



The Florida Lab Link

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Ready Or Not It's Flu Season...

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Influenza is a respiratory infection caused by a variety of flu viruses. The "flu" is a common catch-all term used for a variety of illnesses, but it correctly applies only to respiratory disease caused by the influenza virus. Three viruses in the family *Orthomyxoviridae* cause disease in humans: influenza virus types A and B, which are responsible for annual seasonal epidemics, and influenza virus C, which is rarely described. Influenza A viruses are divided into subtypes based on two proteins on the surface of the virus: the hemagglutinin (H) and the neuraminidase (N). There are 18 different hemagglutinin subtypes (H1 - H18) and 11 different neuraminidase subtypes (N1 - N11). Influenza virus is considered a Category C biothreat agent because it is emerging, readily available, easily disseminated, and capable of causing high morbidity and mortality rates.^{1, 2, 6}

Influenza illness can include any or all of these symptoms: fever, muscle aches, headache, lack of energy, dry cough, sore throat, and runny nose. The fever and body aches can last three to five days and the cough and lack of energy may last for two or more weeks. Early diagnosis of influenza can reduce the inappropriate use of antibiotics and provide the option of using antiviral therapy. However, the accuracy of clinical diagnosis of influenza on the basis of symptoms alone is limited since symptoms from illness caused by other pathogens can overlap considerably with influenza including, but not limited to, *Mycoplasma pneumoniae*, adenovirus, respiratory syncytial virus, rhinovirus, parainfluenza viruses, and *Legionella* spp. Bacterial infections can also occur as a complication of influenza and, if suspected, they should be considered and treated appropriately. In addition, there are many other non-flu viruses that can result in influenza-like illness (ILI) that spread during flu season.³

It is estimated that between 15 percent and 40 percent of the population will develop illness from influenza every year. An average of about 114,000 people per year in the United States (U.S.) have to be admitted to the hospital and approximately 36,000 people die as a result of complications from influenza infection. Anyone can get the flu, and serious problems from influenza can happen at any age but, people who are age 65 years and older, have chronic medical conditions, and very young children are more likely to have complications from influenza.⁶



Influenza viruses are spread from person to person primarily through large-particle respiratory droplet transmission (e.g., when an infected person coughs or sneezes near a susceptible person), which requires close contact between source and recipient persons. The droplets do not remain suspended in the air and generally travel only a short distance (less than or equal to one meter) making contact with respiratory-droplet contaminated surfaces another possible source of transmission. The typical incubation period is one to four days (average is two days). Adults shed influenza virus from the day before symptoms begin through five to ten days after illness onset. Young children shed the virus several days before illness onset, and can be infectious for ten or more days after onset of symptoms. Severely immunocompromised persons can shed virus for weeks to months.⁵

Influenza viruses are enveloped, and have a segmented, single-stranded RNA genome. Hemagglutinin (H) and neuraminidase (N) are envelope proteins responsible for the attachment of influenza virus to host cells, and the release of virus from host cells, respectively. New strains of influenza A and B viruses emerge as the result of point mutations in the H gene (antigenic drift), or in the case of influenza A virus, after reassortment of H and N sequences from two different subtypes (antigenic shift). The emergence of new influenza A subtypes is often responsible for global pandemics. Influenza surveillance programs monitor for the emergence of any novel strains in humans caused by reassortment.²

Influenza surveillance by state and local health departments and the Centers for Disease Control and Prevention (CDC) can provide information regarding the presence of influenza viruses in the community and can also identify the predominant circulating types, influenza A subtypes, and strains of influenza. The Influenza-like Illness Surveillance Network (ILINet) is key to the success of the Florida Department of Health's (DOH) Influenza Surveillance System.^{4, 7}

An ILINet provider conducts surveillance of patient visits each week by age group (0-4 years, 5-24 years, 25-49 years, 50-64 years, and 65+ years) year round for Influenza-like illness (ILI). This data is transmitted via the Internet or faxed to a central database at the CDC and is critical for monitoring influenza's impact in Florida. In combination with other respiratory surveillance data collected by the Florida DOH, Bureau of Epidemiology and the CDC, this data provides a national picture of influenza virus and ILI activity in the U.S., as well as Florida. It can also be used to guide prevention and control activities, vaccine strain selection, and along with diagnostic testing this information can aid clinical judgment and help guide treatment decisions and patient care.⁷



