

Laboratory Diagnostics
PHASES 1/2 - SITUATION A
Novel (new) influenza virus in birds or other animals overseas
RESPONSE ACTION - WATCH

Action Item 1: Integrate and maintain statewide laboratory surveillance/reporting system in New Jersey

- 1.1 Virology performs confirmatory testing to determine type and subtype of positive Influenza Rapid Antigen test specimens from sentinel hospital-based laboratories and health care providers submitted through Communicable Disease Services' (CDS) Influenza Surveillance Program (ISP). See "Virologic Surveillance for Influenza" (Appendix 1.)
- 1.2 Virology submits specimens to Centers for Disease Control and Prevention (CDC) for Influenza strain identification according to the guidelines provided in the United States Department of Health and Human Services (HHS) "Pandemic Influenza Plan Supplement 2: Laboratory Diagnostics," Appendices 2, 3, 4, 5 (<http://www.hhs.gov/pandemicflu/plan/sup2.html>). Routine surveillance specimens are submitted according to guidance provided in "The 2006-2007 WHO Influenza Reagent Kit for Identification of Influenza Isolates, Section V. Shipment of Isolates, Guidelines."
- 1.3 Virology participates in World Health Organization (WHO)/ National Respiratory and Enteric Virus Surveillance System global surveillance program. Refer to <http://www.who.int/csr/disease/influenza/surveillance/en/index.html>.
- 1.4 Virology provides the ISP and stakeholders (sentinel hospital-based laboratories and health care providers) with test information and appropriate forms for clinicians and laboratories regarding proper specimen handling and transport of influenza specimens. See "Instructions for Collection, Testing and Shipping of Influenza Specimens" (Appendix 2).
- 1.5 Patient specimens that screen positive for influenza are shipped as Biological Substances, Category B according to Department of Transportation, 49 Code of Federal Regulations (CFR), Parts 171, 172, 173 and 175, and International Air Transport Association requirements.
http://a257.g.akamaitech.net/7/257/2422/13nov20061500/edocket.access.gpo.gov/cfr_2006/octqtr/pdf/49cfr173.199.pdf

Action Item 2: Adopt protocols put forth by CDC/Association of Public Health Laboratories (APHL) regarding testing of novel influenza viruses and ensures cross-training of staff in these protocols

- 2.1 Virology ensures that Public Health and Environmental Laboratories (PHEL) staff is trained to perform the level of confirmatory testing recommended by CDC/APHL for novel influenza viruses. Two tests are recommended, Virology uses the Food and Drug Administration cleared Laboratory Response Network (LRN) assay to perform this testing. See "CDC/APHL Protocols for Novel Virus Testing" (Appendix 3).
- 2.2 Virology develops and implements cross-training procedures to assist with surge capacity and business continuity. See "PHEL Cross-Training Procedures for Novel Influenza Testing" (Appendix 4).

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Action Item 3: Ensure that protocols for receiving and testing specimens from possible cases infected with a novel virus and protocols to communicate laboratory findings are in place

“See “Surveillance and Testing for Influenza A (H5N1) in Humans – Pandemic Alert Period – Protocol for NJDHSS” in the Surveillance section of this plan (Appendix 10)

