APHL All Member Call:
Highly Pathogenic Avian Influenza A(H5N1)
June 12, 2024

Call Summary

Contact for Questions or Suggestions
APHL Influenza Contact: fluquestions@aphl.org

Select Agents and Toxins Exemption for H5 Avian Influenza Viruses (*Jack Taniewski, USDA*)

Following a request from APHL, USDA issued an initial select agent exemption for highly pathogenic avian influenza (HPAI) H5 on May 3, 2024. On June 6, 2024 USDA was able to issue a total exemption from all select agent regulations for avian influenza H5 for a period of three years. Of note, this exemption is only for influenza H5 and not influenza H7; influenza H7 is still subject to select agent regulations.

While select agent regulations are removed for avian influenza A H5, all other regulations remain applicable, such as H5 regulations issued by the Department of Transportation, NIH, BMBL and others. For more information, please see USDA's Select Agents and Toxins Exemption: H5 Avian Influenza Virus. Please contact DASAT@usda.gov for questions.

Influenza Summer Surveillance Guidance (*Alicia Budd, CDC*)

Influenza surveillance is more critical now than during typical summers. CDC worked with state, tribal, local and territorial partners to develop summer 2024 influenza surveillance guidance. The guidance takes a tiered approach, monitoring specific populations most at risk from exposures and extending outward to the broader population. The high level points of the surveillance include the following:

1. Symptom monitoring among workers and others with recent exposures to HPAI A/H5 infected animals on farms or other locations.
2. Conduct outreach and education to people exhibiting animals (specifically swine, cattle and avian species) at or attending agricultural fairs.
3. Encourage ongoing influenza testing (preferably RT-PCR) of individuals with compatible illness throughout the summer, particular for persons with recent history of relevant exposures.
4. Enhance surveillance for novel influenza detection among severely ill patients by subtyping influenza A positives specimens from patients hospitalized or in the ICU.
5. Enhance surveillance for novel influenza A detections in the community by maintaining the flow of influenza positive specimens to and subtyping of influenza A positives by PHLs and investigation of unexplained clusters of respiratory illness.
6. Monitor influenza surveillance data for unexpected patterns.
7. Local data anomaly detection and investigation.

This summer 2024 influenza surveillance strategy involves looking in multiple places and multiple ways to ensure we aren't missing anything and that we can quickly identify and follow up with HPAI A/H5 cases.

Laboratory Testing Updates (*Todd Davis and John Barnes, CDC*)

Testing operations at the National Influenza Reference Centers (NIRCs) and Influenza Sequencing Centers (ISCs) are being maintained at the same pace as the influenza season. This ensures continual flow of specimens and sequences. Additional resources on summer surveillance are available.

Additionally, CDC is working with commercial laboratories to submit influenza specimens to PHLs for additional testing. They already do this for routine testing of unsubtypable influenza specimens, however CDC is now asking that positive influenza samples that are not tested with the subtyping assay be sent to the state PHL. The logistics are still being worked out with commercial laboratories, specifically in terms of acceptable specimen types and media types to ensure that material sent to PHLs would meet the requirements for testing with the CDC H5 assay.

On May 24, 2024, the FDA granted enforcement discretion for the use of conjunctival swabs as an acceptable specimen type with the CDC Influenza A/H5 Subtyping Kit. Conjunctival specimens still need to be paired with an NP swab in viral transport media. The enforcement discretion is through August 1 2024, but may need an extension.

CDC has been working with CMS to understand what type of verification is needed for conjunctival specimens. CMS indicated that a verification is needed, not a full validation; APHL requested CMS to put their decision in a written memo and is awaiting their response. CDC is working to obtain conjunctival specimens to support verification. They are also trying to help source conjunctival specimens to create contrived samples to help with verifications.

CDC is also working with FDA to help ensure laboratories can test with both VTM and UTM. CDC is currently in discussion with FDA about how to do this quickly. It is a high priority for both CDC and FDA and they hope to have a path forward that will allow laboratories to use both media types for the whole suite of influenza testing assays.

CDC is working with their Chief Medical Officer in the Influenza Division to develop and distribute an SOP for conjunctival specimen collection. CDC plans to have collection guidance and resources on their website next week.

Questions and Answers (Q&A)

Q: How long is the select agent exemption for HPAI A/H5?
A: The HAPI A/H5 exemption is for three years.

Q: Does the HPAI A/H5 exemption apply to human related specimens or only veterinarian specimens?
A: The HPAI A/H5 exemption is for all avian influenza H5 specimens regardless of the source.

Q: If transporting HPAI A/H5, is it still a select agent? Does it need to be transported as select agent?
A: Per USDA, HPAI A/H5 is not a select agent for the next three years. However, APHL will verify the Department of Transportation's requirements as they have their own requirements.

Q: Does the suspension allow PHLs to retain residual confirmed H5 specimens for purposes of test validations?
A: Yes, the HPAI A/H5 exemption allows laboratories to retain residual material. The exemption is for three years.

Q: If PHLs conduct confirmatory testing for HPAI A/H5, do they need a permit to send it to CDC?
A: Currently testing performed at public health laboratories is considered presumptive and not confirmatory. If that were to shift a permit would be required. APHIS Veterinary Services will issue permits for interstate transportation. The Permitting Unit can be contacted by email at apie@usda.gov.

Q: If PHLs conduct confirmatory testing for HPAI A/H5, will they be required to ship specimens as select agents?
A: No, because HPAI A/H5is not a select agent at this time.

Q: Presumptive identification of HPAI A/H5 with the CDC H5 assay is not considered confirmed for transportation purposes, correct?
A: These are not considered confirmed for transportation purposes. These would still be shipped as Cat B to CDC for confirmation.

Q: Are all select agent rules for HPAI A/H5 suspended for three years?
A: Yes.

Q: What do we need to do in order to get material for the verification for conjunctival swabs?
A: CDC is currently working on this and is looking to obtain conjunctival specimens through a potential contract. Please email flusupport@cdc.gov if you would be interested in potentially receiving verification material from CDC so that they can gauge demand.

Q: Are PHLs expected to perform their own verification for conjunctival swab specimens? The best most of us can do is spiking conjunctival specimens with H5 control. Is that going to suffice since most of us do not have access to infected persons with real influenza symptoms?
A: This will be a topic of conversation on next APHL Lab Director call. It is up to individual laboratories to perform their own verification. CDC is working to provide additional H5 control material to PHLs as soon as possible via IRR.

Q: Is there any update on requests for local PHLs to obtain the CDC H5 assay?
A: CDC does not want to add additional laboratories until the remanufactured kit with the H5b component included is available. CDC hopes that new kits will be available in the next few weeks.

Q: If commercial laboratories send specimens to a state PHL that are influenza A or B positive but not subtyped, should the state PHL test them using the CDC Flu/SC2 assay first, followed by subtyping? If the PHL result is discordant with the commercial laboratory (e.g., the PHL gets a negative result), then the PHL does not need to send it to CDC, correct?
A: Correct.

Next call: June 26, 2024 at 2:00 pm