

Testing Criteria for Highly Pathogenic Avian Influenza (HPAI) H5N1 in Humans at PHEL

Guidelines for Clinical and Commercial Laboratories

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Avian Influenza H5N1 Testing Criteria

Send a specimen to the NJDOH Public Health, Environmental and Agricultural Laboratories (PHEAL) in the following circumstances:

- Consult with your local health department to determine if a patient exhibiting signs or symptoms of H5N1 avian influenza infection and/or exposure meets the case criteria to submit a sample for testing.
 - **NJ State Communicable Disease Service's Guidelines on Novel Influenza:**
https://www.nj.gov/health/cd/topics/novel_flu.shtml
- Any specimen that tests positive for influenza A but tests negative for seasonal influenza A subtypes [i.e., A(H1) and A(H3)].
 - This may also be referred to as an "unsubtypeable" influenza A specimen, or "Influenza A, subtype not detected".
 - More details about unsubtypeable influenza specimens are available on PHEL's website [here](#)

Specimen Collection and Storage:

Suspect HPAI H5N1 Cases

- Testing should be performed on persons who meet Epidemiologic criteria **AND either** Clinical **OR** Public Health Response criteria as outlined in the [Highly Pathogenic Avian Influenza A\(H5N1\) Virus in Animals: Interim Recommendations for Prevention, Monitoring, and Public Health Investigations](#)
- Before sending samples to PHEL, contact the [local health department](#) or communicable disease service to obtain **testing authorization**. PHEL will not test specimens received without authorization.
- For persons with suspected HPAI A(H5N1) virus infection, the following specimens should be collected as soon as possible after illness onset or when deemed necessary:
 - A nasopharyngeal swab **and** a nasal swab combined with an oropharyngeal swab (e.g., two swabs combined into one viral transport media vial).
 - If these specimens cannot be collected, a single nasopharyngeal or oropharyngeal swab is acceptable.
 - **If the person has conjunctivitis (with or without respiratory symptoms), both a conjunctival swab and a separate nasopharyngeal swab should be collected.**
 - Patients with severe respiratory disease also should have lower respiratory tract specimens (e.g., an endotracheal aspirate or bronchoalveolar lavage fluid) collected, if possible.

General Laboratory Guidance

- Collect specimens aseptically as soon as possible after symptom onset.
- For detailed instructions on how to collect respiratory specimens see here: [Respiratory Specimen Collection Quick Guide](#).
- Proper [infection control practices](#) should be followed during specimen collection.
 - See also [Interim Guidance for Infection Control Within Healthcare Settings when Caring for Novel Influenza A Viruses Associated with Severe Disease](#)
- All specimens should be labeled clearly with two patient identifiers (e.g. name and DOB) and include a printed paper requisition form with all required information in the package.
- If you are unsure whether a specimen needs to be sent to PHEL immediately, we prefer you freeze the specimen as soon as possible after collection and maintain frozen temperatures during shipping.

Specimen Types

The preferred respiratory specimen type for most respiratory viral testing is a **nasopharyngeal swab** collected into 1-3 mL of **viral transport media**.

- Additional specimen types may also be recommended based on the test requested.

- PHEL accepts: Nasopharyngeal (NP) swabs, Conjunctival swabs, Oropharyngeal (OP) swab, Combined Nasopharyngeal and Oropharyngeal swabs, Nasal mid turbinate swabs, Anterior nasal swabs, Nasopharyngeal wash/aspirate, nasal wash/aspirate, Bronchoalveolar lavage, tracheal aspirate, and pleural fluid.
- Sputum and lung biopsy specimens may be accepted but cannot be tested at PHEL and will need to be forwarded to CDC for testing.
- All swabs should be placed in a transport tube containing 1-3mL viral transport Media (VTM).
- 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.
- Submission of residual specimen volume is acceptable.
 - Laboratories may also consider sending an aliquot (at least 0.5mL) in a secondary tube labeled with 2 patient identifiers (e.g. name and DOB) that is kept frozen.

Storage and Shipping Information:

- Store specimens refrigerated (2-8°C) for no longer than 72 hours from time of collection. If specimen submission and receipt at NJ PHEL will take more than 72 hours, freeze specimens at -70°C or below and ship on dry ice.
 - **Storage temperature must be maintained during specimen transport** (via courier or overnight shipping). If not able to maintain frozen temperature during entire transport (i.e. on dry ice), shipping on frozen cold packs is acceptable. Avoid freeze-thaw cycles.

Test Ordering and Specimen Submission:

Specimen Labeling

- Label each specimen with a minimum of two patient identifiers (e.g. the patient's name and date of birth). Ensure the patient's name and DOB matches the specimen label **exactly**.
- When possible, test requests should be submitted electronically through our Online Ordering and Reporting portal. For a quick reference guide to using the portal, [How to Order Respiratory Testing Online](#)
 - To gain access to this portal, please see instructions located [here](#).
- If you are unable to order test requests electronically, please fill out our current paper requisition form (SRD-1) [here](#).

How to order a Test Request: Avian Influenza H5N1 Diagnostic Testing

- To request influenza testing, please request "Respiratory Viral Surveillance (Influenza + SARS-CoV-2) (90850)"

Select	Abbreviation	Name	Alternate ID1	Collection Information	Host Codes
<input type="checkbox"/>	90850	Respiratory Viral Surveillance (Influenza + SARS-CoV-2)	90850	Other in Not Specified	IO-90850

- NOTE: Some providers may also see a test called "Influenza subtyping (90798)". Please do not use this test order unless instructed.

- Add the selected test then save
- Fill out the required fields marked with a red asterisk:

Order Choices	Clinical Info	Response
90850	T7-Specimen Type?*	<input type="text"/>
	Additional Note	<input type="text"/>
90850	Respiratory- Reason for submission?*	<input type="text"/>
90850	C8. Is the patient currently exhibiting signs and/or symptoms of a respiratory infection?	<input type="text"/>
90850	C9. Has the patient been vaccinated against COVID-19?	<input type="text"/>
90850	C7. Relevant Immunizations:	<input type="text"/>

- The required field Respiratory- Reason for Submission will allow you to provide further details on why the specimen is being sent to PHEL. Choose the most relevant option for your test from the dropdown. If unsure, select 'other'

90850	Respiratory- Reason for submission?*	<input type="text"/>
90850	C3. Hospitalization Status	<input type="text"/>
90850	C3A. ICU:	<input type="text"/>
90850	C3B. Admission Date	<input type="text"/>
90850	C8. Is the patient currently exhibiting signs and/or symptoms of a respiratory infection?	<input type="text"/>

- After filling out any additional relevant information, click "Save" to save the test order.
- **Print the requisition form** which automatically pops up and pair the samples with their requisition forms in the package to be sent to PHEL. Do not place requisition forms directly in contact with specimen tubes in case a tube leaks or breaks in transit.

Specimen Shipping to PHEL

- Specimens may be shipped to the laboratory for receipt Monday- Friday from 8am – 5pm. NJ PHEL is closed on weekends and state holidays.
- For detailed instructions on how to ship specimens to PHEL, please refer to our guidelines available [here](#).
- Questions regarding shipping to the laboratory can be directed to PHEL.SpecimenReceiving@doh.nj.gov