Guidance for use of CDC Influenza IVD Kits

A/B Typing Kit
Targets: INFA (M), INFB (NS), RP

Flu SC2 Multiplex
Targets: INFA (M), INFB (NS), SC2(N), RP

→ **1st line Influenza virus or SARS-2 diagnosis**

A-Subtyping Kit
Targets: INFA (M), pdmINFA (NP), pdmH1 (HA), H3 (HA) ,RP

B-lineage typing Kit
Targets: INFB (NS), BYam (HA), BVic (HA), RP

→ **Determines if typical human epidemic/endemic ("seasonal") influenza virus**

A/H5 Subtyping Kit
Targets: INFA (M), H5a(HA), H5b (HA), RP

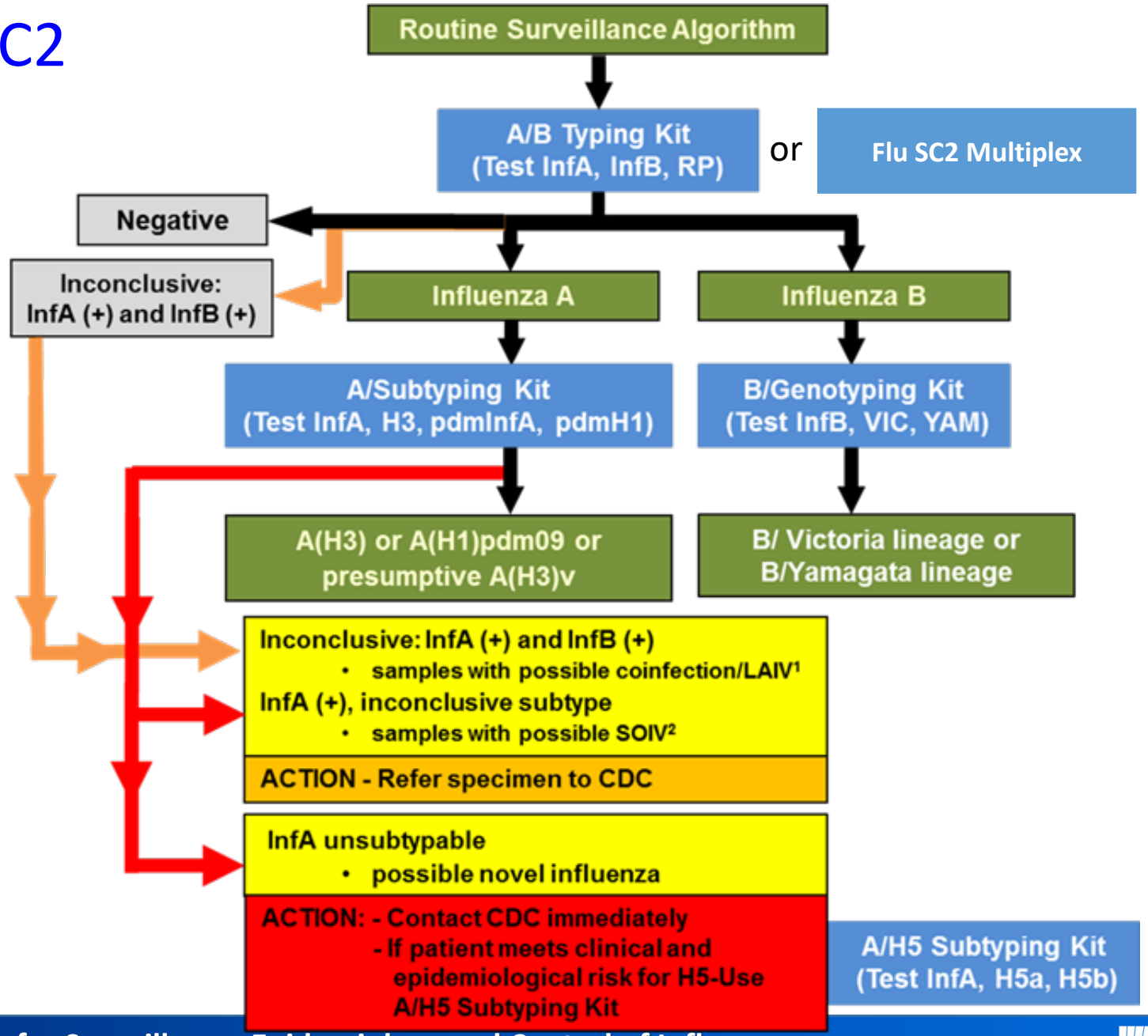
→ **Determines if it is H5 avian influenza virus**

Should not be performed unless the patient meets clinical and epidemiologic criteria for testing suspect specimens (see Case Definitions for Investigations of Human Infection with Avian Influenza A Viruses in the United States (cdc.gov).