The availability and use of commercial Rapid Influenza Diagnostic Tests (RIDT) by laboratories and clinics have substantially increased in recent years. Because influenza RIDTs provide a result in 30 minutes or less, positive results from tests performed during the influenza “season” can significantly impact patient treatment and management however, accuracy depends upon prevalence. The positive and negative predictive values vary considerably depending upon the prevalence of influenza in the community.^{2, 8}

- False-positive (and true-negative) influenza test results are more likely to occur when disease prevalence is low, which is generally at the beginning and end of the influenza season.
- False-negative (and true-positive) influenza test results are more likely to occur when disease prevalence is high, which is typically at the height of the influenza season.⁸

Sensitivity and predictive value of clinical definitions vary, depending on the prevalence of other respiratory pathogens and the level of influenza activity. Among generally healthy older adolescents and adults living in areas with confirmed influenza virus circulation, estimates of the positive predictive value of a simple clinical definition of influenza (acute onset of cough and fever) for laboratory-confirmed influenza infection have varied (range: 79 percent—88 percent).⁵

Because the specificity of RIDTs is less than that of viral culture, the positive predictive value is poor when the tests are performed outside of the influenza season. When influenza activity is low or sporadic, positive RIDT results should be confirmed by additional tests. The RIDTs can be performed on respiratory specimens from suspected cases of novel influenza using standard BSL-2 conditions in a Class II biological safety cabinet.²

How can you protect yourself and your loved ones from influenza? The flu vaccine is the first and most important step in protecting against this serious disease. The CDC recommends a yearly flu vaccine for everyone 6 months of age and older. While there are many different influenza viruses, the seasonal flu vaccine is designed to protect against the main viruses that research suggests will cause the most illness during the upcoming flu season. People should begin getting vaccinated as soon as the flu vaccine becomes available, ideally by October, to ensure that as many people as possible are protected before flu season begins.⁹



Influenza A (H1N1), A (H3N2), and one or two influenza B viruses (depending on the vaccine) are included in each year's influenza vaccine. A flu vaccine can protect against influenza viruses that are the same or related to the viruses in the vaccine; however, seasonal flu vaccine does not protect against influenza C viruses nor will it protect against infection and illness caused by other viruses that also cause influenza-like symptoms. In addition to getting vaccinated, you can take everyday preventive actions like staying away from sick people and washing your hands to reduce the spread of germs. If you are sick with the flu, stay home from work or school to prevent spreading the flu to others.^{1, 9}

For the most current information about influenza in Florida, please see Florida's weekly surveillance report, the Florida Flu Review, which can be found at: <http://www.floridahealth.gov/diseases-and-conditions/influenza/Florida%20Influenza%20Surveillance%20Reports/index.html>.^{5, 6}

References.

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3. Centers for Disease Control and Prevention, **Rapid Diagnostic Testing for Influenza: Information for Clinical Laboratory Directors** - <http://www.cdc.gov/flu/professionals/diagnosis/rapidlab.htm>
4. Centers for Disease Control and Prevention, **Influenza Symptoms and the Role of Laboratory Diagnostics** - <http://www.cdc.gov/flu/professionals/diagnosis/labrolesprocedures.htm>
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6. Florida Department of Health, **Influenza** - <http://www.floridahealth.gov/diseases-and-conditions/influenza/index.html>
7. Florida Department of Health, **Florida ILINet Influenza Surveillance** - <http://www.floridahealth.gov/diseases-and-conditions/influenza/florida-ilinet-influenza-surveillance.html>
8. Centers for Disease Control and Prevention, **Rapid Diagnostic Testing for Influenza: Information for Clinical Laboratory Directors** - <http://www.cdc.gov/flu/professionals/diagnosis/rapidlab.htm>
9. Centers for Disease Control and Prevention, **What You Should Know for the 2014-2015 Influenza Season** - <http://www.cdc.gov/flu/about/season/flu-season-2014-2015.htm>

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ENTEROVIRUS D68 TESTING AT THE FLORIDA DEPARTMENT OF HEALTH, BUREAU OF PUBLIC HEALTH LABORATORIES

Laboratory Testing at BPHL:

Diagnostic enterovirus D68 testing is available at BPHL for hospitalized severely ill children. Enterovirus testing will be performed only on influenza and respiratory syncytial virus (RSV) negative specimens and includes real-time RT-PCR, cell culture, and sequencing or serum neutralization RT-PCR results for enteroviruses are normally available within 48 hours of specimen receipt. Strain typing of enteroviruses takes a minimum of two weeks.