3.1 Virology works with clinical/surveillance/laboratory staff to develop protocols as follows:

- Accepting specimens at PHEL for additional testing to rule out novel influenza virus.
- Specimens submitted to the PHEL for testing for a novel influenza virus are accessioned by the staff of the Specimen Receiving Laboratory located in the Laboratory Building of PHEL Room 216 according to SOP # PHLS-SR-6, “Diagnostic Specimen Receipt and Processing.” Specimen data is entered into the PHEL Laboratory Information Management System (Harvest) and the appropriate test is ordered for influenza. These specimens are referred to the Molecular Lab of the Virology Program. For specimens submitted after normal work hours, on weekends or holidays, specimen testing may occur in advance of accessioning. Whatever the timeframe, testing needs to commence as quickly as possible. Appropriate staff are contacted by the Virology Program Manager or Laboratory Director (or designee) and instructed on how to proceed with testing.
- Testing procedures at PHEL for novel influenza viruses.
To rule in or rule out influenza A/H5, PHEL laboratorians follow protocols provided by the LRN (See 2.1 above) entitled: Procedure for the Identification of Influenza A/H5. Staff continue to monitor this procedure to determine when it is revised and to ensure that the latest revision is used. Specimens that meet the criteria as presumptive positives are forwarded to CDC. Contact information for CDC can be found within the LRN protocol noted above entitled: Detection of Influenza A/H5 by Fluoregenic 5’ Nuclease Assay Using the ABI 7000 sequence Detection System. (7. Reporting Action). The same contact information can be found on the emergency phone contact tree discussed below.
- Notification protocols for reporting of the specimens (both internal and external).
A phone tree has been created to communicate results of novel influenza testing both internally and externally to CDC. This exists on the hard drive of the Virology Program Manager at P:\mydocs\AVIAN or NOVEL FLU. In this folder the contact tree exists as an Excel file (Emergency Contact Tree.xls).

3.2 PHEL’s Laboratory Outreach Program (LOP) communicates the protocols for specimen receipt, testing, and reporting to submitters using the Local Information Network and Communications System (LINCS) and the LRN. LOP maintains databases for Laboratory Medical Directors, Laboratory Administrative Directors, and Microbiology Supervisors.

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These listservs are updated biannually and shared with the NJ Department of Health and Senior Services' (NJDHSS) LINCS administrative staff. LOP maintains a listserv of LRN members that can be used to communicate directly with laboratories as the need arises.

- 3.3 Virology posts specimen collection, shipping and handling protocols on the NJDHSS web site at www.njflupandemic.gov.

Action Item 4: Assess equipment and supplies (e.g., testing and Personal Protective Equipment - PPE) needed to process a large number of specimens

- 4.1 Virology identifies primary and secondary vendors to provide equipment and supplies. See "Equipment, Vendor, Supply List" (Appendix 5). Based on the epidemiology of the disease at the time of the pandemic, the number of specimens that need to be tested is determined by the CDS. During this timeframe, Virology attempts to maintain a minimum of a four week inventory.
- 4.2 Virology acquires in advance equipment and supplies that do not have limited shelf life.
- 4.3 Virology calls other sources of backup equipment and supplies (i.e., CDC, other labs) that may be available to avoid shortages.

Action Item 5: Build partnerships with health care providers and clinical laboratories

- 5.1 LOP maintains partnerships with 67 New Jersey clinical microbiology laboratories that are considered part of the LRN and 30 clinical laboratories that provide basic LRN functions. LOP does this through the maintenance of contact databases, regular email correspondence, emergency preparedness training and inspections, and tabletop and fullscale exercises.
- 5.2 LOP establishes and convenes a PHEL Laboratory Influenza Preparedness Task Force to assess and address on-going operational needs (e.g., surge capacity, training, resources, laboratory protocols). Members represent LOP's 67 clinical microbiology and 30 clinical laboratory partners.

Laboratory Diagnostics
PHASES 1/2 - SITUATION B
Novel (new) influenza virus in birds or other animals in North America
RESPONSE ACTION - WATCH

Action Item 1: Continue activities from Phases 1/2A, Action Items 1, 2, 3, 4 and 5

Action Item 2: Review and modify activities as appropriate to reflect changes in laboratory protocols, situation and guidance documents

Laboratory Diagnostics
PHASES 1/2 - SITUATION C
Novel (new) influenza virus in birds or other animals in NJ
RESPONSE ACTION - WATCH

Action Item 1: Continue activities from Phases 1/2A, Action Items 1, 2, 3, 4 and 5

Action Item 2: Review and modify activities as appropriate to reflect changes in laboratory protocols, situation and guidance documents

Laboratory Diagnostics
PHASE 3 - SITUATION A
Human case of novel (new) influenza virus (no human spread) overseas
RESPONSE ACTION - WATCH

Action Item 1: Work with the NJDHSS Human Resources Safety Officer to establish and implement a worker surveillance program for PHEL staff who may be exposed to novel influenza viruses

- 1.1 PHEL identifies laboratory tasks that put staff at risk for exposure to novel influenza virus.
- 1.2 PHEL, with the DHSS Human Resources Safety Officer, develops a program for monitoring PHEL staff that perform the tasks identified in 1.1 above for illness.
- 1.3 PHEL, in conjunction with the DHSS Human Resources Safety Officer, implements the "Surveillance Protocol for PHEL Staff.

