

Specimen Requirements for Real-Time (rti) Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR) for Zika Virus in Clinical Samples

Methodology:	CDC Zika Virus Real-Time RT-PCR Assay
Performed:	The CDC Zika virus real-time (rti) Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR) Assay is a non-FDA approved assay developed by the CDC which detects the precursor membrane proteins/membrane proteins (prM/M) and the envelope proteins during maturation of the Zika virus. Confirmatory testing of an equivocal result is performed at the CDC.
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 PCR (negative reflex to serum IgM for Zika & dengue)
- Symptomatic 2-12 weeks: urine & serum (positive /equivocal serum IgM; reflex to urine & serum PCR)
- Asymptomatic <2 weeks after exposure: urine & serum PCR (if negative, return 2-12 weeks for serum IgM)
- Asymptomatic 2-12 weeks 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 2-3 business days after approval and receipt of specimen(s).

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.

Urine: Submit an aliquot in a small, sterile, screw cap micro tube. Do not submit in urine collection cups.

A minimum of 1.5 ml serum AND urine is required.

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

Amniotic fluid: A minimum of 0.5 ml WITH serum AND urine. Test performed at CDC.

Tissue: Test performed at CDC; see submission instructions on CDC website.

Required information:

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

Specimen storage / transport: 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 tube) or special handling instruction is not followed;
- 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 (e.g., serum without urine);
- 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: Separated serum or plasma must be refrigerated 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 should be shipped in dry ice.

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).

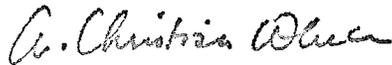
Normal Value: No Zika Virus Nucleic Acid Detected.

Result Notification: 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 (BRS)
State Laboratories Division
Department of Health
2725 Waimano Home Road
Pearl City, Hawaii 96782

Contact: Rebecca Sciulli M.Sc., MT at 808-453-5993 or
808-368-3373
Remedios Gose at 808-453-5984

Approved By:



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

AUG 29 2016

Date