

**Laboratory Preparedness and Response Branch  
Biological Response Section**

**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 <b>non-FDA</b> 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 <b>required</b> before specimens will be tested.
Turn-Around-Time:	Results are reported 2-3 business days after approval and receipt of specimen(s).
Specimen type required:	<p><b>Do not send specimens before consulting with DIB. Any requests for testing will be referred to DIB for review.</b></p> <p>Venous blood sample: Follow device manufacturer's instructions for proper serum or plasma collection and separation. Serum is the preferred specimen. The best type of tube is serum separator (tiger/speckled-top). Red-top (no additives) is also acceptable. For plasma specimens, use sodium citrate collection tube. Do not use heparin (green top) or EDTA (purple top).</p> <p>A minimum of 0.5 ml serum or plasma is required.</p>
Specimen storage/transport:	<p>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.</p> <p>Ship separated specimens on cold packs (i.e. 4°C) within 24 hours. Ship on dry ice if the specimens have been frozen at -20° C or lower.</p>

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 prior to the submission of specimens.

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, which compromise test quality.
- Blood collected with heparin or EDTA tubes;
- Specimen quantity is not sufficient (QNS) to perform the tests.
- Specimen is not received at 4°C or packed in blue ice;
- Frozen specimens not shipped in dry ice.
- Unlabeled or incomplete specimen labeling and documentation.
- 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 SLD Form 81.3. 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 Zika Virus Nucleic Acid Detected

Result Notification: Laboratory reports are electronically relayed to the submitters via the SLD dashboard. An automatic notification will be relayed when a report is available on the SLD dashboard. Laboratories who do not receive automatic notification will be notified by e-mail on the availability of results on the SLD Dashboard. Submitters who do not have access to electronic reports will be notified via fax or by encrypted e-mail.

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  
Remedios B. Gose, MSPH, RM (NRCM)  
Laboratory Preparedness and Response Branch Chief

12/4/19  
Date

Approved By:

Edward P. Desmond  
Edward Desmond, Ph.D.  
Administrator, State Laboratories Division

12/4/2019  
Date