If the test result is presumptive positive, per our FDA approved IFU, the sample can be sent to CDC as a diagnostic specimen for additional testing and confirmation.

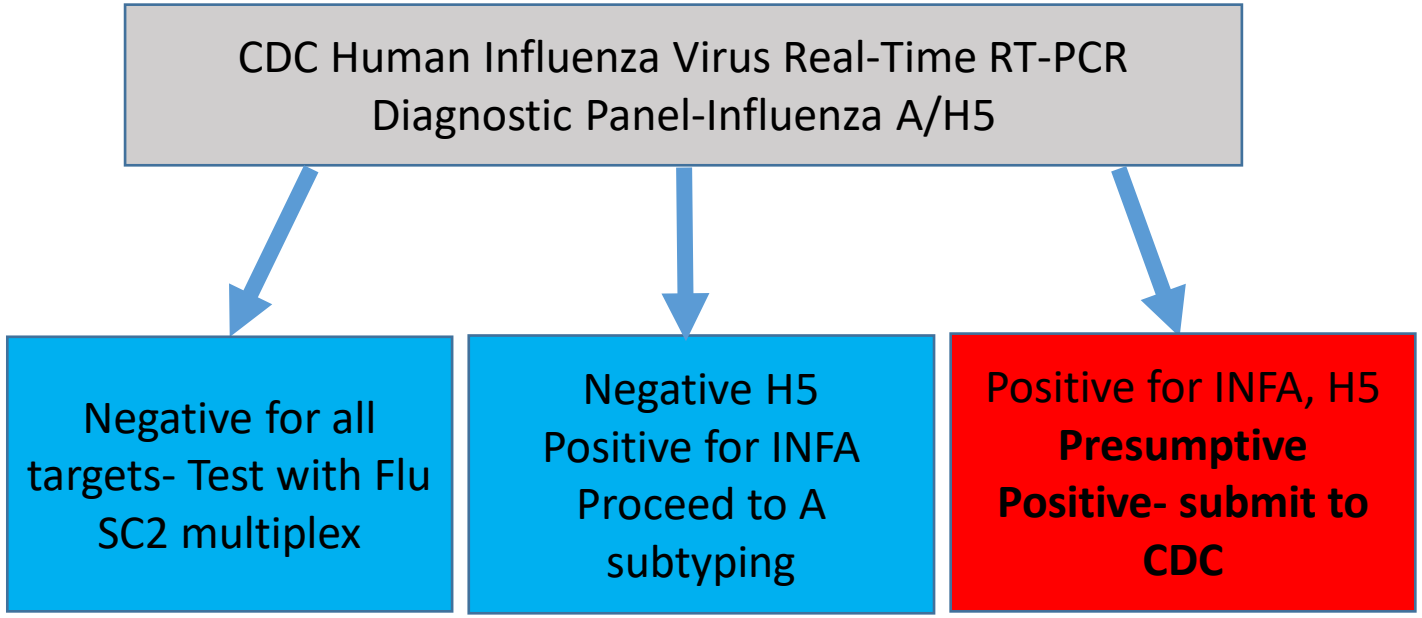
Dx Algorithm with the Flu-SC2 multiplex assay

- The Flu SC2Multiplex can be used interchangeably with the A/ B typing kit.
- ***Note: H5 test should only be administered to those specimens that are A positive, unsubtypable or from patients with known exposure to H5 infected animals/ people***



