SPECIMEN REQUIREMENTS FOR SERUM SPECIMENS SUBMITTED FOR DENGUE IGM CAPTURE ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA)

Revised on June 12, 2007

Methodology: IGM Capture Enzyme Linked Immunosorbent Assay (ELISA)

Performed: The ELISA for IgM antibodies is the most useful serologic procedure available for determining recent infections by dengue virus.

Serological results must always be interpreted in the context of compatible signs and epidemiologic data.

Criteria for testing: Specimens meeting the case definition set by the Disease Investigation Branch (DIB) of the Disease Outbreak Control Division of the Department of Health.

Clinical signs and symptoms compatible with Dengue fever.

Turn-Around-Time:
- Specimens are routinely tested monthly in batches [depending on the frequency of submissions].
- Results are reported out 48 -72 hours after testing.
- Priority testing
  1) May be requested by the Disease Investigation Branch on a case by case basis.
  2) Prior notification of the laboratory is required before submission of the specimens.
  3) Reports are reported 5 days after receipt of the specimen.

Specimen (type) required: A minimum of one (1) mL of serum.

Specimen Collection: Serum collected as early as possible after onset of illness and placed in a sterile container. Most patients become positive by the sixth day after onset of illness. Multiple specimens may need to be collected in case the specimen is collected too early. Detectable IgM antibody usually persists for a maximum of 60 to 90 days.
Specimen storage, packing and transport: Ship specimens in sterile, screw-capped tubes. 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 Epidemiology Specialists of the Disease Outbreak Control Division) should notify DIB and the laboratory prior to the submission of specimens.

Requisition Form: Submitter is responsible for completing MMB Form 81.3 (including but not limited to the following information: patient identifier, date of onset of illness, clinical signs and symptoms, travel history, immunization history, name and address of submitter).

Unacceptable conditions:
- Specimen that is leaking;
- Improper container or handling;
- Obvious microbial contamination;
- Specimen quantity is insufficient to perform the test;
- Unlabeled specimens;
- Improper or incomplete requisition form (MMB Form 81.3);
- No requisition form;
- Specimen label does not match the requisition.

Stability: Serum or plasma specimens may be stored at 2°C to 8°C for a maximum of 14 days. For longer storage, freeze at < -20°C.

Normal Value: No IgM antibody detected to Dengue Virus.

Limitations: Most serologic tests cross react to a variable extent with other members of the flavivirus family. This is a particular problem in areas where dengue and Japanese encephalitis or yellow fever occurs together.

Dengue virus reaches peak titers in the blood before acute illness. Most patients become positive by the sixth day after onset of illness. Detectable IgM
antibody usually persists for a maximum of 60 to 90 days, and is a good measure of recent infection.

Result Notification: Laboratory results are reported to the submitters and Disease Investigation Branch of the DOH Disease Outbreak Control Division.

Test performed at: Virology Section, Medical Microbiology Branch
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Approved by:

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State Laboratories Division Administrator June 15, 2007