Laboratory Outreach Communication System (LOCS) Call

Monday, November 21, 2022, at 3:00PM ET

- **Welcome**
  - Sean Courtney, CDC Division of Laboratory Systems
- **Domestic Preparedness for Sudan Virus Disease**
  - Joanna Prasher, CDC Uganda Ebola Outbreak Response
- **Sysmex Hematology Portfolio and High Risk Sample Processing**
  - Andy Hay, Sysmex America, Inc.
- **Efficacy of Ebola Inactivation Methods**
  - Ninecia Scott and Brian Harcourt, CDC Division of High-Consequence Pathogens and Pathology
- **SARS-CoV-2 Antigen Testing Guidance Update**
  - Muktha Natrajan, CDC Division of Laboratory Systems
- **Diagnostic Influenza Testing for the 2023 Influenza Season**
  - John Barnes, CDC Influenza Division

About DLS

Vision

Exemplary laboratory science and practice advance clinical care, public health, and health equity.

Mission

Improve public health, patient outcomes, and health equity by advancing clinical and public health laboratory quality and safety, data and biorepository science, and workforce competency.

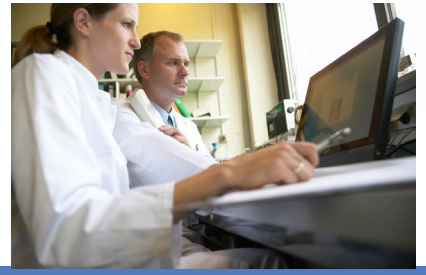
Four Goal Areas

Quality Laboratory Science

- Improve the quality and value of laboratory medicine and biorepository science for better health outcomes and public health surveillance

Highly Competent Laboratory Workforce

- Strengthen the laboratory workforce to support clinical and public health laboratory practice



Safe and Prepared Laboratories

- Enhance the safety and response capabilities of clinical and public health laboratories

Accessible and Usable Laboratory Data

- Increase access and use of laboratory data to support response, surveillance, and patient care

LOCS Calls

https://www.cdc.gov/locs/calls

Find LOCS Call information, transcripts, and audio recordings on this page

Next Scheduled Call

Monday, December 19th
3 PM - 4 PM ET

We Want to Hear From You!

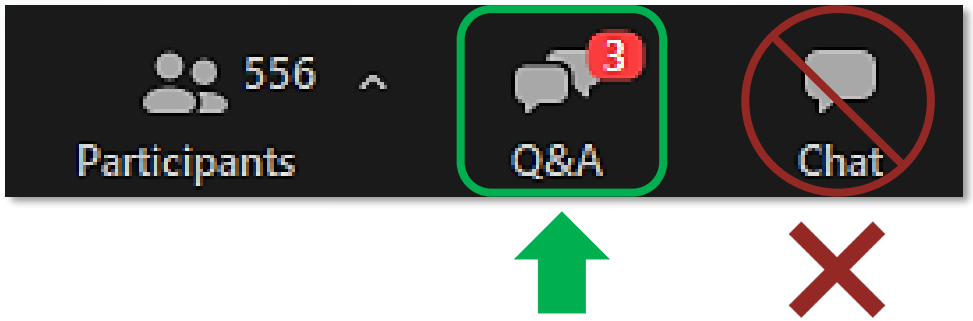
Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov

How to Ask a Question

- **Using the Zoom Webinar System**
  - Click the **Q&A button** in the Zoom webinar system
  - Type your question in the **Q&A box** and submit it
  - Please do not submit a question using the chat button



- For media questions, please contact CDC Media Relations at media@cdc.gov
- If you are a patient, please direct any questions to your healthcare provider

Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.

Domestic Preparedness for Sudan Virus Disease

Joanna Prasher
CDC Uganda Ebola Outbreak Response

Sysmex Hematology Portfolio and high risk sample processing

Andy Hay
CEO
Sysmex America Inc

Comprehensive Portfolio of Hematology Testing Solutions

Consistent operation, reagents, controls and workflow… Providing comparable results across your health network

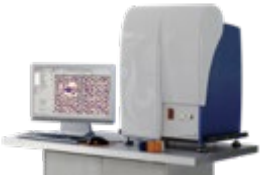
pocH-100*i*

XW-100

XP-300

XN-L 350, 450, 550

DM1200



DM9600

DC-1

XN-1000 R. PR. BPR

XN-1000

XN-2000

XN-3100 with DI-60

Integrated Slide Processing

XN-9100 LTM (TS+A1c)

And to Reference Labs

- Largest labs run >40,000 CBC per night
- Tracks of multiple XN-1000 (10-50)
- Slide makers
- Cellavision imaging systems
- All online, with closed tube sampling, fully automatic and integrated

Comprehensive Portfolio of Hematology Testing Solutions

Consistent operation, reagents, controls and workflow… Providing comparable results across your health network

pocH-100*i*

XW-100

XP-300

XN-L 350, 450, 550

DM1200

DM9600

DC-1

XN-1000 R. PR. BPR

XN-1000

XN-2000

XN-3100 with DI-60

Integrated Slide Processing

XN-9100 LTM (TS+A1c)

Not recommended for use with high risk samples

XW-100

The Sysmex XW-100 is a CLIA Waived hematology instrument with an intended use in clinically uncomplicated patient testing situations. This is from the FDA Intended use statement.

