

Specimen Requirements for West Nile Virus (WNV) IgM and IgG Serology

- Methodology:** IgM Antibody Capture (MAC) Enzyme-Linked Immunosorbent Assay (ELISA) and IgG ELISA
- Performed:** IgM antibody Capture ELISA (MAC-ELISA) is used to detect viral specific IgM antibodies to WNV infection produced during the first few days after onset of clinical symptoms. IgG antibodies on the other hand is less virus-specific than IgM and appears slightly later than IgM antibodies in the course of an infection. Both IgM and IgG ELISA tests are done to compare the relative rise and fall in antibody levels in paired serum samples from a patient.
- 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 will be tested.**
- Turn-Around-Time:** Results are reported 2-3 business days after approval and receipt of specimen. If the initial results are positive, confirmatory testing may delay the reporting of final results. All positive results obtained by ELISA are confirmed by neutralizing antibody testing of acute and convalescent phase serum specimens. Positive specimens will be sent to the CDC, Division of Vector-Borne Infectious Diseases for confirmatory testing.
- Specimen required:** Serum, cerebro-spinal fluid (CSF). Acute and convalescent specimens, if available, should be sent together for a more accurate interpretation of results.
- Specimen Collection:** A minimum of one (1) ml of CSF obtained during the acute phase of illness is required for serology.
- A minimum of one (1) ml of serum is required for the ELISA test. Whole blood or heparinized blood will **not be accepted**. Acute serum should be taken 3-10 days after onset of symptoms. Convalescent serum should be taken 2-3 weeks after the acute serum was obtained.
- Follow device manufacturer's instructions for proper serum collection and separation.

Specimen storage, packing 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 Specialist of the Disease Outbreak Control Division) must notify Rebecca H. Sciulli of the Laboratory Response and Preparedness Program (LPRP) at 368-3373 or 453-5993 prior to the submission of specimens.

Note: It is the responsibility of the submitter to track the arrival of the specimens along with Form 81.3 at the State Laboratories Division to ensure that these specimens are received by the Biological Response Laboratory staff.

Unacceptable conditions:

- 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. Submitter will be asked to submit a repeat specimen. The quality of the test will be compromised if the specimen is not rejected;
- Specimen is not stored properly (should be at 4°C or packed in blue ice) in transit to the lab. Submitter will be asked to re-submit a repeat specimen;
- Specimen quantity is insufficient to perform the tests. Submitters will be notified to re-submit another specimen. If this is not possible, the specimen will be processed but the problem will be stated in the laboratory report.
- Unlabeled specimens;
- Incomplete specimen labeling and documentation;
- Specimen label does not match the requisition.

Stability:

All specimens must be refrigerated at 2-8°C immediately after collection.

Requisition Form:

Each specimen submitted must have a completed Form 81.3. (<http://health.hawaii.gov/statelab/files/2013/05/sld-sld81-3.pdf>) and the West Nile Virus Initial Case & Lab

Submission Form

(<http://health.hawaii.gov/statelab/files/2013/05/sld-wnv-ics.pdf>)

Submitter is responsible for completing both forms (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/IgG antibodies to WNV 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; 453-5993
or
Remedios Gose
808-453-5984

Approved by:



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



Date