

2009-H1N1 Influenza A (Swine Flu): CDC Biosafety Guidance

The following is the H1N1 Biosafety Guidance document provided by the Centers for Disease Control and Prevention (CDC) published on August 15, 2009. It clarifies biosafety concerns when handling H1N1 influenza A specimens and performing in-house testing.

Interim Biosafety Guidance for All Individuals Handling Clinical Specimens or Isolates Containing 2009-H1N1 Influenza A Virus (Novel H1N1) Including Vaccine Strains: These interim recommendations are subject to change as more information becomes available.

This guidance is for all individuals who may perform diagnostic and research activities including rapid diagnostic testing at the point of care with 2009-H1N1 Influenza A virus (Novel H1N1), including vaccine strains. This guidance document was updated to reflect the following:

1. For those performing rapid immunoassay tests for influenza, splash protection is required.
2. For those performing more complex procedures (e.g., direct or indirect fluorescent antibody tests [DFA, IFA], culture, molecular assays), a Class II Biosafety cabinet (BSC) in a Biosafety level-2 (BSL-2) laboratory is required.

Biosafety level-3 (BSL-3) practices are no longer required for viral isolation. The guidance is consistent with the recommendations in Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition, Section VII, Agent Summary Statement for contemporary, circulating human influenza strains (p. 224-226). For interim guid-

ance on specimen collection, processing, and testing for 2009-H1N1 influenza A virus (novel H1N1) visit, <http://www.cdc.gov/h1n1flu/specimencollection.htm>.

Rapid Tests (performed in a variety of laboratory and non-laboratory settings): Many FDA-cleared rapid immunoassay tests for influenza are available, involving different methods and processing steps. Each require assessment of the risks for generation of aerosols or contact with infectious material. Most rapid test methods used at the point of care only include simple steps such as inserting a swab into medium or pipetting specimens and reagents and do not generate aerosols, thus requiring only splash protection. If there is a risk of generating an aerosol with a vortexing step, one should follow the safety guidance in the next section, "Clinical Laboratory Testing (Laboratory Diagnostic Work), Viral Isolation and Laboratory Research." Rapid immunoassay test procedures outside a

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

Anemia	PAP Smear
ANA	PAP Smear Referral
Bioterrorism Event Mgmt	Point-of-Care Testing
Bleeding Disorders	PSA
Chlamydia	Rash Illness
Diabetes	Red Cell Transfusion
Group A Strep Pharyngitis	Renal Disease
Group B Streptococcus	STD
Hepatitis	Thyroid
HIV	Tuberculosis
Infectious Diarrhea	Urinalysis
Intestinal Parasites	Wellness
Lipid Screening	

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Class II Biosafety cabinet (BSC) should be performed to minimize the creation of anticipated splashes and/or aerosols. The appropriate personal protective equipment (PPE) for minimizing risks associated with splash for these types of rapid tests include:

- laboratory coat
- gloves
- eye protection
- facemask (surgical, dental, medical procedure, isolation, or laser masks)*

** If testing is performed in a Class II BSC as described in the next section, use of eye protection and facemask would not be necessary. A laboratory may determine that a splash shield providing protection of the entire face fulfills the need for separate eye protection and facemask.*

Clinical Laboratory Testing (Laboratory Diagnostic Work): Viral diagnostic and research laboratory testing should be conducted in a Biosafety level-2 (BSL-2) laboratory for the following:

- those rapid tests involving steps that could generate aerosols (e.g. vortexing)
- direct or indirect fluorescent antibody tests (DFA, IFA) to detect viral antigens in clinical specimens
- growth of virus in cell culture or embryonated eggs

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Website addresses:

DOH home page: <http://www.doh.wa.gov>
LQA home page: <http://www.doh.wa.gov/lqa.htm>
PHL home page:
<http://www.doh.wa.gov/EHSPHL/PHL/default.htm>

- molecular-based assays
- general laboratory research

Viral isolation and all sample manipulations with the potential for creating an aerosol should be done inside a Class II Biosafety cabinet (BSC) that is certified annually. A BSC designated as Class II should have the following features: unidirectional (laminar) air flow with HEPA filtration (supporting personal and environmental safety). Personal protective equipment (PPE) and personal and environmental protection should include the following based on a site-specific risk assessment:

- laboratory coat
- gloves
- Class II BSC (provides for splash and aerosol protection).