> *It (The XW-100) is not for use in diagnosing or monitoring patients with primary or secondary chronic hematologic diseases/ disorders, oncology patients, critically ill patients, or children under the age of 2.*

XP-300 XN-L 350

The Sysmex XP-300 and XN-L 350 hematology instruments are open tube sampling only and should not be used for the analysis of high risk samples if closed tube sampling options are available

External blood smear preparation required

The standalone Cellavision Digital Morphology Systems from Sysmex require a blood smear to be prepared outside of the instrument.
Labs should follow guidance in the preparation of manual blood smears or use fully automated closed tube sampling systems which are available as part of XN-3100 or XN-9100 configurations

Use of the Sysmex PocHi-100

The Sysmex PocHi-100 may be used to analyse samples from known high risk patients in closed tube sampling mode but Sysmex do not recommend its use inside a BSL level 2 or 3 environment for reasons more associated with the service support of the device than the design and use of the device itself

Sysmex service engineers may not enter BSL level 3 environments in order to service the system and typical service on this instrument is performed by return to base servicing and carriers may not accept the instrument for transportation. Sysmex recommends other instruments as more suitable and in main lab settings above the use of the PocHi-100

A complete range of Hematology Testing Solutions with Closed Tube Sampling able to handle high risk samples as standard practice.

pocH-100*i*

Sysmex believes all samples should be treated as if they may be high risk

Lighting the way with diagnostics

Efficacy of Ebolavirus Inactivation with Sodium hypochlorite and MicroChem Plus

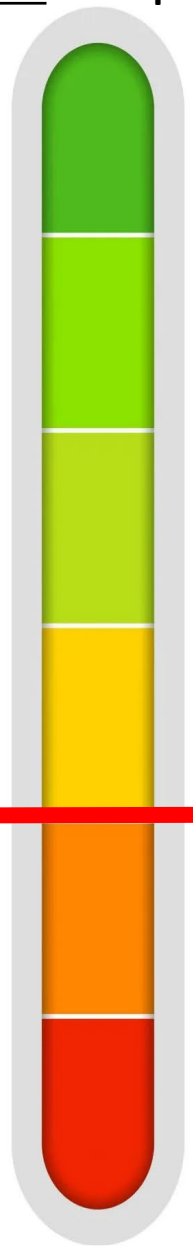
Ninecia Scott, PhD
Laboratory Leadership Service Fellow
tqf1@cdc.gov

CDR Brian H. Harcourt, PhD
Biosafety Team Lead
beh0@cdc.gov

Division of High-Consequence Pathogens and Pathology
Viral Special Pathogens

National Clinical Laboratory Call
11/21/2022

MOST susceptible



ENVELOPED VIRUSES
- CORONAVIRUS
- INFLUENZA(S)
- HEP B
- EBOLA

BACTERIA
- E.COLI
- MRSA
- SALMONELLA
- STAPH
- PSEUDOMONAS

FUNGI *(yeasts and molds)*
- ASPERGILLUS
- CANDIDA
- TRICHOPHYTON

NON-ENVELOPED VIRUSES
- RHINOVIRUS
- NOROVIRUS
- POLIO

MYCOBACTERIUM
- TB
- MYCOBACTERIUM TUBERCULOSIS

BACTERIAL SPORES
- ANTHRAX
- C DIFF
- BACILLUS

LEAST susceptible

MicroChem Plus (1.5%)

Sodium hypochlorite (0.82%)

Sodium hypochlorite (0.82%)

Image modified from Reference 1

There are two concentrations of sodium hypochlorite used in ETUs: **0.5%** and **0.05%.**

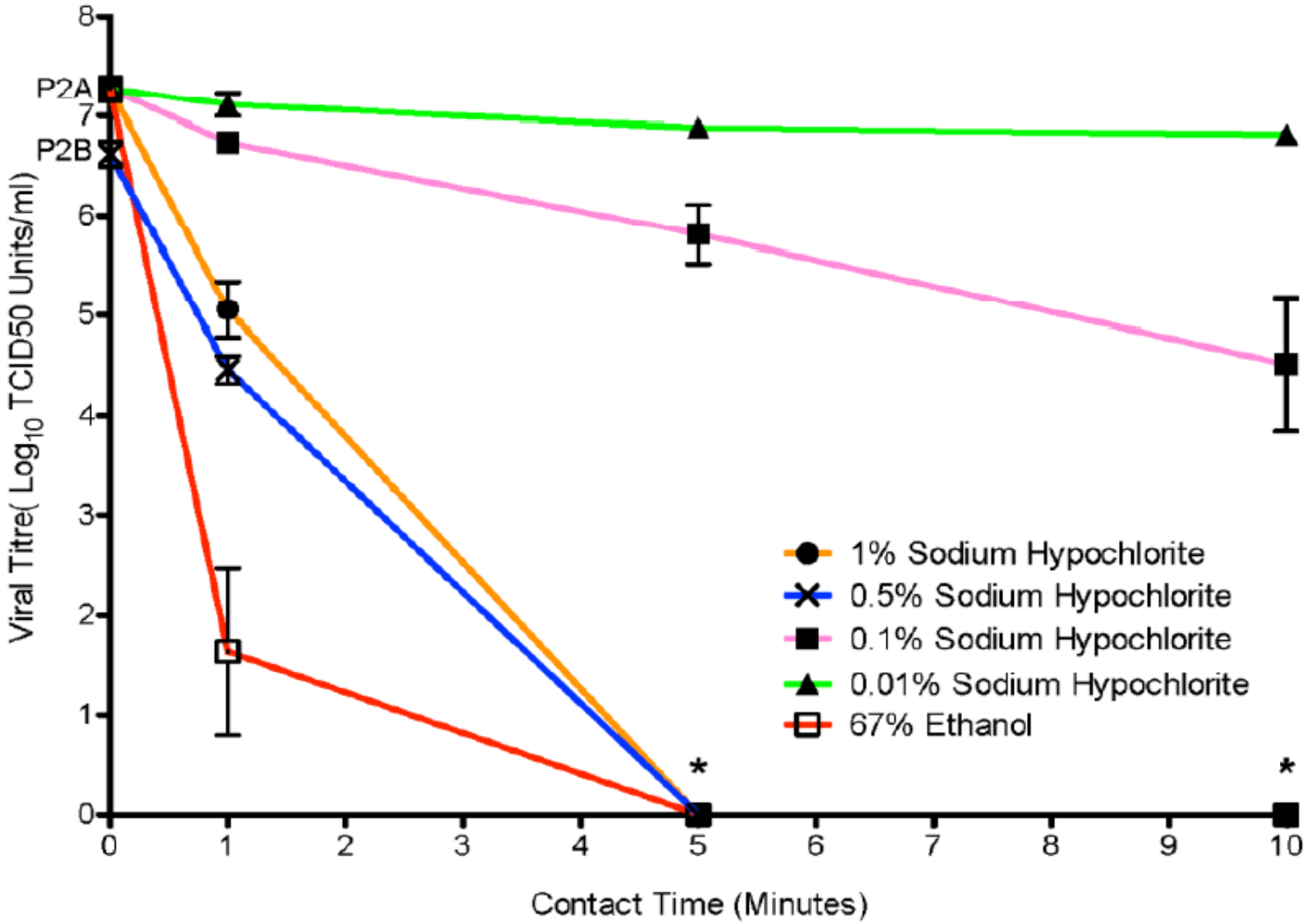
- **0.5%** is used to disinfect most **non-living items**

- **0.05%** is used to disinfect **living tissue/other chlorine-sensitive materials**

REMINDER: Bleach dilutions should be prepared fresh daily.