Testing for People Exposed to Animals with Confirmed H5

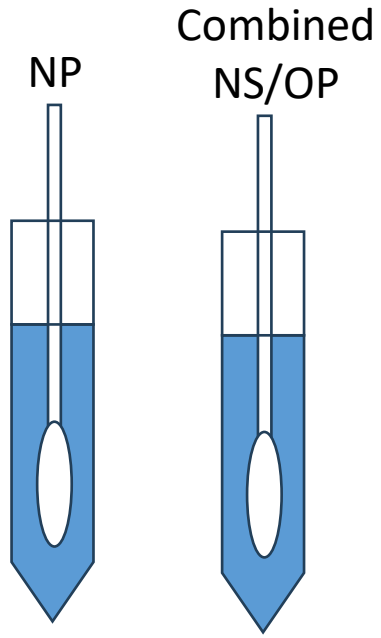
- CDC guidance:
  - Information for People Exposed to Birds Infected with Avian Influenza Viruses | Avian Influenza (Flu) (cdc.gov)
  - Samples from symptomatic people exposed to infected animals with confirmed H5 can be tested **DIRECTLY** with the CDC A/H5 Kit
  - **Option –Test A/B typing, A subtyping, A/H5 simultaneously- Testing with CDC influenza panel does not have to be sequential**



Specimen collection H5

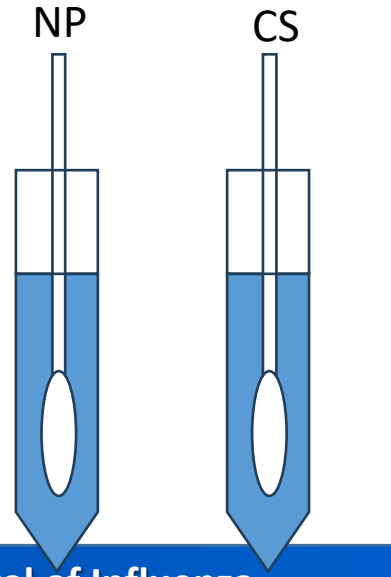
Respiratory

- For testing of individuals that meet clinical and epidemiologic criteria for influenza A(H5N1) with respiratory illness, preferably two specimens should be collected a 1. a nasopharyngeal (NP) swab and 2. a combined nasal swab oropharyngeal swab (e.g., two swabs combined into one viral transport media vial) and minimally a single NP swab should be collected



Conjunctivitis

- Individuals that meet clinical and epidemiologic criteria for influenza A(H5N1) with conjunctivitis (with or without respiratory symptoms) should have two swabs collected as well: 1. a conjunctival swab and 2. an NP swab.



H5 Guidance continued

A/H5: Specimens with presumptive positive or inconclusive results

- A specimen is only presumptively positive for influenza A/H5 if both targets (InfA, H5) are positive.
- A result is inconclusive for A/H5 if the test is positive for A/H5 and is negative for INFA.
- **Please submit any sample with an H5 positive marker IMMEDIATELY to CDC for further evaluation**
- Reminder, please refer to any H5 positive in correspondence as "presumptive" until it is confirmed at CDC

Specimen Notification and Shipping to CDC

***Respiratory Specimens that are Influenza A positive, but have inconclusive results using Influenza A Subtyping or Influenza B Lineage Kits**

Notify CDC **IMMEDIATELY** (flusupport@cdc.gov) and send the following clinical specimens to CDC **IMMEDIATELY** for diagnostic testing and/or further characterization:

- Influenza A positive (InfA Ct value <35), negative for H1pdm or H3 (“unsubtypable”)
- Presumptive positive for other subtypes (e.g., H5)
- Inconclusive indicating an atypical/novel influenza A virus

CDC Contact
Marie Kirby, Ph.D.
Team Lead, Genomics and Diagnostics Team
VSDB/ID
Phone: 404-718-7689
Fax: 404-639-2350
Email: flusupport@cdc.gov
Email: pbi0@cdc.gov

Diagnostic Specimen Submission

Complete two forms:

1) **Influenza Specimen Submission Form** and indicate the following specific information**:**

- **Reason for Submission:** Diagnosis
- **If Clinical Specimen**: Indicate specimen type
- **Type/Subtype:** Inconclusive
- **Comments:** Provide any relevant rRT-PCR data

2) CDC Specimen Submission Form, CDC 50.34, which is required for all diagnostic submissions when results can be reported back to a patient or healthcare provider.

Note: Send completed form(s) and tracking information electronically to flusupport@cdc.gov. Include hard copies of both forms in the shipment.

Ship to:

Marie Kirby, Ph.D.
Centers for Disease Control and Prevention
Influenza Division, H23-6 (Unit 198)
c/o STAT
1600 Clifton Rd, NE
Atlanta, GA 30329