APHL All Member Call:
Highly Pathogenic Avian Influenza A(H5N1)
July 24, 2024

Call Summary

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

FDA's Milk Testing Activities *(Angela Swinford and Jaqueline Woods, FDA*)

FDA has shared their Standard Operating Procedure for Extraction and Detection of Influenza A virus in Milk and Milk Products through the Bacteriological Analytical Manual (BAM) Additional Chemistry and Microbiology Resources Used by the Foods Program. The method is suitable for fluid milk, sour cream and dehydrated milk products (rehydrated with water) and also has a cheese protocol. FDA is continuing development of H5 subtyping methods and will make those available on the same site. The influenza A/H5 subtyping assay in development and likely will be available in the next one-two weeks.

CDC Laboratory Updates (*Becky Garten, CDC*)

FDA recently accepted an update to include Universal Transport Medium (UTM) as acceptable specimen transport media. Updated instructions for use have been distributed to public health laboratories using the International Reagent Resource Points of Contact (IRR). CDC is updating documentation to now include UTM in all CDC guidance.

For patients who are only presenting with conjunctivitis, CDC recommends collection of both (1) conjunctival swab and (2) nasopharyngeal swab specimens placed in separate tubes of Viral Transport Media (VTM) or UTM.

For patients presenting with both conjunctivitis and respiratory symptoms, CDC recommends collection of three clinical specimens: (1) a conjunctival swab, (2) a nasopharyngeal swab, and (3) a combined nasal swab and oropharyngeal (throat) swab, each placed into a separate tube of VTM or UTM.

For patients presenting with respiratory symptoms, CDC recommends collection of the following clinical specimens: (1) a nasopharyngeal swab and (2) a combined nasal swab and oropharyngeal (throat) swab, each placed into a separate tube of VTM or UTM.

As more data associated with this virus are collected, CDC continues to refine which are the best specimens to collect.

This information is also available here: CDC Interim Recommendations for Prevention, Monitoring, and Public Health Investigations (June 20, 2024).

Other specimens which are approved for the H5 assay are listed in the Instructions for Use Package Insert:

- Upper respiratory tract clinical specimens:

    - Nasopharyngeal swabs [NPS]
    - Nasal swabs [NS]
    - Throat swabs [TS]
    - Nasal aspirates [NA]
    - Nasal washes [NW]
    - Dual nasopharyngeal/throat swabs [NPS/TS]
- Lower respiratory tract infections:
    - Bronchoalveolar lavage [BAL]
    - Bronchial wash [BW]
    - Tracheal aspirate [TA]
    - Sputum
    - Lung tissue

Enhanced Summer Surveillance

CDC and APHL have determined a process by which influenza samples from commercial laboratories including Labcorp and Quest Diagnostics will be submitted to National Influenza Reference Centers (NIRCs) for additional subtype testing. Samples submitted to NIRCs will be included in the appropriate jurisdiction's surveillance data and will contribute toward state right size goals

Questions and Answers (Q&A)

Q: Are PHLs expecting to receive verification material to test conjunctival swabs?
A: CDC has not identified a source for verification material at this time. In the meantime, laboratories that are in need of verification material can reach out to APHL at fluquestions@aphl.org. APHL may be able to provide limited assistance.

Q: What is known about asymptomatic H5N1 in humans?
A: Historic cases for H5N1 have been very sick individuals detected after patients were hospitalized and intubated. There is not a lot of data on mild or asymptomatic patients, however data from this current outbreak has contributed to recent seroprevalence studies: https://www.cdc.gov/ncird/whats-new/H5N1-seroprevalence-studies.html

Q: Can you please comment on how state labs might use FDA's Influenza A and the forthcoming H5 tests for milk products? Can these be used for state-initiated surveillance for raw milk? What are the other uses?
A: FDA will use the tests to screen food samples. FDA would send non-negative samples for viability testing and confirmation. PHLs could set up a similar program if desired.

Q: What is the status of the new lot of H5 subtyping kits?
A: Manufacturing is complete and quality assurance is ongoing. Existing kits that are currently available in IRR and placed at PHLs will be continued to be used without the H5b component will continue to be used until exhausted. The corrected H5b manufactured component will go out after supplies the current lot are used, in an effort to conserve reagents.

Q: Will the reporting algorithm and language change back to when the new kits come back?
A: Yes, CDC will confirm the reporting algorithm and language when new kits are distirbuted.

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