Reference 2

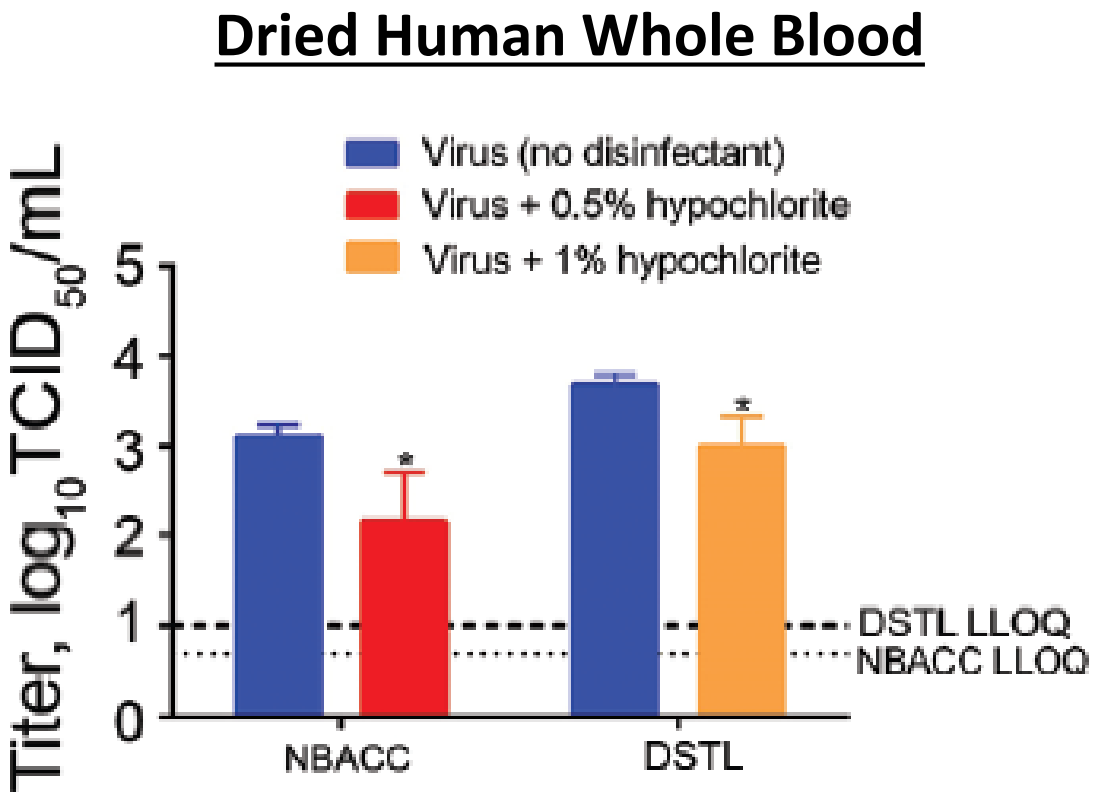
0.5-1% sodium hypochlorite effectively inactivates ebolaviruses with 5 minutes contact time with a soiled load



*limit of detection

Cook et. al. 2015 (Reference 3)

1% sodium hypochlorite is not as effective at inactivating ebolaviruses in dried blood



NBACC: National Biodefense Analysis & Countermeasures Center
DSTL: Defence Science and Technology Laboratory
LLOQ: Lower Limit of Quantification
* Significant difference (<0.05) compared to control

Modified from Figure 1, Smither et. al. 2018 (Reference 4)

MicroChem Plus effectively inactivates ebolaviruses with 5 minutes contact time

Table II

Reduction factors of three disinfectants against Ebola virus

Huang et. al. 2022 (Reference 5)

Test product	Concentration	Reduction factor					
		Contact time					
		15 s	30 s	1 min	2 min	4 min	8 min
MCP	5%	>4	>4	>4	>4	>4	>4
	1.67% (5%/3)	>4	>4	>4	>4	>4	>4
	0.56% (5%/9)	>4	>4	>4	>4	>4	>4
	0.19% (5%/27)	2.06	3.47	>4	>4	>4	>4
	0.06% (5%/81)	0.01	0.03	0	0.11	0.19	0.28

Dried Human Whole Blood

Disinfectant and volume, µL	Mean log_{10} $TCID_{50}$ (SD) disinfected	Mean log_{10} $TCID_{50}$ (SD) control	log difference
1.5%, 10 min			
Micro-Chem Plus, 30	2.8 (0.5)	3.4 (0.5)	0.6
Micro-Chem Plus, 100	1.5 (0.1)	2.9 (0.2)	1.4

Smither et. al. 2018 (Reference 4)

Key Take-Aways

- Treat all samples the same -as if they contain a high-risk pathogen
- Ebolaviruses are enveloped viruses, the most susceptible type of viruses to disinfectants
- Inactivation data for one ebolavirus is applicable to all members of the virus family (i.e., Ebola, Sudan, Marburg, etc..)
- 0.5%-1% sodium hypochlorite effectively inactivates ebolaviruses on stainless steal surfaces with a soiled load
- 1% sodium hypochlorite is not as effective at inactivating ebolaviruses in dried whole blood
- 5% MicroChem Plus effectively inactivates ebolaviruses
- 1.5% MicroChem Plus is not as effective at inactivating ebolaviruses in dried whole blood (blood should be soaked off with disinfectant)
- If you have instruments that may need to be decontaminated, contact the manufacturer for instructions.

Questions?

References

1. COVID-19 Sanitization Services | Rapid Restoration (rapidrestorationmn.com)

2. E-Lecture_DisinfectionAndWasteManagementInTheETU.pdf (cdc.gov)

3. Cook BW, Cutts TA, Nikiforuk AM, Poliquin PG, Court DA, Strong JE, Theriault SS. Evaluating environmental persistence and disinfection of the Ebola virus Makona variant. Viruses. 2015 Apr 14;7(4):1975-86. doi: 10.3390/v7041975. PMID: 25875372; PMCID: PMC4411685.

