

Specimen Requirements for Zika Virus IgM Capture ELISA (MAC-ELISA) (FDA Emergency Use Authorization)

Methodology:	IgM Antibody Capture (MAC) Enzyme-Linked Immunosorbent Assay (ELISA)
Performed:	The Zika MAC ELISA is intended for the qualitative detection of Zika virus IgM antibodies in human sera or cerebrospinal fluid (CSF) submitted with a patient-matched serum specimen. 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 (recent history of travel to geographic regions during a period of active Zika virus transmissions at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated as part of a public health response).
Criteria for Testing:	Department of Health 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 before consulting 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.

Cerebrospinal fluid (CSF): A minimum of 1.5 ml WITH serum. **CSF can only be tested when submitted with patient-matched serum.**

Required information:

1. Date of onset of symptoms
2. Date of specimen collection
3. Any **pertinent travel history** (3 months prior)

Specimen Handling/storage: Refrigerate specimens at 4°C or maintain on ice for no longer than 24 hours. If storage / transport will exceed 24 hours, freeze at -20°C or lower.

Ship separated specimens on cold packs (i.e. 4°C) within 24 hours. Ship on dry ice if the specimens have been frozen at -70° 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 the Disease Investigation Branch (DIB).
Please notify DIB and the SLD Biological Response Section (BRS) 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 (e.g., heparin or EDTA tube) or 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 tests. 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;
- Specimen quantity is insufficient to perform the tests;
- Incomplete submission;
- Unlabeled or incomplete specimen labeling and documentation; Submitter will be notified to provide correct information and corrected Form 81.3;
- Specimen label does not match the requisition.

Stability: Refrigerate at 2-8°C for no longer than 24 hours. If the specimen cannot be transported to the State Laboratories Division within 24 hours after collection and separation, it should be frozen at -20°C or lower. Frozen samples must be shipped in dry ice if possible.

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: Negative: No evidence of recent Zika virus infection detected.

Reporting of results: Laboratory results are reported to the Client Services or the designated clinical laboratory contacts by FAX. Copies of laboratory reports are also sent to the Disease Investigation Branch (DIB) of the DOH Disease Outbreak Control Division (DOCD) and are 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), R.B.P.
Wk: 808-453-5993, Cell: 808-368-3373 or
Remedios Gose at 808-453-5984 or 808-554-9992

Approved by:



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

11-16-16

Date