Laboratory Preparedness and Response Branch
Biological Response Section

Specimen Requirements for Zika Virus IgM Capture ELISA (MAC-ELISA)

Methodology:	IgM Antibody Capture (MAC) Enzyme-Linked Immunosorbent Assay (ELISA) - *InBios*
Performed:	The Zika MAC ELISA is intended for the qualitative detection of Zika virus IgM antibodies in human sera. Individuals must meet CDC Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (history of residence in or travel to geographic regions during a period of active Zika virus transmissions, or other epidemiologic criteria for which Zika virus testing may be indicated as part of a public health response). Test results are for the presumptive detection of IgM antibodies to Zika virus.
Criteria for Testing:	Department of Health (DOH) approval by the Disease Investigation Branch (DIB), Disease Outbreak and Control Division (DOCD), is **required** before specimens will be tested. **See DOH Medical Advisory of 8/2/2016** Pregnant women with possible Zika exposure: - Symptomatic <2 weeks: urine & serum (negative PCR reflex to serum IgM for Zika & dengue) - Symptomatic 2-12 weeks: urine & serum (positive /equivocal serum IgM; reflex to urine & serum PCR) - Asymptomatic 2-12 weeks with previous (<2 weeks) negative PCR: urine & serum (positive /equivocal serum IgM; reflex to urine & serum PCR) - Any >12 weeks: urine & serum; test based on condition (see Medical Advisory) - Any amniotic fluid with urine & serum (performed at CDC) - Tissue specimens (see submission procedures on CDC website). Non-pregnant patients with possible Zika exposure:

- Symptomatic <2 weeks: urine & serum PCR (negative reflex to serum IgM)
- Symptomatic 2-12 weeks: serum IgM for Zika & dengue (positive /equivocal **may** reflex to serum PRNT; see MMWR of 7/26/2016)

Patients with neurological symptoms & possible Zika exposure:

- Neurological symptoms <7 days: CSF, urine, & serum PCR
- Neurological symptoms >7 days: CSF, urine, & serum; CSF or serum IgM **may** reflex to PCR

Turn-Around-Time: Results are reported 3-7 business days from receipt of specimen approved by the State Epidemiologist or DIB designee.

Specimen type required: **Do not send specimens without prior consultation with DIB. Any requests for testing will be referred to DIB for review.**

Venous blood sample: Follow device manufacturer's instructions for proper serum collection and separation. 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) **are unsuitable** for testing. A minimum of 1.5 ml serum is required.

Specimen Handling/storage: Separated serum should not remain at 20-25°C for more than 8 hours. Refrigerate specimens at 4°C for no longer than 48 hours. If storage/transport will exceed 48 hours, freeze at -20°C or lower.

Ship separated specimens on cold packs (i.e. 4°C) within 48 hours. Ship on dry ice if the specimens have been frozen at -20° C or lower.

Follow instructions for Class B - Biological Substance of the U.S. Department of Transportation (U.S. DOT) and International Air Transport Association (IATA) for packing and shipping.

Specimen submission: Submitters: Clinical laboratories and DIB.
Please notify DIB and the State Laboratory Division (SLD) Biological Response Section prior to the submission of specimens.

Criteria for Rejection:	**Specimen without prior approval from the State Epidemiologist or DIB Epidemiologist Investigator.** • 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 instructions are not followed, which compromise test quality. Submitter will be asked to submit another specimen. • Specimen quantity is not sufficient (QNS) to perform the test. Submitters will be notified to submit another specimen. • Specimen is not received at 4°C or packed in blue ice. • Frozen specimens not shipped in dry ice. • Hemolyzed serum. • Unlabeled or incomplete specimen labeling and documentation; Submitter will be notified to provide correct information and corrected SLD Form 81.3 • Specimen label does not match the requisition.
Requisition Form:	Each specimen submitted must have a completed SLD Form 81.3. Submitter is responsible for completing the SLD Form 81.3 (including but not limited to the following information: at least 2 patient unique identifiers, date of onset of illness, signs and symptoms, travel history – 3 months prior, 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:	Negative: No IgM antibodies to Zika virus 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:

Edward P. Desmond — 12/4/2019

Edward Desmond, Ph.D. — Date
Administrator, State Laboratories Division