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Interim Guidance on Specimen Collection, Processing, and Testing for Patients with Suspected Swine-Origin Influenza A (H1N1) Virus Infection

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Objective: To provide interim guidance on appropriate specimen collection, storage, processing, and testing for patients with suspected swine-origin influenza A (H1N1) virus infection.

Case Definitions

A *confirmed case* of S-OIV infection is defined as a person with an acute febrile respiratory illness with laboratory confirmed S-OIV infection at CDC by one or more of the following tests:

1. real-time RT-PCR
2. viral culture

Case definitions for *probable and suspected* cases can be found at: http://www.cdc.gov/swineflu/casedef_swineflu.htm

Duration of viral shedding

The duration of shedding with swine-origin influenza A (H1N1) virus is unknown. Therefore, until data are available, the estimated duration of viral shedding is based upon seasonal influenza virus infection. Infected persons are assumed to be shedding virus and potentially infectious from the day prior to illness onset until resolution of fever. Infected persons should be assumed to be contagious up to 7 days from illness onset. Some persons who are infected might potentially shed virus and be contagious for longer periods (e.g. young infants, immunosuppressed, and immunocompromised persons).

Testing for swine-origin influenza A (H1N1) virus

Clinicians should consider testing suspected cases of swine-origin influenza A (H1N1), especially those with severe illness, by obtaining an upper respiratory specimen to test for swine-origin influenza A (H1N1) virus.

Preferred respiratory specimens: The following should be collected as soon as possible after illness onset: nasopharyngeal swab/aspirate or nasal wash/aspirate. If these specimens cannot be collected, a combined nasal swab with an oropharyngeal swab is acceptable. For patients who are intubated, an endotracheal aspirate should also be collected. Specimens should be placed into sterile viral transport media (VTM) and immediately placed on ice or cold packs or at 4°C (refrigerator) for transport to

laboratory. Recommended infection control guidance is available for persons collecting clinical specimens: http://www.cdc.gov/swineflu/guidelines_infection_control.htm and for laboratory personnel: http://www.cdc.gov/swineflu/guidelines_labworkers.htm

Swabs

Ideally, swab specimens should be collected using swabs with a synthetic tip (e.g. polyester or Dacron®) and an aluminum or plastic shaft. Swabs with cotton tips and wooden shafts are not recommended. Specimens collected with swabs made of calcium alginate are not acceptable. The swab specimen collection vials should contain 1-3ml of viral transport medium (e.g. containing protein stabilizer, antibiotics to discourage bacterial and fungal growth, and buffer solution), such as M4RT or the BD Universal Viral Transport System (<http://www.bd.com/ds/productCenter/220240.asp>)

Storing Clinical Specimens: 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.

Shipping clinical specimens: Clinical specimens should be shipped on dry ice in appropriate packaging.

All specimens should be labeled clearly and include information requested by your state public health laboratory. Suspected case specimens shipped from the state public health laboratory to CDC should include all information required for seasonal influenza surveillance isolate or specimen submission.

Recommended Tests

Real-time RT-PCR for influenza A, B, H1, H3 at a State Health Department Laboratory is recommended. Currently, swine-origin influenza A (H1N1) 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 \leq 30) it is more suggestive of a novel influenza A virus. Confirmation as swine-origin influenza A (H1N1) virus is performed at CDC currently, but may be available in state public health laboratories soon.

Other influenza tests

Rapid influenza antigen test: Also, these tests have unknown sensitivity and specificity to detect human infection with swine-origin influenza A (H1N1) virus in clinical specimens, and have suboptimal sensitivity to detect seasonal influenza viruses. Therefore, a negative rapid test could be a false negative and should not be assumed a final diagnostic test for swine-origin influenza 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 swine-origin influenza A (H1N1) virus in clinical specimens. Therefore, a negative immunofluorescence could be a false negative and should not be assumed a final diagnostic test for swine-origin influenza infection.

Viral culture: Isolation of swine-origin influenza A (H1N1) virus is diagnostic of infection, but may not yield timely results for clinical management. A negative viral culture does not exclude infection with swine-origin influenza A (H1N1) virus.



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