GUAM PUBLIC HEALTH LABORATORY GUIDELINES

SPECIMEN REQUIREMENTS FOR DETECTION AND SERO-TYPING OF DENGUE-1-4

Methodology:	**CDC DENV-1-4 Real-Time Diagnostic Assay through Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR**
Performed at GPHL Lab:	CDC DENV-1-4 Real-Time RT-PCR Assay is an FDA approved assay intended for use on an Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument: • For the diagnosis of dengue in serum collected from patients with signs and symptoms consistent with dengue (mild or severe) during the acute phase; • For the identification of dengue virus serotypes 1, 2, 3 or 4 from viral RNA in serum or plasma (sodium citrate) collected from human patients with dengue during the acute phase; • To provide epidemiologic information for surveillance of circulating dengue viruses.
Criteria for testing:	Testing of clinical blood specimens (serum) with the CDC DENV-1-4 Real-Time RT-PCR Assay should not be performed unless the patient meets clinical and/or epidemiologic criteria for testing suspect dengue cases. **Note**: Negative results obtained with this test do not preclude the diagnosis of dengue and should not be used as the sole basis for treatment or other patient management decisions.
For private clinics and providers:	**Specimen Submission Guidelines** 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. Send forms with the specimen. 3. Refrigerate serum at 4°C or maintain on ice for no longer than 24 hours. If storage/transport will exceed 24 hours, freeze serum at -20°C or lower. 4. Send frozen specimens to GPHL business day Mondays-Fridays 8AM-430PM.

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:	• Once there is a clinical diagnosis of suspected dengue, 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 tested.
Specimen Transport, Storage and Stability	Store and transport specimens in frozen state. For USAPI Laboratories follow the PIHOA Shipping Mechanism Guidelines.
Specimen Submission	• 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. The submitting facility must notify Microbiologist or alternate of GPHL at (671) 735-7153/158/355 prior to submitting/ shipping specimens. **NOTE: It is the responsibility of the submitter to track the arrival of the specimens along with the Dengue Specimen form at GPHL to ensure that these specimens are received by the Laboratory staff.**
Rejection Criteria	• 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 • Unlabeled specimens; • Illegible/ incomplete labeling/documentation.
Submission Form	Specimen Laboratory Submission Form • Each specimen submitted must have a completed GPHL Dengue Submission Form, with the patient name, patient identification number, type of specimen, date/time of collection, submitter, date of onset, travel history, date shipped/sent to GPHL, 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:	Specimens run will be batched. Laboratory reports will be forwarded to the submitting facility, territory epidemiologist, and the BCDC Administrator via Facsimile. Any other request for copies of laboratory reports, apart from that stipulated above will not be accepted.
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Reference:

1. CDC DENV-1-4 Real Time RT-PCR Kit Package Insert