January 28, 2025

Background

The Centers for Disease Control and Prevention (CDC) has historically required confirmation of positive influenza A(H5) results identified at public health laboratories (PHLs) performing testing with CDC's 510k A(H5) in vitro diagnostic (IVD) assay. Confirmation of these results via repeat testing performed at CDC has been required to facilitate national notifiable disease reporting, address challenges with shipping specimens positive for influenza A(H5) and streamline submission of specimens to the CDC influenza Division for genetic sequencing and viral characterization (Novel Influenza A Virus Infections| CDC).

Process Change

CDC recognizes that the current influenza A(H5) confirmatory testing strategy presents challenges for PHLs involved in the ongoing response to influenza A(H5); therefore, **CDC has updated testing recommendations for laboratories using CDC's 510(k) influenza A/H5 IVD assay as indicated below.** This change is intended to reduce confusion and potential delays resulting from the "presumptive" classification of influenza A(H5) cases. Treatment and case management should not wait for subtyping or confirmatory testing for A(H5), especially if an individual reports contact with influenza A(H5) virus infected animals or close contact with an influenza A(H5) virus infected person.

CDC has the following updated recommendations for state or local PHL performing influenza A(H5) testing with CDC's 510(k) A(H5) IVD assay:

1. When influenza A(H5) is detected in humans, the first three (3) identified cases by a PHL should be treated as presumptive positive and the PHL must send specimens from those three cases to CDC for confirmation.
2. Testing at PHLs is performed according to the IFU of CDC's 510k A(H5) IVD assay, including meeting clinical, epidemiologic, and public health response criteria for patient testing.
3. A(H5) subtyping results from the PHL will be immediately reported to CDC (by email to flusupport@cdc.gov and phone call to influenza Division POC(s) and/or CDC's Emergency Operations Center).
4. Due to the need for further virologic characterization, all influenza A(H5) positive samples (minimum of 500µl or total amount available if less) should be sent to CDC within 24 hours of detection (or Monday following a Friday, Saturday, Sunday or holiday detection) or as soon as possible.

Additional Information

Symptomatic persons who are suspected with influenza A(H5) virus infection based on a history of direct or close exposure to animals with A(H5) virus infection or to a human case of A(H5) virus infection, and clinical findings, should be started on antiviral treatment with oseltamivir as soon as possible without waiting for influenza testing results (https://www.cdc.gov/bird-flu/hcp/novel-av-treatment-guidance/index.html). Epidemiology investigations including case information, contact tracing, and human and animal health investigations are essential for all confirmed influenza A(H5) cases.

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service has temporarily exempted A(H5) avian influenza viruses from the requirements of the select agent and toxin regulations until June 2027 (Select Agents and Toxins Exemption: H5 Avian Influenza Virus | Select Agents and Toxins | Federal Select Agent Program). This exemption has facilitated the transport of specimens confirmed with the virus during the ongoing influenza A(H5) response. The end of this exemption will necessitate an evaluation of the impacts of the select agent and toxin regulations on the use of CDC's 510k A(H5) IVD assay by state and local PHLs for confirmatory testing of influenza A(H5) cases.