Action Item 2: Develop a list of all PHEL staff by job function so that appropriate personnel can be offered vaccine when vaccine becomes available

Action Item 3: Continue to build partnerships with health care providers and clinical laboratories

- 3.1 LOP maintains partnerships with 67 New Jersey clinical microbiology laboratories that are considered part of the LRN and 30 clinical laboratories that provide basic LRN functions. LOP does this through the maintenance of contact databases, regular email correspondence, emergency preparedness training and inspections, and tabletop and fullscale exercises.
- 3.2 LOP maintains the PHEL Laboratory Influenza Preparedness Task Force to assess and address on-going operational needs (e.g., surge capacity, training, resources, laboratory protocols). Members represent LOP's 67 clinical microbiology and 30 clinical laboratory partners.
- 3.3 The Task Force membership is reviewed and updated and a meeting is conducted in 2008 to determine the Task Force Goals for 2008. Meetings are conducted as needed.

Laboratory Diagnostics

PHASE 3 - SITUATION B

**Human case of novel (new) influenza virus (no human spread) in North America
RESPONSE ACTION – WATCH**

PHASE 3 - SITUATIONS C and/or D

**Human case of novel (new) influenza virus (no human spread) in NJ and/or
First case of human to human spread of novel (new) influenza overseas
RESPONSE ACTION – ALERT**

PHASE 3 - SITUATIONS E and/or F

**First case of human to human spread of novel (new) influenza in North America and/or NJ
RESPONSE ACTION – RESPONSE**

Action Item 1: Continue activities from Phases 1/2A, Action Items 1, 2, 3, 4 and 5 and from Phase 3A, Action Items 1, 2 and 3

Action Item 2: Review and modify activities as appropriate to reflect changes in laboratory protocols, situation and guidance documents

Laboratory Diagnostics

PHASE 4 - SITUATION A

**Clusters of cases of human spread overseas
RESPONSE ACTION - ALERT**

Action Item 1: Continue activities from Phases 1/2A, Action Items 1, 2, 3, 4 and 5 and from Phase 3A, Action Items 1, 2 and 3

Action Item 2: Review and modify activities as appropriate to reflect changes in laboratory protocols, situation and guidance documents

Action Item 3: Determine the number of specimens to be processed to conduct virologic surveillance as resources decrease

- 3.1 Virology and PHEL management evaluate resources (human and supplies) available to process specimens and estimates the number of specimens that can be safely processed in a week.
- 3.2 Virology notifies the ISP as to the number of specimens that can be processed.

**Action Item 4: Develop a surge capacity plan for specimen submission
See “Surge Capacity Plan for Specimen Receipt and Disposal” (Appendix 6)**

- 4.1 PHEL management, based on the number of specimens to be processed develops a surge capacity plan.
- 4.2 PHEL management, with the ISP, develops a mechanism for decreasing daily intake of specimens.

Laboratory Diagnostics
PHASE 4 - SITUATION A
Clusters of cases of human spread overseas
RESPONSE ACTION – ALERT

- 4.3 Virology, with the ISP, provides guidance to submitters describing :
- which specimens PHEL will be requested as the outbreak evolves;
 - how many specimens each facility submits; and
 - the time-frame for submission of specimens (e.g., Northeast hospitals submit specimens on Monday).
- 4.4 PHEL works with their stakeholders to develop a transportation mechanism to receive specimens in a timely manner based on the plan described above. This could include the use of the current NJDHSS courier system, commercial carrier, local police and/or law enforcement.

