GUAM PUBLIC HEALTH LABORATORY GUIDELINES

COLLECTION, PROCESSING, AND STORAGE REQUIREMENTS FOR CEREBROSPINAL FLUID (CSF)/SERUM/ WHOLE STOOL/RESPIRATORY-NASOPHARYNGEAL (NP) OR OROPHARYNGEAL (OP) SWAB SPECIMENS IN CLINICAL SAMPLES FROM SUSPECT ACUTE FLACCID MYELITIS (AFM) CASES

Methodology:	CDC Acute Flaccid Myelitis (AFM) Specimen Collection Instructions, Handling and Shipping, Shipping Address
Specimen Submission Guidelines:	• Call the DPHSS at 671-689-3942 for pre-approval, before collecting and sending specimens for suspected Measles/Rubeola. **NO SPECIMEN WILL BE ACCEPTED WITHOUT PRIOR CONSULTATION.** • Once vetted/approved by DPHSS, complete the specimen submission form with patient's name (last name, first name), date of birth, unique Identification (ID) number/specimen ID number, date of collection, time of collection, initial of collector. • Specimens collected should be packaged and transported within the facility without attempting to open collection specimen container. Wrap the specimen with absorbent material and place in a sealable specimen biohazard transport bag and into a secondary watertight, leak-proof secondary receptacle. • Specimens for transport to the GPHL must be placed in a sealed biohazard transport bag and placed in a sealed, decontaminated primary sterile container. • Fill out COMPLETELY the GPHL Submission Form. • Call the GPHL (671) 300-9082 or (671) 300-9085 to inform staff of the specimen delivery.
Performed at Healthcare Facility:	Collection of Cerebrospinal Fluid (CSF)/Serum/Whole Stool/Respiratory-Nasopharyngeal (NP) or Oropharyngeal (OP) swab specimens shall be carried out by clinicians to avoid causing patients discomfort or compromising the quality or quantity of the sample by using standard protocols recommended to patients suspected of having AFM as early as possible in the course of illness, preferably on the day of onset of acute flaccid limb weakness. Clinicians should: follow the instructions on the table (page 4 of 4) and CDC's Job Aid for Clinicians (Attachment #1); place sample in biohazard specimen transport bag with GPHL Submission Form (Attachment #2), and AFM: Patient Summary Form (Attachment #3) for each specimen submitted; please refer to Instructions for Completing the AFM Patient Summary Form (Attachment #4); deliver to Guam Public Health Central Laboratory (GPHL). If any of the serum samples were collected after the

Centers for Disease Control and Prevention (CDC):	patient had received intravenous immune globulin (IVIG), steroid treatments, or plasmapheresis/plasma exchange, please indicate the Date of Therapy on the Patient Summary Form. Note: Pathogen-specific testing should continue at hospital or private laboratories, and may include CSF, Serum or Whole Blood, Stool, and Respiratory specimens. CDC will: test for potential infectious, noninfectious, and post-infectious causes, including possible immune-mediated mechanisms or host responses to AFM; prioritize testing of CSF and Serum to optimize yield of an etiologic agent or possible mechanism for AFM; conduct poliovirus testing of Stool specimens to rule out the presence of poliovirus, and routine enterovirus/rhinovirus (EV/RV) testing and typing of Respiratory specimens.
Guam Public Health Central Laboratory:	Note: Since the testing protocols include several assays that are not performed under the Clinical Laboratory Improvement Amendments (CLIA) nor intended for Clinical Diagnosis, CDC will be unable to provide patient-specific results for certain tests that are performed. Results following testing of samples that may indicate a possible cause of AFM will be rapidly disseminated. Results from certain tests, such as EV/RV testing and typing and stool testing, will be shared with the health department upon completion. Prior to processing and shipping, the laboratory will email Will Seldon (wweldon@cdc.gov), Heather Jost (ifs2@cdc.gov), and limbweakness@cdc.gov, regarding what is being processed and shipped. Ensure proper and timely Handling and Shipping of clinical specimens from patients suspected to have AFM to CDC to optimize yield from specialized testing.
Laboratory Criteria:	Note: CDC advises overnight shipment to arrive CDC on Tuesday through Friday, and no shipment of specimens on Friday or over the weekend. Confirmatory Laboratory Evidence: Magnetic Resonance Image (MRI) showing spinal cord lesion largely restricted to gray matter (negative or normal MRI performed within 2 hours after onset of limb weakness does not rule our AFM; MRI studies performed 72 hours or more should also be reviewed if available). Supportive Laboratory Evidence: CSF with pleocytosis (WBC count >5 cells/mm^3).
Specimen Required:	The laboratory requires Cerebrospinal Fluid (CSF), Serum, Whole Stool, Respiratory - Nasopharyngeal (NP) or Oropharyngeal (OP) swab specimens respectively, each with: 1. GPHL Specimen Submission Form (GPHL DPHSS_FRM_05/18/16) 2. Acute Flaccid Myelitis (AFM): Patient Summary Form (Version 5.0, 9/13/17)