Acceptable Specimens

1. Respiratory specimens from acutely ill children within three days of symptom onset are preferred: throat or nasal swab, nasopharyngeal (NP)/oropharyngeal (OP) swabs, deep respiratory samples, and fresh or frozen tissues
2. Swabs should be placed in a vial of viral transport media and labeled appropriately
3. The value of other specimens (e.g. stool, rectal swab, serum, cerebrospinal fluid) for the detection of enterovirus D68 is undetermined at this time

Test Order

1. Complete BPHL DH1847 submission form
2. Virology section of form:
 - A. Indicate specimen type and source
 - B. Choose tests 1810 (Enterovirus PCR), and 1800 (Enterovirus Virus culture)
 - C. Include relevant clinical symptoms (respiratory)

Shipping

1. Package samples according to IATA/DOT packaging instructions for Biological Substances UN3373 and transport to BPHL Jacksonville or Tampa using the address printed on the DH1847 submission form.
2. Ship refrigerated samples in a cooler box with sufficient frozen gel ice packs within four days of collection to keep specimens cool. Ship frozen samples in a cooler box with dry ice.
3. Ship overnight for next day delivery Tuesday through Friday.
4. Contact BPHL **before** sending shipments for Saturday delivery

For additional questions, please contact the Bureau of Public Health Laboratories—Tampa at (813) 974-8000 or the Bureau of Public Health Laboratories—Jacksonville at (904) 791-1540.



HAZARDOUS LABEL CHANGES EFFECTIVE OCTOBER 1, 2014

Dr. Pat Payne, NLTN Packaging and Shipping Consultant has written a description of the changes to dry ice and infectious substances (6.2) labels.

Are You Prepared for Hazard Label Changes Effective October 1, 2014?

By Dr. Patricia Payne, NLTN Packaging and Shipping Consultant

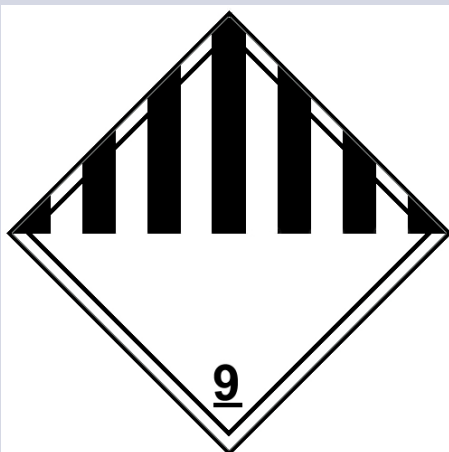
As of October 1, 2014, dry ice and infectious substance (6.2) hazard labels will change. The new hazard labels can be used immediately.

Except for size and color, the Division 6.2 (infectious substance hazard label must be as below:

These changes came about due to changes in the role of the Centers for Disease Control and Prevention (CDC) and to align with international air regulations. CDC is no longer accepting calls providing notice of incidents involving an infectious substance. Therefore, it was necessary to remove the text in the lower half of the infectious substance label containing that information.



Except for size and color, the Class 9 (Miscellaneous Hazardous Materials) hazard label used for dry ice must be as below:



The thin horizontal line running across the Class 9 hazard label at its midpoint was removed. The presence of that line on the Class 9 label has resulted in some international shipments being delayed in transit in order to re-label according to international regulations. Although this has not necessarily affected packages containing infectious substances packed on dry ice, it applies to all Miscellaneous Hazardous Material packages and thus, applies to our packages.