Action Item 5: Develop a surge capacity plan to scale back or eliminate non-essential public health lab services

See “Surge Capacity Plan for Eliminating Non-Essential Lab Services” (Appendix 7)

- 5.1 The Director of PHEL’s Public Health Laboratory Services creates a list of all laboratory services provided and develops a mechanism by which each is deemed essential or not. The Director works with the PHEL Assistant Commissioner to finalize the list.
- 5.2 PHEL management works with the ISP to develop a plan to eliminate services based on essential status and available resources.
- 5.3 PHEL management creates a plan to test specimens “Between Waves” that are received during the pandemic but not tested due to limitations in staff resources.

Action Item 6: Develop a retention plan that details the length of time specimens are held before they are discarded

See “Surge Capacity Plan for Specimen Receipt and Disposal” (Appendix 6)

- 6.1 PHEL management develops a plan detailing how to store specimens that are received but not tested and the priority order for testing them.
- 6.2 PHEL management develops a plan detailing how long to store specimens that have already been tested.
- 6.3 PHEL management develops a plan for safe disposal of specimens.

Laboratory Diagnostics
PHASE 4 - SITUATION B
Clusters of cases of human spread in North America
RESPONSE ACTION - RESPONSE

Action Item 1: Continue activities from Phase 1/2A, Action Items 1, 2, 3, 4 and 5 and from Phase 3A, Action Items 1, 2 and 3

Action Item 2: Review and modify activities as appropriate to reflect changes in laboratory protocols, situation and guidance documents

Laboratory Diagnostics
PHASE 4 - SITUATION C
Clusters of cases of human spread in NJ
RESPONSE ACTION - RESPONSE

Action Item 1: Continue activities from Phases 1/2A, Action Items 1, 2, 3, 4 and 5 and from Phase 3A, Action Items 1, 2 and 3

Action Item 2: Review and modify activities as appropriate to reflect changes in laboratory protocols, situation and guidance documents

1.1 PHEL receives from ISP the plan for submission of specimens, based upon testing capacity.

Laboratory Diagnostics
PHASE 5 - SITUATION A
Widespread cases of human to human spread of novel (new) influenza virus overseas
RESPONSE ACTION - RESPONSE

Action Item 1: Continue activities from Phases 1/2A, Action Items 1, 2, 3, 4 and 5 and from Phase 3A, Action Items 1, 2 and 3

Action Item 2: Review and modify activities as appropriate to reflect changes in laboratory protocols, situation and guidance documents

Action Item 3: Implement surge capacity plans developed in Phase 4A

- 3.1 Using LINCS and the LRN listserv, PHEL notifies submitters that sampling is being limited.
- 3.2 PHEL implements surge capacity plans for specimen receipt and retention. See “Surge Capacity Plan for Specimen Receipt and Disposal” (Appendix 6).
- 3.3 PHEL management implements the plan for elimination of non-essential lab services. See “Surge Capacity Plan for Eliminating Non-Essential Lab Services” (Appendix 7).

Laboratory Diagnostics
PHASE 5 - SITUATIONS B and/or C
Widespread cases of human to human spread of novel (new) influenza virus
in North America and/or NJ
RESPONSE ACTION - RESPONSE

Action Item 1: Continue activities from Phases 5A

Action Item 2: Review and modify activities as appropriate to reflect changes in laboratory protocols, situation and guidance documents

Laboratory Diagnostics
PHASE 6
Increased and sustained transmission in the general population
RESPONSE ACTION - RESPONSE

Action Item 1: Continue activities from Phase 5A

Action Item 2: Review and modify activities as appropriate to reflect changes in laboratory protocols, situation and guidance documents

Laboratory Diagnostics
BETWEEN WAVES
RESPONSE ACTION - ALERT

**Action Item 1: Test stored specimens according to the “Between Waves” plan
See Phase 4A, Action Item 4, Task 4.3**

Action Item 2: Assess performance and develops modifications as required

Action Item 3: Assess and restocks supply inventory

Action Item 4: Assume routine operations until the next wave