4. Smither SJ, Eastaugh L, Filone CM, Freeburger D, Herzog A, Lever MS, Miller DM, Mitzel D, Noah JW, Reddick-Elick MS, Reese A, Schuit M, Wlazlowski CB, Hevey M, Wahl-Jensen V. Two-Center Evaluation of Disinfectant Efficacy against Ebola Virus in Clinical and Laboratory Matrices. Emerg Infect Dis. 2018 Jan;24(1):135–9. doi: 10.3201/eid2401.170504. PMID: 29261093; PMCID: PMC5749448.

5. Huang Y, Xiao S, Song D, Yuan Z. Efficacy of disinfectants for inactivation of Ebola virus in suspension by integrated cell culture coupled with real-time RT-PCR. J Hosp Infect. 2022 Jul;125:67-74. doi: 10.1016/j.jhin.2022.04.008. Epub 2022 Apr 25. PMID: 35483643.

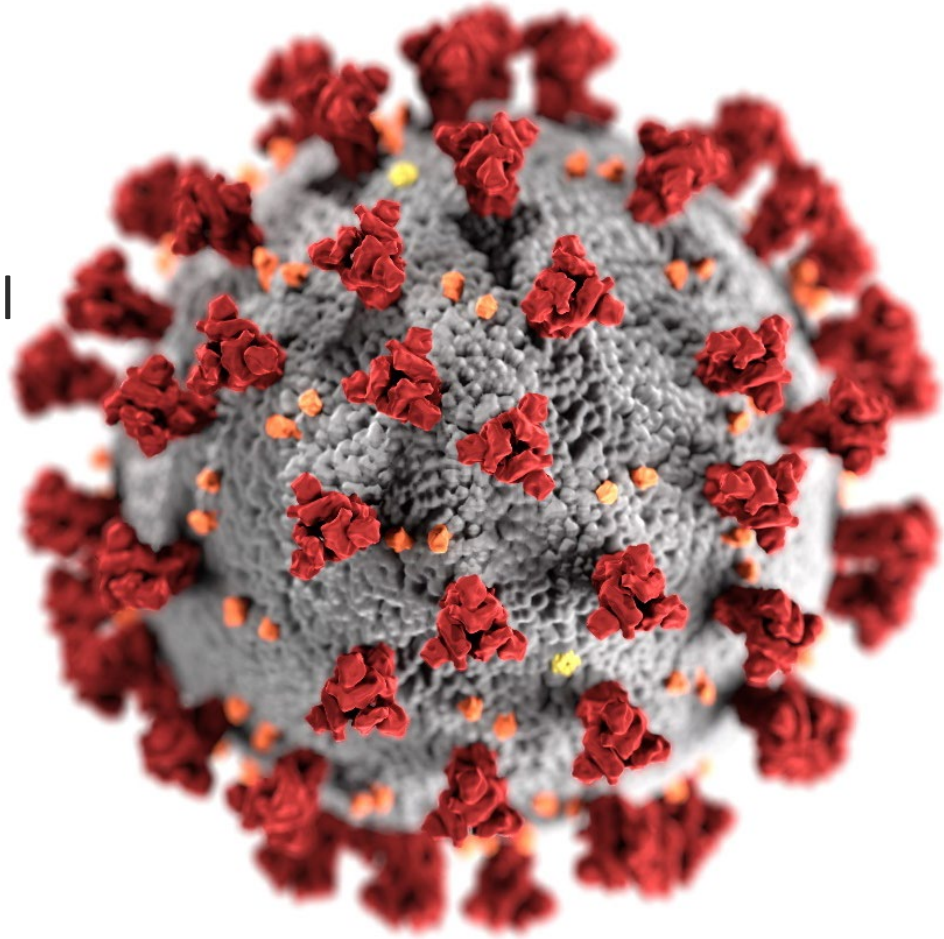
SARS-CoV-2 Antigen Testing Guidance Update

Muktha Natrajan, PhD

Health Scientist

Laboratory Outreach Communication System (LOCS) Call

Monday, November 21, 2022



cdc.gov/coronavirus

Antigen Testing in Healthcare Settings and Testing Sites

- **Who the guidance is for:**
  - Healthcare providers who order antigen tests, receive antigen test results, or perform point-of-care antigen testing.
  - Laboratory and testing professionals and public health practitioners who perform antigen testing and reporting in a laboratory setting or at the point of care.
  - Not intended to be used as self-testing guidance for the general public
- **As of November 4, 2022**
  - There are 51 antigen diagnostic test products with FDA emergency use authorization, 21 of which are authorized for home use
- **CDC is updating communications about testing, giving actionable information on testing decisions and streamlining existing content**

