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:

[Signature]
Remedios B. Gose, MSPH, RM (NRCM)
Laboratory Preparedness and Response Branch Chief

[Signature]
Edouard P. Desmond
Edward Desmond, Ph.D.
Administrator, State Laboratories Division

12/4/19
Date

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