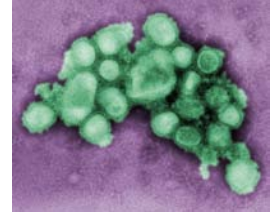


## REGARDING RAPID FLU TESTS FOR NOVEL H1N1 INFLUENZA (SWINE FLU) VIRUS

The currently circulating novel H1N1 influenza virus (also referred to as swine flu) is an influenza A virus. Rapid influenza diagnostic tests can help in the diagnosis and management of patients who present with signs and symptoms compatible with influenza. Such tests detect seasonal influenza A and B viral nucleoprotein antigens in respiratory specimens.



**Data is not yet available to inform recommendations on the use of rapid influenza diagnostic tests in patients with novel H1N1 virus infection.** However, it is reasonable to assume that rapid diagnostic tests that detect influenza A viral nucleoprotein antigen can detect novel H1N1 flu infection in respiratory specimens as these nucleoprotein antigens are highly conserved across influenza A viruses. **The sensitivity and specificity of the different rapid tests is not yet known for this novel virus.**

The US Centers for Disease Control (CDC) has received anecdotal reports of false positive and false negative results. Clinicians may consider using rapid diagnostic tests as part of their evaluation of patients with signs and symptoms compatible with influenza, **but results should be interpreted with caution.** Final confirmation of novel H1N1 flu infection can only be made by reverse-transcription polymerase chain reaction (RT-PCR) or viral culture.

### Reliability and Interpretation of Rapid Influenza Test Results

The reliability of rapid influenza diagnostic tests depends largely on the conditions under which they are used, and are entirely based on the experience with seasonal influenza.

- For detection of seasonal influenza virus infection, sensitivities of rapid diagnostic tests are approximately 50-70% when compared with viral culture or RT-PCR, and specificities of rapid diagnostic tests for influenza are approximately 90-95%. **Sensitivity and specificity of these tests for detection of the novel H1N1 flu virus are unknown.**

Test sensitivity may vary depending on when in the course of illness the specimen is collected. Respiratory specimens for testing should be collected in the first 4-5 days of illness when viral shedding is greatest.

Given these limitations, the decision of whether or not to test patients with rapid influenza diagnostic tests should be based upon the patient's presenting symptoms, whether or not cases of novel H1N1 have been confirmed in the area, and/or the patient's risk for severe disease or other complications.

**In areas with many new confirmed cases of novel H1N1 flu infection and where community spread of H1N1 is occurring, patients who test positive on a rapid influenza diagnostic test can be treated empirically with antiviral medications if clinically indicated without further testing.**

- How to interpret a negative result: **Novel H1N1 flu virus infection cannot be excluded when a patient tests negative for influenza A by rapid antigen test.** If the patient has an epidemiologic link to a confirmed case (i.e. had close contact with a confirmed case), or has either traveled to or resides in a community where there are one or more confirmed novel H1N1 cases, further testing and treatment should be based upon clinical suspicion, severity of illness, and risk for complications. If there is no epidemiologic link and the patient has mild illness, further testing and treatment are not recommended.

Sources: US Centers for Disease Control: [http://www.cdc.gov/h1n1flu/guidance/rapid\\_testing.htm](http://www.cdc.gov/h1n1flu/guidance/rapid_testing.htm) and <http://www.cdc.gov/h1n1flu/identifyingpatients.htm>

REGARDING H1N1 "Swine Flu" TESTING  
FOR ALL MD NOW PATIENTS



By Florida Law, all medical treatments, prescriptions and orders for laboratory tests are issued under a Medical Practitioner's license and must be based on a medical evaluation which requires a physical examination of all new patients and must include appropriate documentation - such as a patient's vital signs and other important clinical observations.

Therefore it is MANDATORY that all patients receiving influenza testing, treatment, orders for lab work or other clinical evaluations as well as prescriptions for pharmaceuticals must be physically seen and evaluated by a physician or medical practitioner and the visit must be appropriately documented in the medical record. As with all illnesses and injuries, any treatment or pharmaceuticals prescribed at MD Now will be issued solely upon the discretion of your healthcare practitioner based on their clinical opinion and medical examination.

As of June 30, 2009, the Florida Department of Health has determined ninety percent of positive influenza tests in the state public health laboratory in recent weeks have been positive for the new 2009 influenza A H1N1 "swine flu" virus, rather than the seasonal influenza viruses that were circulating last winter and spring. There have been at least 1200 persons reported in Florida with lab-confirmed novel 2009 influenza A H1N1 infection.

Therefore, if you are a patient who tests positive for Influenza A via a rapid flu test, your practitioner may determine that no further testing is required and may recommend treating your flu symptoms empirically for the H1N1 "Swine Flu" virus. This means that because of the high likelihood you do have the H1N1 virus if you test positive for Influenza A via rapid flu test, your practitioner may decide to treat you exactly as though you had tested positive for the H1N1 virus. If you are in a high risk category, your practitioner may decide not to delay treatment to await results of further testing.

Likewise, if you are in a high risk category and you do not test positive for Influenza A with rapid flu test are experiencing symptoms of the flu, your practitioner may still decide to treat you empirically for the flu based on your clinical symptoms and the possibility of a false negative result. (See Page One: "Important Information for Our Patients Regarding Rapid Flu Tests for the Novel H1N1 Influenza 'Swine Flu' Virus").

Per the CDC, a person who is at high-risk for complications of novel influenza (H1N1) virus infection is defined as the same for seasonal influenza at this time. As more epidemiologic and clinical data become available, these risk groups might be revised:

- Children younger than 5 years old. The risk for severe complications from seasonal influenza is highest among children younger than 2 years old.
- Adults 65 years of age and older.
- Persons with the following conditions:
  - Chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological (including sickle cell disease), neurologic, neuromuscular, or metabolic disorders (including diabetes mellitus);
  - Immunosuppression, including that caused by medications or by HIV;
  - Pregnant women;
  - Persons younger than 19 years of age who are receiving long-term aspirin therapy;
  - Residents of nursing homes and other chronic-care facilities.

**IMPORTANT: If you are not in a high risk category and you decide you would still like further and specific laboratory testing for the H1N1 "Swine Flu" virus, please be advised your insurance company may not cover the costs of such testing, in which case you would be fully responsible for the cost of this particular test.**

**Most private health insurances vary considerably. The only way to be certain whether you are covered for swine flu testing is for you to contact your health plan directly to determine if you may be eligible for reimbursement.**

Sources: <http://www.cdc.gov/h1n1flu/recommendations.htm> and [http://www.doh.state.fl.us/Disease\\_ctrl/epi/swineflu/Guidance\\_6-30.pdf](http://www.doh.state.fl.us/Disease_ctrl/epi/swineflu/Guidance_6-30.pdf)