Laboratory Preparedness and Response Branch
Biological Response Section

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 (DOH) will be tested.**
Turn-Around-Time:	Results are reported 4-7 business days after approval and receipt of specimen(s). 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. 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 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.

Specimen storage, packing and transport:	Ship separated serum or plasma on cold packs (i.e. 4°C). Ship on dry ice if the specimens have been frozen at -20°C or lower. 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 and the DIB. Please notify DIB and the State Laboratory Division (SLD) Biological Response Section (BRS) prior to the submission of specimens. **Note:** It is the responsibility of the submitter to track the arrival of the specimens along with SLD Form 81.3 at the SLD to ensure that these specimens are received by the BRS staff.
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 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. • Hemolyzed serum or plasma. • Unlabeled specimens or 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 SLD Form 81.3 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 SLD Form 81.3 including but not limited to the following information: at least two patient unique identifiers, date of onset of illness, signs and symptoms, travel history, 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:	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 DIB of the DOH DOCD will be posted to the DOCD SharePoint.
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