Specimen Processing, Shipping, and Handling	Guam Public Health Laboratory (GPHL) will process, ship, and handle: • Frozen samples at -20°C; • Arrangements to ship the samples overnight to CDC, frozen on dry ice; • Completed hard copies of the AFM Patient Summary Form and the CDC Specimen Submission Form (CDC Form 50.34) for each specimen submitted. Note: For Test Order Name, select "Picornavirus Special Study"; • If submitting ten (10) or more patient specimens, providing an electronic line listing by email, using the following headers in this order: Patient ID Number, Date of Birth, Onset Date, Fatal Y/N (Yes or No), Specimen ID Number, Specimen Collected Date, and Specimen Type; • Shipping to Shipping Address: Dr. Will Weldon, Centers for Disease Control and Prevention, 1600 Clifton Road, NE Unit 76, Building 17, Room 6124, Atlanta, GA 30329-4027 USA. Contact Numbers - Office: 404-639-5485; Mobile: 404-216-6183; Email: wweldon@cdc.gov)
Specimen Transport and Submission to CDC:	• Store and transport specimens at -20°C, frozen on dry ice. • Ensure when transporting human cerebrospinal fluid, blood or serum, stool, and respiratory specimens, all applicable regulations for transport of potentially infectious biological specimens are met. • For future testing sent to reference laboratory, follow the current PIHOA Shipping Mechanism Guidelines and/or consult references provided by the International Air Transport Association (IATA).
Rejection Criteria	• Stool Swab specimen; • 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; • Frozen specimen is not received at -20°C or packed in dry ice; • Frozen specimen not shipped in dry ice; • Unlabelled specimens; • Illegible/ incomplete labeling/documentation.
Submission Form	Specimen Laboratory Submission Form if applicable Each specimen submitted must be labeled with the assigned patient identification number, type of specimen, date/time of collection, submitter, and/or other applicable and 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:	Results following testing of samples from multiple cases that may indicate a possible cause of AFM will be rapidly disseminated. Results from certain tests such as EV/RV testing and typing and stool testing, will be shared with the health department upon completion.
Contact:	Alan Mallari, Microbiologist III, GPHL Phone: (671) 300-9080 or (671) 300-9081 alan.mallari@dphss.guam.gov Lea Nisay, Microbiologist II, GPHL (Alternate) Phone: (671) 300-9083/ FAX: (671) 300-9098 lea.nisay@dphss.guam.gov Anne Marie Santos, GPHL, Central Laboratory Administrator Phone: (671) 300-9082 or (671) 300-9085 annemarie.santos@dphss.guam.gov

Table - Specimens to Collect and Send to CDC for Testing Suspect AFM Cases

Specimen Type	Minimum Amount	Collection	Storage	Shipping	Comments
Cerebrospinal Fluid (CSF)	1 mL	Spun and processed; standard cryovial tube; collect at same time or within 24 hours of serum if feasible.	Freeze at -20°C	Ship on dry ice	CSF will be used for special studies; EV/RV testing will be batched and results returned as sample amount allows.
Serum*	0.4 mL	Spun and processed; Tiger/red top tube; collect at same time or within 24 hours of CSF is feasible.	Freeze at -20°C	Ship on dry ice	Serum will be used for special studies; no individual results will be returned.
Whole Stool	≥1 gram	Collect in sterile container, no special medium required. Please do not send a rectal swab†	Freeze at -20°C	Ship on dry ice	Two samples total, collected at least 24 hours apart, both collected as early in illness as possible within 14 days of illness onset. Results for EV/RV and poliovirus testing will be returned as testing completed.
Respiratory – Nasopharyngeal (NP) or Oropharyngeal (OP)	1 mL	Store in viral transport medium	Freeze at -20°C	Ship on dry ice	EV/RV testing and typing will be performed and results returned.

In the event of death, please send the following specimens, if possible:

Specimen Type	Minimum Amount	Collection	Storage	Shipping	Comments
Fresh-frozen tissue	N/A	Place directly on dry ice or liquid nitrogen	Freeze at -70°C	Ship on dry ice	Representative sections from various organs are requested, but particularly from brain/spinal cord (gray and white matter), heart, lung, liver, kidney, and other organs as available.
Formalin-fixed or formalin-fixed, paraffin-embedded tissue	N/A	Avoid prolonged fixation-tissues should have been fixed in formalin for 3 days then transferred to 100% ethanol.	Room temperature	Ship at room temperature with paraffin blocks in carriers to prevent breakage.	See comment above regarding frozen tissue.

Reference:

CDC Specimen Collections Instructions from suspect AFM cases (https;//www.cdc.gov/acute-flaccid-myelitis/hcp/instructions.html), page last reviewed: July 3, 2018, page last updated: October 17, 2018. Content source: National Center for Immunization and Respiratory Diseases, Division of Viral Diseases.