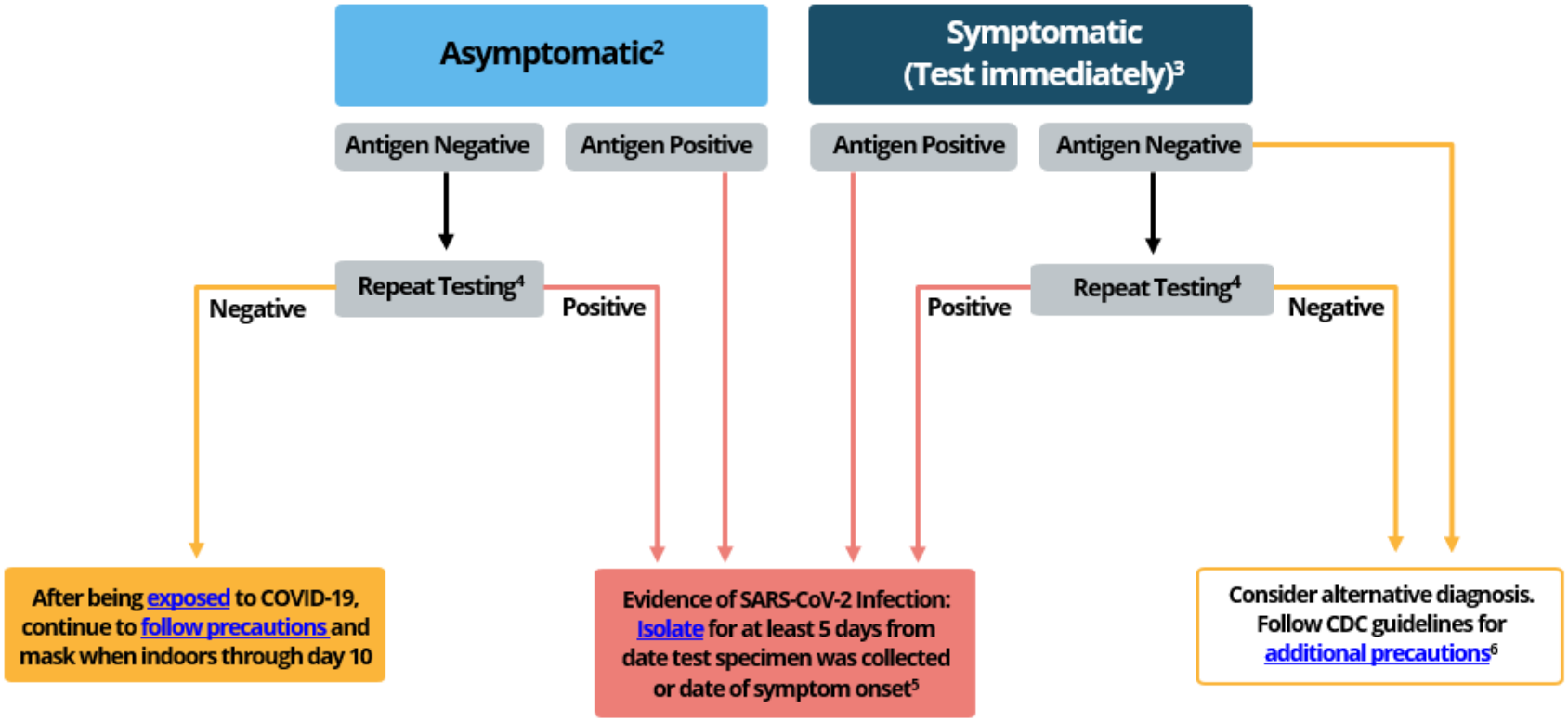
https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Antigen Testing in Healthcare Settings and Testing Sites

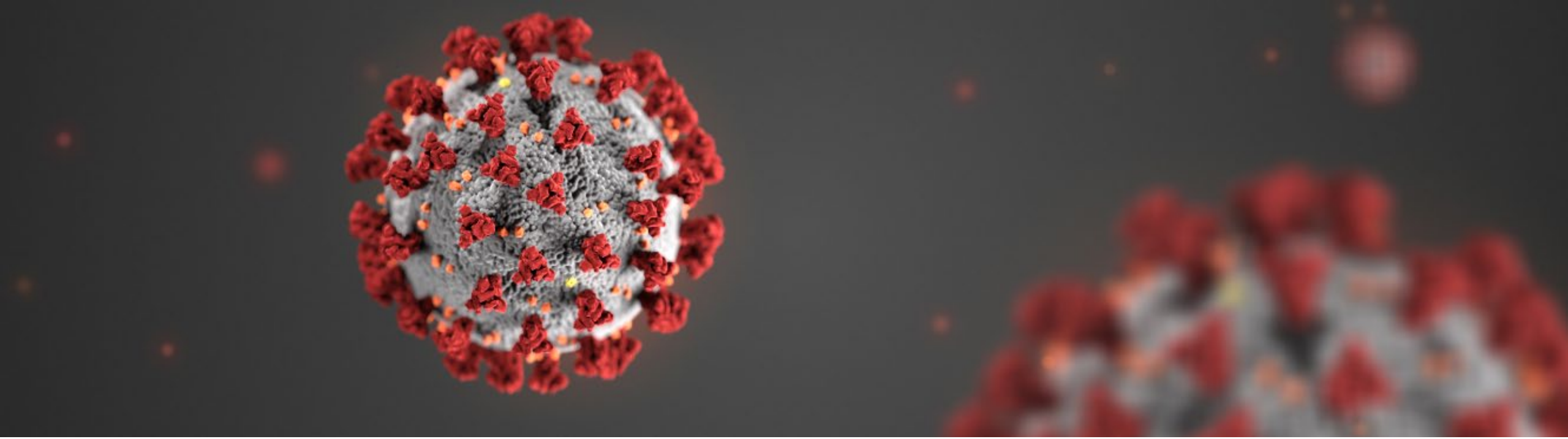
- **Removed:**
  - Serial Testing section
  - Table for differences between NAAT and Antigen Tests (now located on the Overview of Testing page)
  - Consideration of contact or vaccination status when determining repeat testing for negative results

- **Updated:**
  - Order of information based on clinical decision-making (start with General Guidance, Interpreting antigen Test Results)
  - Information on when to consider repeat testing in symptomatic and asymptomatic individuals
  - Antigen testing algorithm figure

Recommendations to Healthcare Providers on Interpreting Antigen Test Results for Diagnostic Purposes[1]