For more information, see *Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition, Section IV, Laboratory Biosafety Level Criteria* (p. 44-49) at the following website: <http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>

Laboratory waste: All biohazardous waste disposal procedures should be followed as outlined in your facility's standard laboratory operating procedures. Steam autoclaving is the preferred method for all decontamination processes. Alternative methods may be considered based on applicable local, state, and federal regulations, as well as on a site-specific risk assessment.

Appropriate disinfectants: Several chemical disinfectants including chlorine, alcohols, peroxygen, detergents, iodophors, quaternary ammonium and phenolic compounds are effective against human influenza viruses if used at the correct concentration for the appropriate contact time as specified in the manufacturer's recommendations.

Decontaminate work surfaces and equipment as soon as possible after specimens are processed. Studies have shown that influenza viruses can survive on environmental surfaces and can infect a person for up to 2–8 hours after being deposited on the surface. More information on disinfection and sterilization is provided in "Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition Appendix B" (<http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>).

Occupational Health: All personnel should self-monitor for fever and other symptoms such as cough, sore throat, runny or stuffy nose, body aches, headache, chills, and

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fatigue. Report any influenza-like illness to your supervisor immediately.

Personnel who have had an occupational exposure to any infectious agent, including 2009-H1N1 influenza A (novel H1N1), should immediately inform their supervisor or manager. Antiviral chemoprophylaxis is available and should be considered. For additional information on antiviral treatment, visit <http://www.cdc.gov/h1n1flu/recommendations.htm> to view a copy of the “Interim Guidance on Antiviral Recommendations for Patients with Confirmed or Suspected Swine Influenza A (H1N1) Virus Infection and Close Contacts.”

Additional Resources:

- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition: <http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm>
- <http://www.osha.gov/Publications/OSHA3327pandemic.pdf>
- Evaluation of Rapid Influenza Diagnostic Tests for Detection of Novel Influenza A (H1N1) Virus --- United States, 2009: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5830a2.htm?s_cid=mm5830a2_e

2009 H1N1 Influenza WAPHL Update

by Yolanda Houze, DOH/PHL

In November of 2008, the Washington State Public Health Laboratories (WAPHL) participated in a full-scale exercise involving an influenza pandemic. During this exercise we were able to test our pandemic planning and response capability to see where there were gaps. We artificially removed some staff from the lab by giving them a “Go Home Sick” card just so we could see the impact of having staff out due to illness. It didn’t take long to realize that those staff remaining would not be able to keep up with the workload of the lab. From that time until March of this year we concentrated on training more staff to perform flu testing by the rRT-PCR method, which we, along with five other labs in the country, had validated for CDC and the FDA.

On Sunday, April 28th, the WAPHL Director was asked to provide influenza testing for two Seattle travelers who had just returned from Mexico. The previous week there had been news releases about an influenza outbreak in Mexico. Because the WAPHL had been one of the laboratories to validate the CDC rRT-PCR influenza test and staff had been trained to perform it, the laboratory was ready to respond. Having this capability also meant that the laboratory was able to quickly implement the CDC Swine Flu assay which was shipped the following weekend.

Since April 28th the laboratory has tested more than 2335 samples and found more than 970 positive for H1N1. We continue to test based on the criteria established by the Communicable Disease Epidemiology Division. During May and June the laboratory had to perform both diagnostic and surveillance testing since few labs had the H1N1 test capability. Commercial labs are now able to test for this virus, and the WAPHL will focus more on the surveillance testing. H1N1 testing will be performed this fall for:

- Deceased patients and critically ill patients (i.e. ICU admission) suspected to have influenza
- Hospitalized patients who have tested positive for influenza
- Patients involved in outbreaks of influenza, after approval from the local health jurisdiction

The CDC H1N1 protocol requires that testing be done from the following sample types:

- Nasopharyngeal swabs in Viral Transport Medium (VTM)
- Throat swab in VTM
- Nasal aspirate (not nasal wash) in VTM
- Nasopharyngeal/throat swab in VTM
- Viral Isolate (shipped on dry ice)

We’ve learned a lot these past few months, but having had a plan in place and exercising it made a huge difference in our ability to respond when we needed to. We will continue to keep clinical laboratories informed of any changes in our test-

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ing criteria through email notifications and by posting information on the Department of Health Website at <http://www.doh.wa.gov/h1n1/>. Click on “Public Health and Health Care” and scroll to “Guidance.”