A recent notice was released concerning the size of the marking of the UN/ID number and letters UN, indicating that ICAO will require the size of the packages and at least 6 mm high for non-bulk packaging as of January 1, 2015. Although that notice has

generated concern in the medical community, that requirement was added to the DOT and IATA transportation regulations in 2013. As only non-bulk packaging is allowed for category A and B infectious substances, any labels or pre-labeled packages purchased in the past two years for infectious substances likely have the correct height markings. Some label vendors will be changing all their labels to the 12 mm height to allow them to be used on both non-bulk and bulk packaging. Please be aware either height 6 mm or 12 mm is allowed for use on non-bulk packages used for division 6.2 hazardous materials.

Please refer all packaging and shipping questions to Dr. Payne via email: aphlpayne@twc.com.



CHEMICAL THREAT (CT) PREPAREDNESS TRAINING

The CT laboratory coordinators are continuing to reach out to the health and medical community by offering training for CT preparedness at hospitals and county health departments (CHDs). This training covers chemical terrorism awareness and the collection of clinical specimens after a chemical terrorism event. Hospital and CHD staff play an important role in the response to a chemical exposure event since clinical specimens will be collected for analysis. For your convenience and to increase participation, this training can be presented at your facility. Each course lasts approximately one hour with one 15-minute break between courses. Florida clinical laboratory and nursing continuing education credits will be offered. Training manuals, "hands on" exercise materials, and CT preparedness kits will be provided. This training is recommended for physicians, nurses, epidemiologists, emergency department personnel, phlebotomists, hospital and health department laboratory personnel, and others who may collect clinical specimens. Contact the CT laboratory coordinators in your region for more information (see the Bureau of Public Health Laboratories Directory on the back of this document for contact information).

LABORATORY RESPONSE NETWORK (LRN) TRAINING—BIOLOGICAL DEFENSE

The BPHL is currently offering an LRN Sentinel Laboratory training course at no cost to you at your facility. This training follows the American Society for Microbiology (ASM) Sentinel Level Clinical Laboratory Protocols for Suspected Biological Threat Agents and Emerging Infectious Diseases. Scheduling the training at your facility is a relatively painless process. Determine when you would like to have the training and how many people will be attending. A time will be set up that is convenient for all. The training materials are provided, as well as the biodefense reference manuals for your laboratory.

The training syllabus includes: 1) an overview of the LRN; 2) the ASM protocols for ruling out potential bioterrorism agents and how to refer a sample to the state LRN Public Health reference laboratory when a bioterrorism agent cannot be ruled out; 3) the role of the sentinel laboratory in responding to pandemic influenza; 4) a brief introduction to packaging and shipping of infectious substances; 5) an introduction to the CDC Select Agent Program; and 6) the College of American Pathologists Laboratory Preparedness Exercise (CAP LPX).

This class awards Florida clinical laboratory continuing education credits based on five hours of instruction. Please contact Betty Wheeler at (904) 791-1568 (Betty.Wheeler@FLhealth.gov) to schedule a class for your facility.



AMERICAN SOCIETY FOR MICROBIOLOGY (ASM) SENTINEL LEVEL CLINICAL LABORATORY PROTOCOLS FOR SUSPECTED BIOLOGICAL THREAT AGENTS AND EMERGING INFECTIOUS DISEASES

The American Society for Microbiology (ASM) Sentinel Level Clinical Laboratory guidelines for *Burkholderia* and *Francisella tularensis* were revised October 2014. Updated guidelines can be found at the ASM website: <http://www.asm.org/index.php/issues/sentinel-laboratory-guidelines>. Please remember to update all of your laboratory's biodefense reference manuals.

These protocols reflect the standard practices for specimen processing, as well as agent specific guidance. In addition to promoting standardization and uniformity of testing, adherence to and maintaining the highest level of safety practices is emphasized in the respective protocols.

COLLEGE OF AMERICAN PATHOLOGISTS LABORATORY PREPAREDNESS EXERCISE (CAP LPX)

Participation in the CAP LPX provides a means to exercise the capabilities and rule-out or refer processes for biological threat agents so that Sentinel Laboratories will be ready for a real event. Thanks to all of the Sentinel Laboratories that participated in the 2014 College of American Pathologists Laboratory Preparedness Exercise (CAP LPX) April and September challenges. If you would like to participate in the 2015 CAP LPX and are not already on our list of participants, or would like to be removed from our list of participants, please contact Betty Wheeler at 904-791-1568 or email Betty.Wheeler@FLhealth.gov.

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