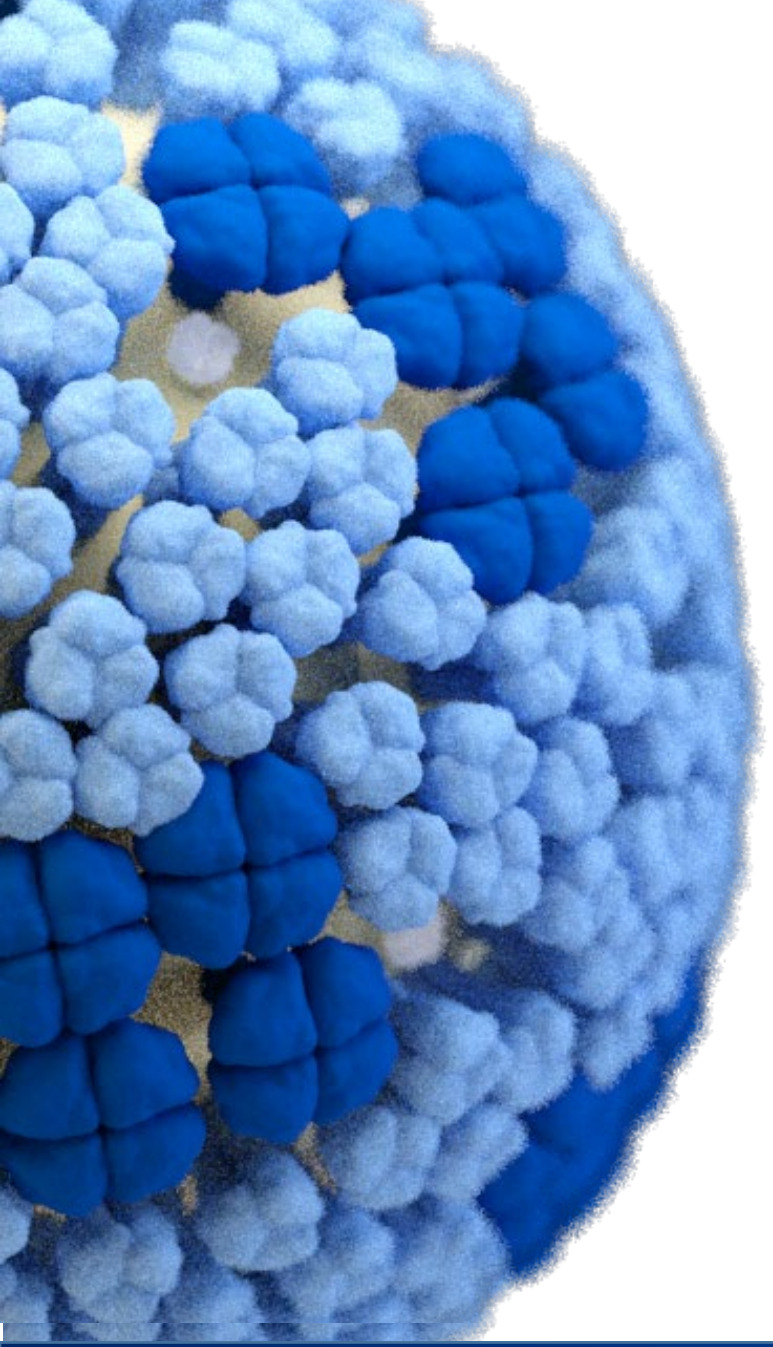


1. This guidance does not apply to congregate, high-risk, and healthcare settings.
2. For those who are traveling: follow guidance for domestic and international travel during the COVID-19 pandemic. Take precautions while traveling. Certain high-risk settings may need to test as part of a screening testing program.
3. Symptomatic individuals should take general public health precautions to prevent spreading an illness to others.
4. In situations where test sensitivity is of paramount importance, NAAT testing should take place as soon as possible, and not longer than 48 hours after the initial antigen testing. If the results are discordant, the NAAT result should be interpreted as definitive. If using another antigen test, follow FDA guidance on repeat testing.
5. See CDC's guidance on treatments for COVID-19, particularly if individual is at high-risk of severe disease from COVID-19. Also see CDC's guidance on Isolation and Exposure to COVID-19.
6. Early diagnosis and treatment are important in preventing severe illness for many pathogens that cause acute febrile respiratory diseases; additional diagnostic testing should be pursued in conjunction with repeat/confirmatory testing for COVID-19.



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



Diagnostic Influenza Testing for the 2023 Influenza Season

John R Barnes, PhD
Team Lead, Genomics and Diagnostics Team
Virology Surveillance and Diagnosis Branch

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 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 it is a "seasonal" influenza

