Specimen Requirements for Chikungunya Virus IgM Capture ELISA

Methodology:	IgM Antibody Capture (MAC) Enzyme-Linked Immunosorbent Assay (ELISA)
Performed:	IgM antibody Capture ELISA (MAC-ELISA) is used to detect viral specific IgM antibodies to Chikungunya virus produced toward the end of the first week of illness. **Only specimens meeting the case definition established by the Centers for Disease Control & Prevention (CDC) and the Disease Investigation Branch (DIB) of the Disease Outbreak and Control Division (DOCD) of the Department of Health (DOH) will be tested.**
Turn-Around-Time:	Results are reported 3-7 business days after approval and receipt of specimen.
Specimen type required:	Generally, the test of choice >5 days after onset of symptoms is IgM antibody. PCR is the test of choice ≤ 5 days. Convalescent serum specimens may be of value, especially if acute serum is negative and there is high clinical suspicion. Serum specimens with Equivocal Chikungunya PCR results may reflex to IgM antibody testing. On a case by case basis, specimens submitted for Chikungunya PCR testing may also be tested for IgM antibody. Prior approval by the Epidemiologist investigator(s) or the SLD Laboratory Director is required.
Specimen Collection:	A minimum of one (1) ml of serum is required for the ELISA test. Whole blood will **not be accepted**. Heparin (green top) and EDTA (purple top) **<u>are unsuitable</u>** for testing. Chikungunya virus antibodies normally develop toward the end of the first week of illness. Acute serum should be taken 3-7 days after onset of symptoms. Convalescent serum should be taken 2-3 weeks after the acute sample, and can be helpful in patients whose acute phase samples test negative. Follow device manufacturer's instructions for proper serum collection and separation.

Specimen storage and transport:	Ship specimens with cold packs to keep the specimens at 4°C. 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, Epidemiology Specialists of the Disease Outbreak Control Division) must notify Rebecca H. Sciulli of the Laboratory Response and Preparedness Program (LPRP) at 368-3373 or 554-9992 or the BRS Laboratory at 453-5984 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 handling instructions are not followed, which compromise test quality. Submitter will be asked to submit another specimen. • Specimen is received at 4°C or packed in blue ice; • Specimen quantity is not sufficient (QNS) to perform the tests. Submitters will be notified to submit another specimen. • If a specimen is irretrievable, the specimen will be processed but the problem will be documented in the laboratory report. • Unlabeled specimens; • Incomplete specimen labeling and documentation; • Specimen label does not match the requisition.
Stability:	All serum specimens must be refrigerated at 2-8°C immediately after collection.
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: patient identifier, date of onset of illness, signs and symptoms, travel history, immunization history, 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 IgM antibodies to Chikungunya virus detected.
Result Notification:	Laboratory results are reported to the submitters by electronic reporting system or via FAX. Laboratory reports for the Disease Investigation Branch (DIB) of the DOH Disease Outbreak Control Division (DOCD) will be posted to the DOCD SharePoint.
Test performed at:	Biological Response Section Laboratory Preparedness and Response Program State Laboratories Division Department of Health 2725 Waimano Home Road Pearl City, Hawaii 96782
Contact:	Rebecca H. Sciulli, M.Sc., M.T. (AMT) 808-368-3373; 554-9992 Remedios Gose at 808-453-5984

Approved by:

A. Christian Whelen

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

8/28/2015
Date