

# UPHL Guidelines for Influenza Sample Submission

## Seasonal Influenza and 2009 Pandemic Influenza A (H1N1)

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Revised January 26, 2010

Utah Public Health Laboratories (UPHL) offers Influenza testing (both for seasonal and 2009 Pandemic Influenza A (H1N1)) for hospitalized patients and for select other cases that have been screened and authorized for outbreak characterization testing by the Utah Department of Health's (UDOH) Bureau of Epidemiology. These tests are offered at no charge since they are used for public health surveillance purposes. UPHL is using a real time PCR (Polymerase Chain Reaction) testing protocol and kit provided by the Centers for Disease Control and Prevention (CDC). This protocol has strict rules for how it can be used for testing as defined by the Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA). UPHL must follow these rules for legal purposes.

We ask that our clients and providers be aware of and comply with these restrictions. CDC provides PCR kits to UPHL and CDC/FDA have authority to deny us the use of these kits if UPHL does not follow rules for the use of this kit. Complying with the following steps will ensure that testing will be completed in a timely, legal, and scientifically sound manner.

In order to ensure that testing is completed and results are reported promptly, the following criteria are required for samples to be tested at the UPHL for 2009 Pandemic Influenza A (H1N1) and Seasonal Influenza by PCR. Testing for specimens that do not meet the following criteria will be cancelled.

1. Sample sources approved in the FDA's EUA will be tested. UPHL can NOT do any off-label testing. Currently approved sample sources are:
  - a. Nasopharyngeal swabs (NPS),
  - b. Nasal swabs (NS),
  - c. Throat swabs (TS),
  - d. Dual NPS/TS swabs,
  - e. Nasal aspirates (NA), and/or
  - f. Viral culture isolates from patients with signs and symptoms of respiratory infection

*\*\*\*PLEASE NOTE that nasal washes and deep respiratory specimens (tracheal aspirates and bronchoalveolar lavage) are NOT acceptable specimens because FDA has not validated them yet for use with their PCR Influenza test kit. We will notify providers when this specimen source has been approved.*
2. Please mark the correct sample source on the test request form (sample sources listed above are the only approved sources for this test). Questionable sample sources (such as a sample identified as a nasal aspirate containing swabs, or a sample identified as a nasopharyngeal swab containing a large swab) cannot be tested.
3. UPHL is a Clinical Laboratory Improvement Amendments (CLIA) inspected laboratory. UPHL must comply with Federal Regulatory requirements to be compliant under their authority. In order to be compliant with standard CLIA regulations, specimen containers must be labeled with patient identification. If a sample container is not labeled, the sample cannot be tested.

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4. Specimen collection date must be provided. Specimens older than seven days cannot be tested. Shipping through UPS, FEDEX or other over-night or two day delivery service is recommended in order to receive samples within this time frame. Please keep samples cool and follow the appropriate packaging and shipping guidelines from the US Department of Transportation.
5. Collect two swab specimens if you are planning to do an in-house rapid influenza test. (Once a swab has been used for a rapid test, it cannot be used by UPHL for test confirmation.) Download a copy of the test request form [here](http://health.utah.gov/epi/h1n1flu/Lab/LabForm.html) (<http://health.utah.gov/epi/h1n1flu/Lab/LabForm.html>). Specimens should be placed into 1-3 ml of viral transport media such as M4. (Note: Culturettes and similar collection devices are for bacteria and cannot be used.) Package the specimen with the test request form. Keep specimens at 4°C until shipped to the lab. Send specimens within 72 hours of collection. Ship specimens refrigerated (on wet ice) as a category B infectious substance. Assure that the specimen will be received at UPHL within 72 hours of collection.
6. Test request forms must be completely filled out with the following required information in order for testing to be conducted:
  - Patient Name
  - Patient Date of Birth
  - Patient Age
  - Patient Sex
  - Patient County (not country) of Residence
  - Patient State of Residence
  - Provider Code
  - Specimen Collection Date
  - Specimen Source/Site
  - If patient is hospitalized
  - Facility where patient is hospitalized

Please note: the previous practice of UPHL calling providers for information if criteria are not met has been discontinued.

We suggest that you mark your provider code on a test request form and then make copies for use throughout the season. If you need assistance finding your provider code or setting up a provider code, please call UPHL at 801-965-2400 or 801-965-2561.

We are dedicated to providing the best service possible and value your assistance in assuring these criteria are met.

If you have further questions or need assistance regarding laboratory issues, please call the Molecular Biology Lab at 801-965-2561. For questions related to testing of individuals or clusters, contact your local health department or UDOH epidemiology 801-538-6191.