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

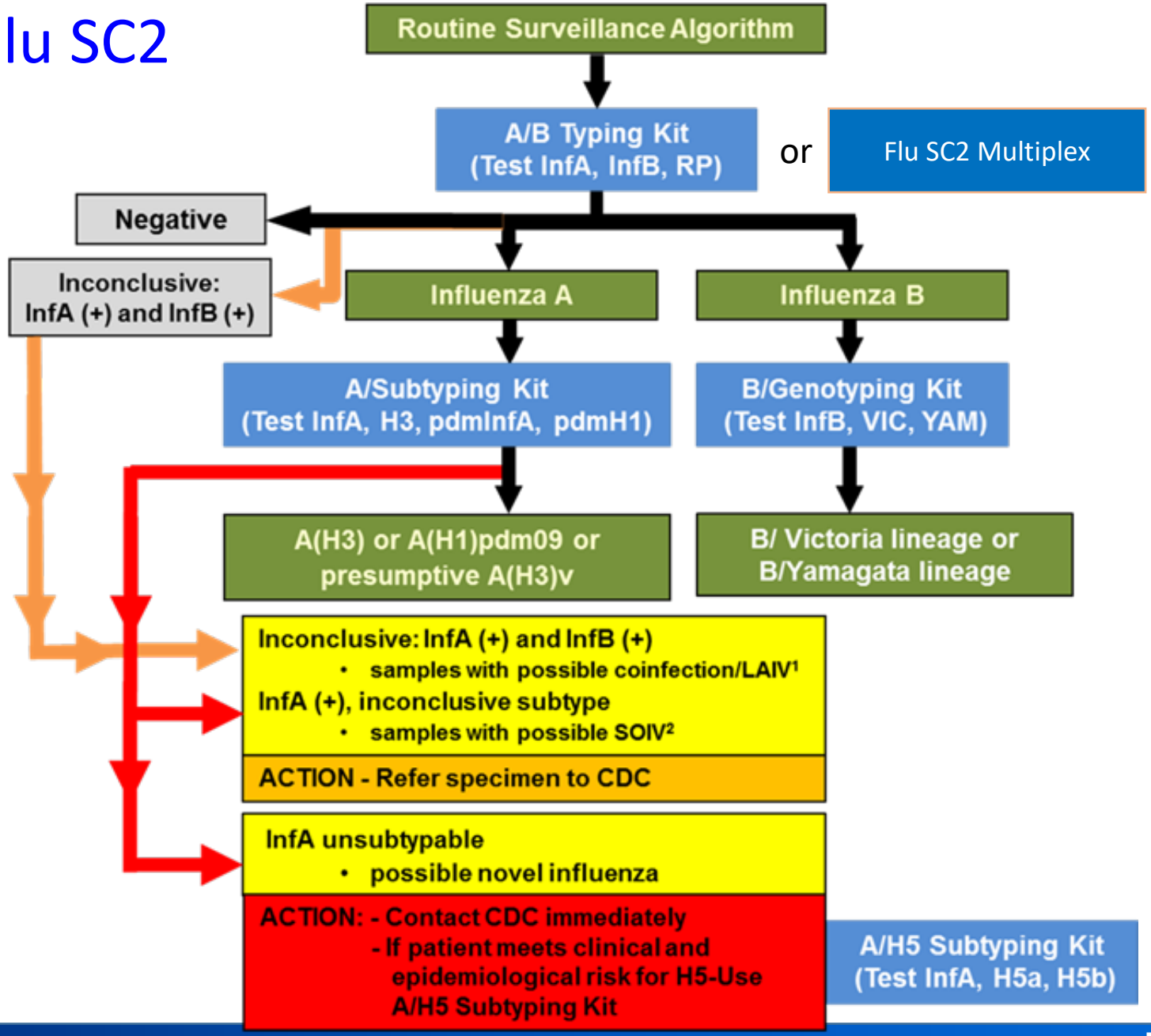
A/H7 Subtyping Kit
Targets: H7(HA) ,RP

→ Determines if it is H5 or H7 avian influenza

Should not be performed unless the patient meets clinical and epidemiologic criteria for testing suspect specimens

Dx Algorithm with the Flu SC2 multiplex

- The Flu SC2Multiplex can be used interchangeably with the A/ B typing kit.
- Note: if you want to return subtype/ lineage results make sure that use the approved extraction methods outlined in the subtyping and lineage typing IFU



Pandemic threats: Please be on the lookout for atypical viruses!

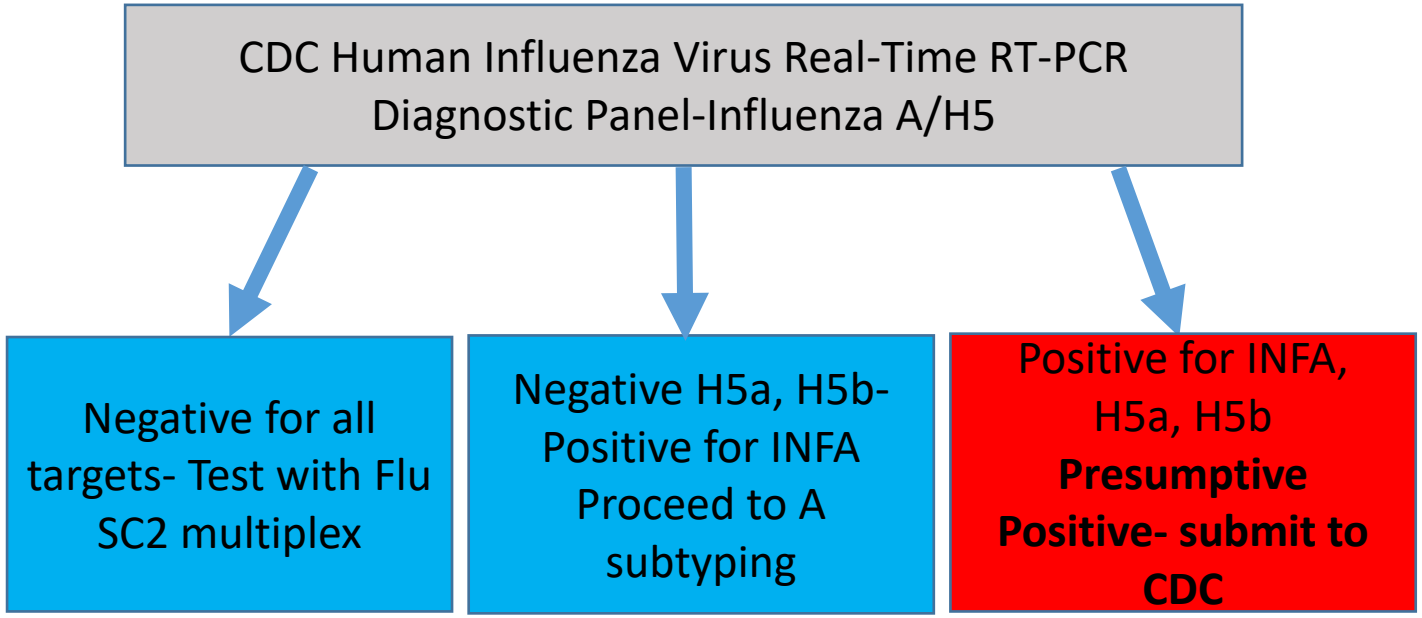
- Globally, influenza circulation continues, especially in avian and swine populations
- In the last 2 years, human cases of zoonotic influenza subtypes H1N1v, H1N2v, H3N2v, H3N8,H5N1, H5N6, H5N8, H9N2 and H10N3 have been detected
- ***Immediately submit specimens that test positive for influenza A (<35) but lack reactivity for H1pdm09 or H3 subtypes as a diagnostic specimen to CDC!***
- B Yamagata Viruses

Diagnostic Results for Variant Viruses

Viruses	Clade	InfA	pdmInfA	pdmH1	H3
A/Hawaii/70/2019 (human seasonal)	H1N1pdm09	+	+	+	-
A/Ohio/24/2017_1A.1	H1v_1A.1	+	+	±*	-
A/Ohio/35/17_1B.2.1	H1v_1.B2.1	+	+	-	-
A/Hunan/42443/2015	H1v_1C.2.3	+	+	-	-
A/Hong Kong/45/2019 (human seasonal)	H3N2	+	-	-	+
A/West Virginia/2011	H3v cluster IV	+	+	-	+
A/Ohio/28/2016	H3v 2010.1	+	+	-	+
A/Hawaii/28/2020	H3v cluster I	+	+	-	+
* Weak positive					

Testing for People Exposed to Birds with Confirmed H5

- CDC guidance:
  - Information for People Exposed to Birds Infected with Avian Influenza Viruses | Avian Influenza (Flu) (cdc.gov)
    - **Positive PCR for H5 would be considered a select agent and must be reported and shipped to CDC per select agent guidelines**
  - **Option –Test A/B typing, A subtyping – quicker option to get potentially zoonotic influenza in CDC's hands more quickly**



H5 Guidance continued

A/H5: Specimens with presumptive positive or inconclusive results

- A specimen is only presumptively positive for influenza A/H5 if all three targets (InfA, H5a and H5b) are positive.
- A result is inconclusive for A/H5 if the test is positive for InfA and has only one of the two H5 markers testing positive.
- **Positive PCR for H5 would be considered a select agent and must be reported, handled and shipped per select agent guidelines**

H7 EUA Guidance

A/H7 (Eurasian Lineage): Specimens with presumptive positive or inconclusive results

- A specimen is only “Influenza A Detected; Subtype Eurasian H7 detected” if both targets (InfA and EuH7) are positive.

