



EDDIE BAZA CALVO
GOVERNOR

RAY TENORIO
LIEUTENANT GOVERNOR

GOVERNMENT OF GUAM

DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
DIPATTAMENTON SALUT PUPBLEKO YAN SETBISION SUSIAT



JAMES W. GILLAN
DIRECTOR

LEO G. CASIL
DEPUTY DIRECTOR

GUAM PUBLIC HEALTH LABORATORY GUIDELINES
SPECIMEN REQUIREMENTS FOR ZIKA VIRUS
IN CLINICAL SAMPLES

Methodology:	CDC Zika Virus Real-Time (rti) Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR) Assay
<p>Performed at Hawaii State Lab:</p> <p>Criteria for testing:</p>	<p>CDC Zika Virus Real-Time RT-PCR Assay is a non-FDA approved assay developed by the CDC</p> <ul style="list-style-type: none"> • For the detection of the precursor membrane proteins/membrane proteins (prM/M) and the envelope proteins during maturation of the Zika virus. • In which a Confirmatory testing of an equivocal result is performed at the CDC. <p>Testing of clinical blood specimens (serum) with the CDC Zika Virus Real-Time RT-PCR Assay should not be performed unless the patient meets clinical signs and/or symptoms compatible with Zika virus infection and/or specimens meeting the case definition set and/or updated by the CDC and/or the Bureau of Communicable Disease Control (BCDC) under the Division of Public Health of the Department of Public Health and Social Services (DPHSS).</p> <p>Clinical Findings are characteristically acute onset of fever with maculopapular rash, arthralgia, or conjunctivitis. Other commonly reported symptoms include myalgia and headache. Clinical illness is usually mild with symptoms lasting for several days to a week.</p> <p>Note: Negative results obtained with this test do not preclude the diagnosis of Zika virus and should not be used as the sole basis for treatment or other patient management decisions.</p>
For private clinics and providers:	<p>Specimen Submission Guidelines</p> <ol style="list-style-type: none"> 1. Submit minimum of 1ml serum collected in red top or in separator tube (marble or tiger-top). 2. Fill out required form(s) completely. Include the following information date of onset of illness, signs and symptoms and travel history. Zika specimens must be collected within the first seven (7) days from onset of signs and symptoms. Send forms with the specimen. 3. Refrigerate serum at 4°C or maintain on ice for no longer than 24 hours. If

GOVERNMENT OF GUAM
DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
DIPATTAMENTON SALUT PUPBLEKO YAN SETBISION SUSIAT

	<p>storage/transport will exceed 24 hours, freeze serum at -20°C or lower.</p> <p>4. Send frozen specimens to GPHL Mondays-Fridays 8AM-430PM.</p>
Specimen Required:	The laboratory requires a blood sample taken during the acute period of the disease (first 7 days of symptoms). Note: If the patient makes the first visit to the physician on or after day 7 of onset of the symptoms, that sample is likely not to render a positive RT-PCR result.
Specimen Collection:	<ul style="list-style-type: none"> • Once there is a clinical diagnosis of suspected Zika virus, take a venous, whole blood sample. • Follow serum specimen collection devices manufacturer instructions for proper collection, separation and storage methods. Separated serum samples should be frozen at -20 °C and sent or shipped in dry ice to GPHL. If dry ice is not available, separated serum should be maintained on ice or in a refrigerator for no longer than 2 hours before it is either frozen at -20 °C or sent to GPHL.
Specimen Transport, Storage and Stability	<p>Store and transport specimens in frozen state.</p> <p>For USAPI Laboratories, follow the PIHOA Shipping Mechanism Guidelines.</p>
Specimen Submission	<ul style="list-style-type: none"> • Ensure that when transporting human blood, plasma or serum specimens, all applicable regulations for transport of potentially infectious biological specimens are met. • Transport/ship human serum or plasma samples in dry ice. <p>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.</p> <p>The submitting facility must notify BT Microbiologist or alternate of GPHL at (671) 735-7153/158/355 prior to submitting/ shipping specimens.</p> <p>NOTE: It is the responsibility of the submitter to track the arrival of the specimens along with the Zika Specimen form at GPHL to ensure that these specimens are received by the Laboratory staff.</p>
Rejection Criteria	<ul style="list-style-type: none"> • Specimen is not collected in a proper container or special handling instruction is not followed; • Specimen quantity is insufficient to perform the test; • Specimen received in a container that is leaking; • Specimen is not received at 4°C or packed in ice pack; • Frozen specimen not shipped in dry ice; • Blood collected with heparin or EDTA tube; • Unlabelled specimens;

GOVERNMENT OF GUAM
DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
DIPATTAMENTON SALUT PUPBLEKO YAN SETBISION SUSIAT

	<ul style="list-style-type: none"> • Illegible/ incomplete labeling/documentation.
Submission Form	<p>Specimen Laboratory Submission Form</p> <ul style="list-style-type: none"> • Each specimen submitted must have a completed Hawaii State Laboratory Submission HSLD Form 81.3, with the patient name, patient identification number, type of specimen, date/time of collection, submitter, date of onset, travel history, date shipped/sent to GPLH, test(s) requested and other pertinent information • Submission forms that are not consistent with the specimen submitted will be rejected and requesting facility will be asked to re-submit. • Submission forms must not be in direct contact with the specimen(s). • Fill out required form(s) COMPLETELY. >Incomplete forms will be rejected.
Result Notification:	<p>Laboratory reports will be forwarded by GPLH, to the submitting facility, territory epidemiologist, and the BCDC Administrator via Facsimile.</p> <p>Any other request for copies of laboratory reports, apart from that stipulated above will not be accepted.</p>
Contact:	<p>Alan Mallari, Microbiologist II, GPLH (671) 735-7158/355 alanjohn.mallari@dphss.guam.gov</p> <p>Joy S. Villanueva, Medical Technologist II, GPLH(Alternate) (671) 735-7153 (671) 735-7158 FAX joy.villanueva@dphss.guam.gov</p> <p>Anne Marie Santos, GPLH Administrator (671) 735-7153/7158 Annemarie.santos@dphss.guam.gov</p> <p>Josephine T. O'Mallan, BCDC Administrator, Guam Department of Public Health & Social Services (671) 735-7142; (671) 888-9276 (emergency) Josephine.omallan@dphss.guam.gov</p>

Reference:

1. CDC Zika Virus Real Time RT-PCR Assay LPRP, BRS SOP
2. CDC Zika Clinical Evaluation and Disease; January 24, 2016.