



H5N1 INFLUENZA

Protocol Overview and Methods:

Causative agent is an *Influenza* virus. Human cases of *Influenza A* of *Influenza A* (H5N1) infection have occurred in several Asian and Middle Eastern countries. It is believed that human H5N1 cases result from contact with infected birds or surfaces contaminated with excretions from infected birds. Sporadic human cases have occurred after recent direct or close contact with infected poultry that were sick or dead, and nearly 600 human H5N1 cases have been reported in 15 countries to WHO since November 2003, resulting in approximately 60% mortality. Other H5N1 risk factors include visiting a live poultry market and prolonged, unprotected close contact with a sick H5N1 patient.

The Delaware Public Health Laboratory (DPHL) can identify H5N1 via molecular real time reverse-transcriptase polymerase chain reaction (qRT-PCR).

- Molecular methods are used to detect specific segments of deoxyribonucleic acid (DNA) that these organisms contain. If present, DNA segments from *Influenza* H5N1 are amplified until there is a sufficient quantity for the instrument to detect. **Any positive qPCR results are considered preliminary positive and must be sent to CDC for confirmation.**

Specimens:

Specimens for laboratory testing should be submitted to the DPHL only for patients who meet clinical and epidemiologic criteria. Testing for *Influenza* type A (H5N1) is indicated for hospitalized patients with:

- radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness for which an alternate diagnosis has not been established, **AND**
- history of travel within 10 days of symptom onset to a country with documented H5N1 avian influenza in poultry and/or humans (For a listing of H5N1-affected countries, see the WHO web site at <http://www.who.int/en/> .)

Testing for *Influenza* type A (H5N1) should be considered on a case-by-case basis in consultation with public health epidemiologists for hospitalized or ambulatory patients with:

- documented temperature of $>38^{\circ}\text{C}$ ($>100.4^{\circ}\text{F}$), **AND**
- one or more of the following: cough, sore throat, shortness of breath, **AND** history of contact with domestic poultry (e.g., visited a poultry farm, household raising poultry, or bird market) or a known or suspected human case of influenza A (H5N1) in an H5N1-affected country within 10 days of symptom onset.

Chain of custody procedures must be followed for environmental samples or any samples, specimens, materials that could be used as evidence in a legal proceeding. All forms are available on the DPHL website: <http://dhss.delaware.gov/dph/lab/labs.html>.

24/7 Emergency Contact Number: 1-888-295-5156

Revised: 03/2012

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- Contact Information:** DPHL Director: 302-223-1520. Answering service is available at the same number during non-business hours. Please indicate the nature of the call so that notification to DPHL is not delayed.
- Authorization for Specimen Submittal:** Authorization for laboratory specimen submittal must be given by the DPHL Director, DPHL Deputy Director, or Bioterrorism Coordinator.
- Acceptable Specimens for Testing Include:**
- All respiratory samples such as: upper respiratory tract clinical specimens (including nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes and dual nasopharyngeal/throat swabs) and lower respiratory specimens (including bronchoalveolar lavage (BAL), bronchial wash, tracheal aspirate, sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection.
 - Viral culture material from any of these sources listed above.
- Handling of Specimens:**
- Biosafety practices: Latex or similar gloves should be worn while collecting specimen. Other personal protective equipment should be used as necessary. For suspected aerosols, a respirator should be worn.
- Packaging Instructions:**
- Influenza virus detection kits for specimen collection are available from the DPHL. These kits contain a requisition form, 1 screw-capped tube with 2 ml of sterile transport media and 1 flexible slender nasopharyngeal swab. Contact the DPHL at (302) 223-1520 to obtain specimen collection kits.
 - A flexible nasopharyngeal swab is to be placed into a screw-capped tube with 2 ml of sterile transport media. **Sample must be kept at 2-8°C. Do not freeze.**
 - Specimens must be bagged in a biohazard bag, the bag decontaminated, and bagged again. Outside of outer bag must also be decontaminated with 10% bleach.
 - Receiving specimens at DPHL: Authorized specimens are accepted at the back of the building by the loading dock. Submitter must present a government issued ID and have chain of custody forms completed.
 - Other Information: For locations of courier pick-up sites, specimen submission forms, and other information, see the DPHL website at <http://www.dhss.delaware.gov/dhss/dph/lab/labs.html>.
- Reporting Results:**
- Results: A positive or negative test result may be issued upon completion of qPCR. Most qPCR results can be available between 4-24 hours from receipt of specimen.
 - Preliminary Positive: All positive qPCR results for H5N1 are preliminary and must be confirmed by CDC by culture.
 - Negative: Negative qPCR results for H5N1 are confirmed negatives. No CDC confirmation is necessary.
 - Notification Procedure: Upon confirmation of results by CDC, the Laboratory Director, Deputy Laboratory Director, or Bioterrorism Coordinator will notify the submitter of test results.