- A result is inconclusive for A/H7 (Eurasian lineage) if the test is positive for EuH7 and is negative for InfA.

- Note: Testing with the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H5 or A/H7 (Eurasian Lineage) Assay should only be performed when the patient meets clinical and epidemiologic criteria for testing suspect specimens.

- **Positive PCR for H5 would be considered a select agent and must be reported, handled and shipped per select agent guidelines**

Diagnostic Specimen Submission

Respiratory Specimens with Inconclusive results using the CDC Influenza A Subtyping or Influenza B Lineage Kits

Notify CDC **IMMEDIATELY** (flusupport@cdc.gov) and send the clinical specimen to CDC **IMMEDIATELY** for further characterization:

- Influenza A that cannot be subtyped with InfA Ct value <35
- Presumptive positive A/H3v similar to those circulating in swine
- Inconclusive indicating possible variant influenza A virus similar to those circulating in swine

Send the clinical specimen to CDC for further characterization:

- Inconclusive influenza B viruses that are unable to be genotyped

Note: Influenza A that cannot be subtyped with InfA Ct value >35, the sample may be reported as inconclusive.

- Report may indicate that the subtype could not be determined due to low viral titer.
- These specimens do not need to be sent to CDC for verification following consultation with CDC

CDC Contact
John Barnes, Ph.D.
Team Lead, Genomics and Diagnostics Team
VSDB/ID
Phone: 404-639-2434
Fax: 404-639-2350
Email: flusupport@cdc.gov
Email: fzq9@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:

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

CDC Social Media

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Thank You For Your Time!

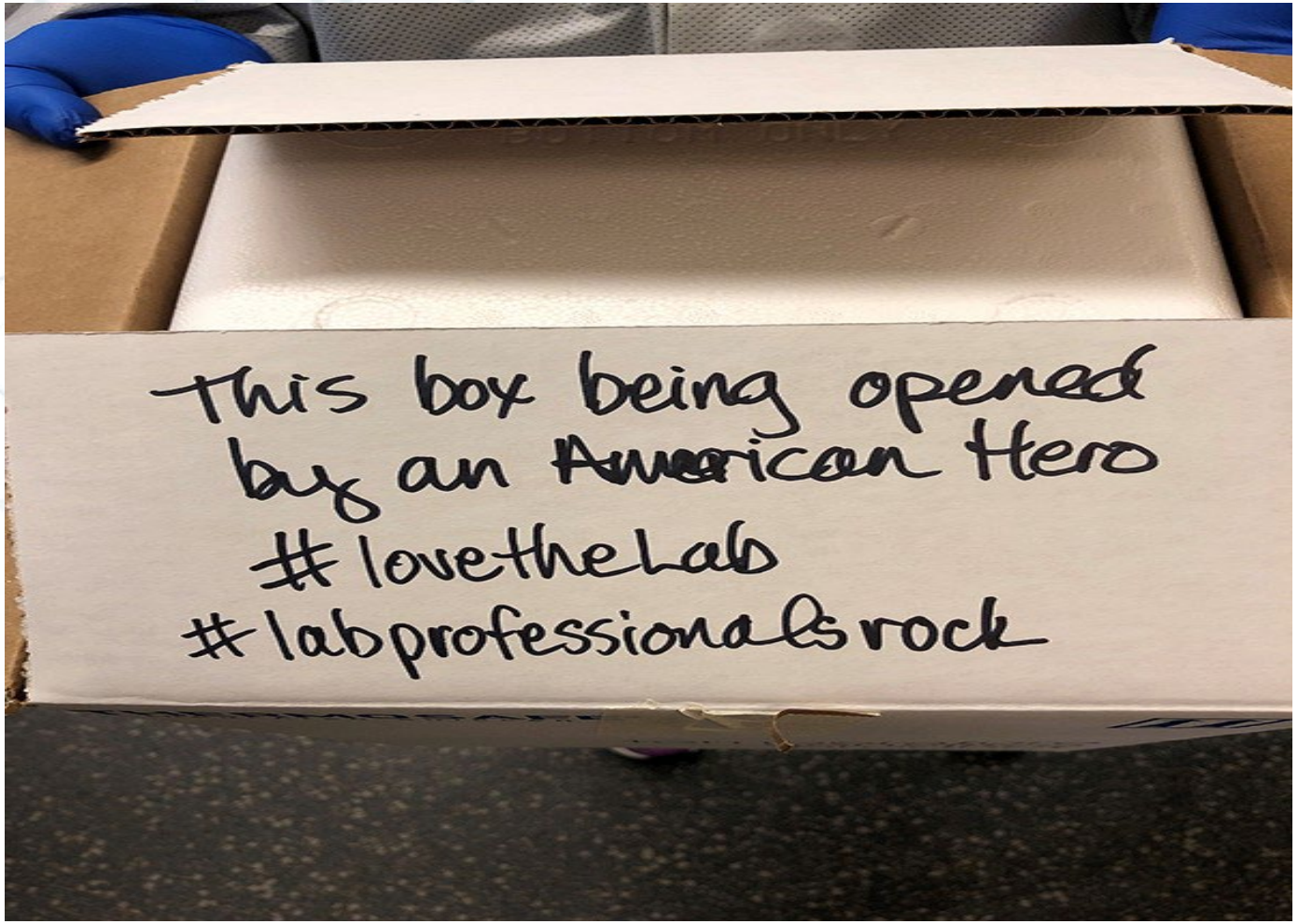

Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov