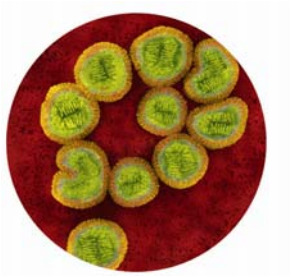
Interim Guidance and Information
2009 H1N1 Influenza A Virus



Key Facts about the 2009 H1N1 Influenza A situation:
As more ill persons have been identified and more epidemiologic and clinical information has been gathered, CDC recommends that testing be prioritized for those with severe respiratory illness and those at highest risk of complications from influenza. Patients with uncomplicated disease due to confirmed novel influenza A (H1N1) virus infection have experienced fever, chills, headache, upper respiratory tract symptoms (cough, sore throat, rhinorrhea, shortness of breath), myalgias, arthralgias, fatigue, vomiting, or diarrhea. Clinicians should test persons for the novel influenza (H1N1) virus if they have an acute febrile respiratory illness or sepsis-like syndrome. Certain groups may have atypical presentations including infants, elderly and persons with compromised immune systems. Priority for testing includes persons who 1) require hospitalization or 2) are at high-risk for severe disease. Clinicians should be aware of local guidance on testing and should use their clinical judgment in addition to this guidance for deciding when to test for novel influenza A (H1N1). For complete details: http://www.cdc.gov/h1n1flu/identifyingpatients.htm or http://www.cdc.gov/h1n1flu/casedef_swineflu.htm.

Preferred respiratory specimens:
Specimens should be collected as soon as possible after illness onset. Collection of nasopharyngeal swabs/aspirates or nasal washes/aspirates is preferred. If these specimens cannot be collected, a combined nasal swab with an oropharyngeal swab is acceptable. Specimens should be placed into sterile viral transport media and immediately placed on ice or cold packs or at 4°C (refrigerator) for transport to the laboratory.
For complete details: http://www.cdc.gov/h1n1flu/specimencollection.htm.

Specimen Collection & Transport:
Ideally, swab specimens should be collected using swabs with a polyester or Dacron® tip and an aluminum or plastic shaft. Calcium alginate swabs are not acceptable, and swabs with cotton tips and wooden shafts are not recommended. Specimen collection vials should contain 1-3 ml of viral transport medium, such as Remel M4RT®. All respiratory specimens should be kept at 4°C until they can be placed at -70°C. If a -70°C freezer is not available, specimens should be kept at 4°C, preferably no longer than 1 week. Clinical specimens should be shipped on dry ice in appropriate packaging.

Safety:
The most up to date, relevant information, can be found at:
http://www.cdc.gov/h1n1flu/guidelines_labworkers.htm
http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm.

Test recommendations:
Real-time RT-PCR for influenza A, B, H1, H3 at a State Health Department Laboratory is recommended. Currently, 2009 H1N1 Influenza A virus will test positive for influenza A and negative for H1 and H3 by real-time RT-PCR. If reactivity of real-time RT-PCR for influenza A is strong (e.g. Ct ≥ 30), it is more suggestive of a novel influenza A virus. Confirmation as 2009 H1N1 Influenza A virus is performed at CDC currently, but may be available in state public health laboratories soon.

Rapid influenza antigen testing:
Commercially available rapid tests can detect and distinguish between influenza A and B viruses. The ability of these tests to detect this new strain of virus has not been determined. A patient with a positive rapid test for influenza A may meet the criteria for a probable case. A negative rapid test may be a false negative and should not be assumed a final diagnostic test for 2009 H1N1 Influenza A virus infection.

Immunofluorescence (DFA or IFA):
These tests can distinguish between influenza A and B viruses. A patient with a positive for influenza A by immunofluorescence may meet criteria for a suspected case. However, it is not possible to differentiate from seasonal influenza A viruses. Immunofluorescence depends upon the quality of a clinical specimen, operator skills, and has unknown sensitivity and specificity to detect human infection with 2009 H1N1 Influenza A virus in clinical specimens. A negative immunofluorescence could be a false negative and should not be assumed a final diagnostic test for 2009 H1N1 Influenza virus infection.

Viral culture:
Isolation of 2009 H1N1 Influenza A virus is diagnostic of infection, but may not yield timely results for clinical management. A negative viral culture does not exclude infection with 2009 H1N1 Influenza A virus.

The above information is adapted from content provided by the Centers for Disease Control and Prevention (CDC) at www.cdc.gov/h1n1flu.

Last Updated: 5/8/2009

Xpect® Flu A&B

A rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigen (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients.

Each kit contains 20 test devices, Specimen Diluent (20 ml), Dilution tubes (20), Disposable transfer pipettes (20), and Quality control swabs (1 Flu A positive; 1 Flu B positive).

- Simple to perform walk-away procedure
- Easy-to-read results in 15 minutes
- Convenient room temperature storage
  - R24600
  - R246003: Xpect® Flu A&B Control Swabs – 20 sets

MicroTest™ Collection & Transport Systems (M4RT® & M6™)

MicroTest™ are trusted, reliable collection and transport systems that provide ample fill volume to run multiple tests. MicroTest™ can be used for long-term culture storage and is compatible with culture, immunoassays, and molecular diagnostics.

	M4RT®	M6™
Use	Viruses, *Chlamydia*	Universal*
Storage	Room Temperature	Room Temperature
Fill Volume	3 ml	1.5 ml
72/Pk Transport Tubes	Transport media in 15 ml conical tube	
	R12505	R12530
100 Kits/Pk with transport media in 15 ml conical tube; zip seal bag	w/ 1 plastic shaft and 1 mini-tip aluminum shaft swab	
	R12578	R12582
	w/micro-tipped flocked swab (NPG swab)	
	R12566	R12561

*Universal = Viruses, *Chlamydia*, *Ureaplasma*, *Mycoplasma*
Products have 18 mos. dating from date of manufacture.

Imagen™ Influenza A+B

For detection and identification of Influenza virus strains A and B in clinical specimens and cultures. Sufficient for 50 tests.

- Single step procedure with results in 30 minutes
- Easy-to-read immunofluorescence
- Convenient room temperature storage
  - K610511-2
  - S611230-2: Positive Control Slide (each)

Additional Tests:

BinaxNOW® Influenza A/B Kit

Rapid, one-step lateral flow test that will differentiate between Flu A and Flu B within 15 minutes.

- R25416: 22/kit
- R25400: BinaxNOW® Nasopharyngeal Accessory Pack