Remember the things that you can do to help prevent the spread of colds and flu---

- Cover your cough
- Wash your hands
- Stay home when you are sick

Stay Healthy!

H1N1 Influenza Websites of Interest

- Washington State Department of Health: <http://www.doh.wa.gov/h1n1/>
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition: <http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>
- <http://www.osha.gov/Publications/OSHA3327pandemic.pdf>
- CDC: Evaluation of Rapid Influenza Diagnostic Tests for Detection of Novel Influenza A (H1N1) Virus --- United States, 2009: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5830a2.htm?s_cid=mm5830a2_e

Training Course: Basic Course in Microscopic Examination of Vaginal Fluid (Wet Mount)

The Washington State Public Health Laboratories and University of Washington Seattle STD/HIV Prevention Training Center are sponsoring a training course on the Microscopic Examination of Vaginal Fluid (Wet Mount) on Friday, November 13, 2009 from 9:00 a.m. - Noon.

This half-day workshop is designed for healthcare providers, nurses, and laboratory personnel performing vaginal wet mounts. Topics discussed in the course include specimen handling, performance, and interpretation of microscopic examination of vaginal wet mounts. Discussion includes proper collection of specimens, result reporting, CPT Coding, and quality assurance practices. Participants will perform actual microscopic examination of vaginal wet mounts.

Participants receive 0.3 CEUs for completion of this course. The registration fee is \$100. Please register online at www.seatlestdhivptc.org.

For more information or an application, please contact:

- seaptc@u.washington.edu, or
- call 206-685-9850.

16th Annual Clinical Laboratory Conference

The 16th Annual Washington State Clinical Laboratory Conference will be held at the Tukwila Community Center on November 9, 2009 from 8:00 am – 4:30 pm. Dennis Weissman will present the Keynote address entitled “*Update on Health System Reform and Medicare Payment & Policy Changes: How Do Labs & Pathologists Fit In and What’s Ahead For 2010?*” Michael Astion, MD, PhD, from the University of Washington, will present a session entitled “*Improving The Use of Laboratory Tests in Healthcare Systems.*” Daniel Jernigan, MD, MPH, Deputy Director of the Influenza Division at CDC will provide an update on the H1N1 virus at the state, national, and international levels. The remainder of the program will be finalized shortly. The conference flyer will be distributed by e-mail in the next couple of weeks and will be available on the LQA website at http://www.doh.wa.gov/hsqa/fsl/lqa_updates.htm. If you have any questions, please contact Leonard Kargacin at leonard.kargacin@doh.wa.gov or phone (206) 418-5416.

16th Annual Clinical Laboratory Conference

November 9, 2009
8:00 a.m. - 4:30 p.m.

Tukwila Community Center

The program will be available soon on the LQA web-site:

http://www.doh.wa.gov/hsqa/fsl/lqa_updates.htm

If you would like to receive a copy of the program, contact Leonard Kargacin:

phone: (206) 418-5416

e-mail: leonard.kargacin@doh.wa.gov

Calendar of Events

PHL Training Classes:

(<http://www.doh.wa.gov/ehsphi/phl/training/train.htm>)

Basic Course in Urine Sediments

October 15 OR 16 Shoreline

Northwest Medical Laboratory Symposium

October 21-24 Seattle

16th Annual Clinical Laboratory Conference

November 9 Tukwila

2010 ASCLS-WA Spring Meeting

April 22-24, 2010 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

For persons with disabilities, this document is available upon request in other formats. To submit a request, please call 1-800-525-0127 (TTY/TDD) 1-800-833-6388).



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