) of the Department of Health (DOH).
Turn-Around-Time:	Results are reported 2-3 business days after approval and receipt of specimen(s).
Specimen type required:	Venous blood sample: Follow device manufacturer's instructions for proper serum or plasma collection and separation. Serum is the preferred specimen. The best type of tube is serum separator (tiger/speckled-top). Red-top (no additives) is also acceptable. For plasma specimens, use sodium citrate collection tube. Do not use heparin (green top) or EDTA (purple top). A minimum of 0.5 ml serum or plasma is required. CHIK specimens must be collected within the first five (5) days from onset of signs and symptoms.
Specimen storage / transport:	Refrigerate serum or plasma at 4°C or maintain on ice for no longer than 24 hours. If storage/transport will exceed 24 hours, freeze serum or plasma at -20°C or lower.

	Ship separated serum or plasma on cold packs (i.e. 4°C) within 24 hours. Ship on dry ice if the specimens have been frozen at -20°C or lower. Follow packing and shipping instructions of the U.S. Department of Transportation (U.S. DOT), and the International Air Transport Association (IATA) for Biological Substance, Category B.
Specimen submission:	Submitters: Clinical laboratories and the DIB. Please notify DIB and the State Laboratory Division (SLD) Biological Response Section (BRS) prior to the submission of specimens.
Criteria for rejection:	• Specimen is received in a container that is leaking. Specimen **will not be processed** if the safety of the laboratory worker is compromised. • Specimen is not collected in a proper container or special handling instruction is not followed, which compromise test quality. • Blood collected with heparin or EDTA tubes. • Specimen quantity is not sufficient (QNS) to perform the tests. • Specimen is not received at 4°C or packed in blue ice; • Frozen specimens not shipped in dry ice. • Unlabeled or incomplete specimen labeling and documentation. • Specimen label does not match the requisition.
Stability:	Separated serum or plasma must be refrigerated at 2-8°C for no longer than 24 hours. If the specimen cannot be transported to the SLD within 24 hours after collection and separation, it should be frozen at -20°C or lower. Frozen samples should be shipped in dry ice.
Requisition Form:	Each specimen submitted must have a completed SLD Form 81.3. Submitter is responsible for completing SLD Form 81.3 including but not limited to the following information: at least two patient unique identifiers, date of onset of illness, signs and symptoms, travel history, immunization history, test(s) requested, name and address of submitter. Requisition forms shall be placed in a separate bag and shall not be packed with the specimen(s).

Normal Value:	No Chikungunya Virus Nucleic Acid Detected.
Result Notification:	Laboratory reports are electronically relayed to the submitters via the SLD dashboard. An automatic notification will be relayed when a report is available on the SLD dashboard. Laboratories who do not receive automatic notification will be notified by e-mail on the availability of results on the SLD Dashboard. Submitters who do not have access to electronic reports will be notified via fax or by encrypted e-mail.
Test performed at:	Biological Response Section (BRS) Laboratory Preparedness and Response Branch (LPRB) State Laboratories Division Department of Health 2725 Waimano Home Road Pearl City, Hawaii 96782
Contact:	Remedios Gose at (808) 453-5993 or (808) 554-9992 or Cheryl Daquip at (808) 453-5984 or (808) 453-6641

Reviewed By:

Remedios B. Gose — 12/4/19

Remedios B. Gose, MSPH, RM (NRCM) — Date
Laboratory Preparedness and Response Branch Chief

Approved By:

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