

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

GUAM PUBLIC HEALTH LABORATORY GUIDELINES SPECIMEN REQUIREMENTS FOR DETECTION OF INFLUENZA A, B and SUBTYPING

	1. Cepheid GeneXpert Flu (Influenza) PCR
Methodology:	2. ABI 7500 Fast Dx Real-Time PCR (CDC Human Influenza Virus Real-Time RT Diagnostic Panel)
Performed at GPHL Lab:	1. The Cepheid GeneXpert Flu (Influenza) assay is an FDA-cleared automated, real-time RT-PCR assay for the qualitative detection of Influenza A and Influenza B viral RNA. It differentiates 2009 Influenza H1N1 from seasonal Influenza A and B.
	2. The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel is used in an FDA-cleared real-time RT-PCR assay using ABI 7500 Fast Dx Real-Time instrument. It will detect influenza virus type A or B. It will also determine the subtype of seasonal human influenza (A, H1, H3, pdmA, pdmH1) and it will also detect the genetic lineage of influenza B (B/Victoria or B/Yamagata).
	Clinicians should suspect Novel Influenza A (H1N1) in person with ILI who:
	1. Have had close contact with a person who is a swine-origin influenza confirmed case; OR
	2. Traveled to a community in the United States or internationally where there are one or more confirmed swine-origin influenza cases; OR
	3. Resides in a community where there are one or more confirmed swine-origin influenza A (H1N1) cases; OR
	 Patients presenting with sepsis syndrome (unexplainable); OR Patients presenting with respiratory distress syndrome.
	ILI is defined as fever (temperature of 100°F (37.8°C) or greater) and a cough and/or a sore throat in the absence of a KNOWN cause other than influenza.
For private	Specimen Submission Guidelines
clinics and providers:	 Submit one sample in M4 media (M4 media will be provided by PH upon request). Refer to Specimen Collection instructions below for acceptable specimens.
	 Fill out required form(s) <u>COMPLETELY</u> (GPHL Influenza Submission Form AND other required forms). Send forms with the specimen.
	3. Freeze specimens immediately after collection.
	 Send frozen specimens to Guam Public Health laboratory Mondays-Fridays 8AM-430PM.

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Specimen	Preferred respiratory specimens:
Required:	1. Nasal swabs
	2. Nasopharyngeal swabs / aspirates
	3. Nasal wash / aspirates
Specimen Collection:	Use only swabs provided in the M4 collection kit. No substitution of swabs.
	For Nasal Sample – To collect a nasal swab sample insert the sterile swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab a few times against the nasal wall.
	For Nasopharyngeal Sample – To collect a nasopharyngeal swab sample, insert the sterile swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times.
	For Nasal Wash or Aspirate Sample –
	• For Older Children and Adults:
	With the patient's head hyper-extended instill about 2.5 ml of sterile normal saline into one nostril with a syringe. To collect the wash, place a clean, dry specimen container directly under the nose with slight pressure on the upper lip. Tilt the head forward and allow the fluid to run out of the nostril into the specimen container. Repeat for the other nostril and collect the fluid into the same specimen container.
	• For Younger Children:
	The child should sit in the parent's lap facing forward with the child's back against the parent's chest. The parent should wrap one arm around the child in a manner that will restrain the child's body and arms
	Fill an aspiration bulb or bulb syringe with up to 2.5 ml of sterile normal saline (depending on the size of the child), and instill the saline into one nostril while the head is tilted back. Release the pressure on the bulb to aspirate the specimen back into the bulb. Transfer the specimen into a clean, dry specimen container. Repeat the process for the child's other nostril and transfer the specimen into the same specimen container.
	Label each specimen with a unique identifier, type of specimen and date of collection.
	Place Swabs in biohazard specimen transport bag, seal and freeze. Place Submission form in outside pouch when sending to GPH laboratory.
Specimen Transport, Storage and Stability	Store and transport specimens in frozen state. Do not freeze-thaw.

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Specimen Submission	The submitting facility must notify BT Microbiologist or alternate of GPHL at (671) 300-9080 or 300-9081
	NOTE: It is the responsibility of the submitter to track the arrival of the specimens along with the Influenza Specimen Laboratory Submission form at GPHL to ensure that these specimens are received by the Laboratory staff.
Rejection Criteria	 Thawed specimens. Specimen quantity is insufficient to perform the test; Specimen received in a container that is leaking. Specimen is not collected in a M4 media or special handling instruction is not followed; Transport media is expired; Swab with calcium alginate, wooden shafts, cotton- tipped; Specimen subjected to repeated freeze-thaw cycle. Unlabelled specimens; Illegible/ incomplete Submission forms (e.g., no date of onset, travel history, etc.) Specimen label does not match the Submission form.
Submission Form	 Influenza Specimen Laboratory Submission Form Each specimen submitted must have a completed 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 Illegible 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 once every week. Laboratory reports will be forwarded to the submitting facility and the BCDC Administrator via FAX. Any other request for copies of laboratory reports, apart from that stipulated above will not be accepted.
Contact:	Alan Mallari, Microbiologist III, GPHL (671) 300-9080 or (671) 300-9081 alanjohn.mallari@dphss.guam.gov Lea Nisay, Microbiologist II, GPHL(Alternate)

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Contact (cont.)	 (671) 300-9083 (671) 300-9098 FAX lea.nisay@dphss.guam.gov Anne Marie Santos, Central Laboratory Administrator, GPHL (671) 300-9082 or (671) 300-9085 annemarie.santos@dphss.guam.gov

References:

- 1. CDC Interim Guidance for Screening for Novel Influenza A (H1N1) (Swine Flu) by State and Local Health Departments, Hospitals and Clinicians in Regions with Few or No Reported Cases of Novel Influenza A (H1N1). May 1, 2009
- CDC Interim Guidance on Specimen Collection, Processing and Testing for Patients with Suspected Swine-Origin Influenza A (H1N1) Virus Infection. April 30, 2009
- 3. CDC Interim Guidance on Case Definitions to be Used for Investigations of Swine-Origin Influenza A (H1N1). April 30, 2009
- 4. GeneXpert Flu Assay package insert

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