Clinical Laboratory COVID-19 Response Call

Monday, September 20, 2021, at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **SARS-CoV-2 Variants Update**
  - John Barnes, CDC Laboratory and Testing Task Force for the COVID-19 Response
- **Flu Testing Guidance**
  - Manish Patel, CDC Influenza Division
- **FDA Update**
  - Tim Stenzel, U.S. Food and Drug Administration (FDA)

Division of Laboratory Systems (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.

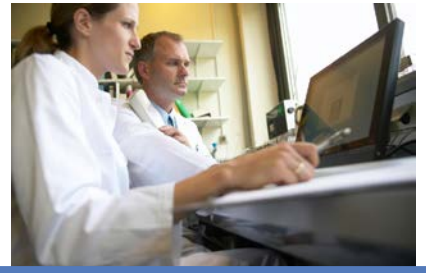
Four Goal Areas

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

New Free Online CLIA Training

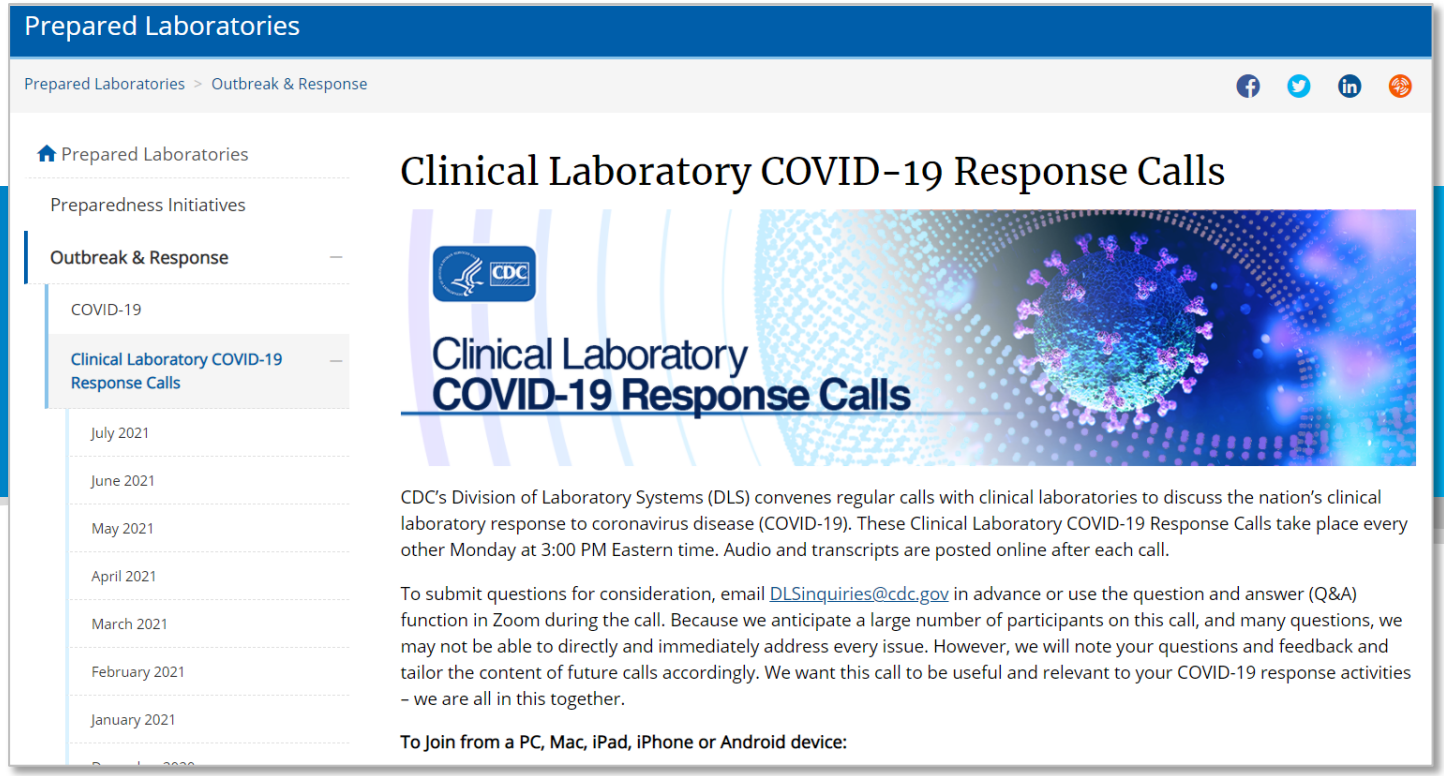
Introduction to the Clinical Laboratory Improvement Amendments 1988 (CLIA)

- Find it at www.cdc.gov/labtraining
- Equips learners with foundational information about CLIA
- CEUs: 1.5 contact hours P.A.C.E. credit
- Duration of course is 1.5 hours
- Designed for anyone with a role associated with clinical laboratory testing, including those conducting tests or supporting other activities related to the clinical testing process

CDC Preparedness Portal

https://www.cdc.gov/csels/dls/preparedlabs/covid-19-clinical-calls.html

Find CLCR call information, transcripts, and audio recordings on the CDC Preparedness Portal



Schedule for Clinical Laboratory COVID-19 Response Calls

The next call will be on **Monday, October 4** from

3:00 PM to 4:00 PM EDT

We Want to Hear from You!

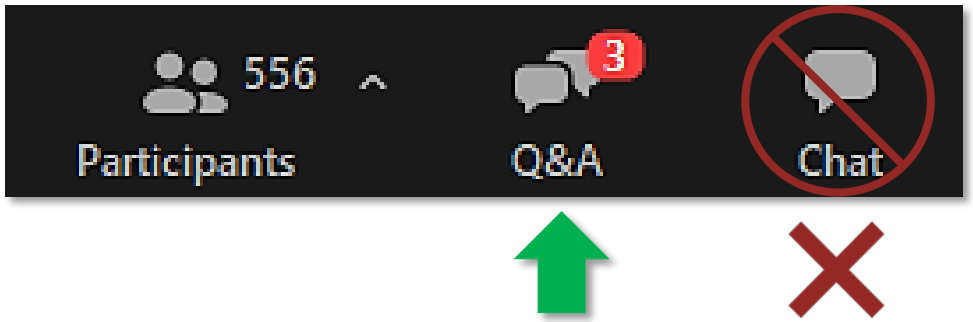
Training and Workforce Development

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



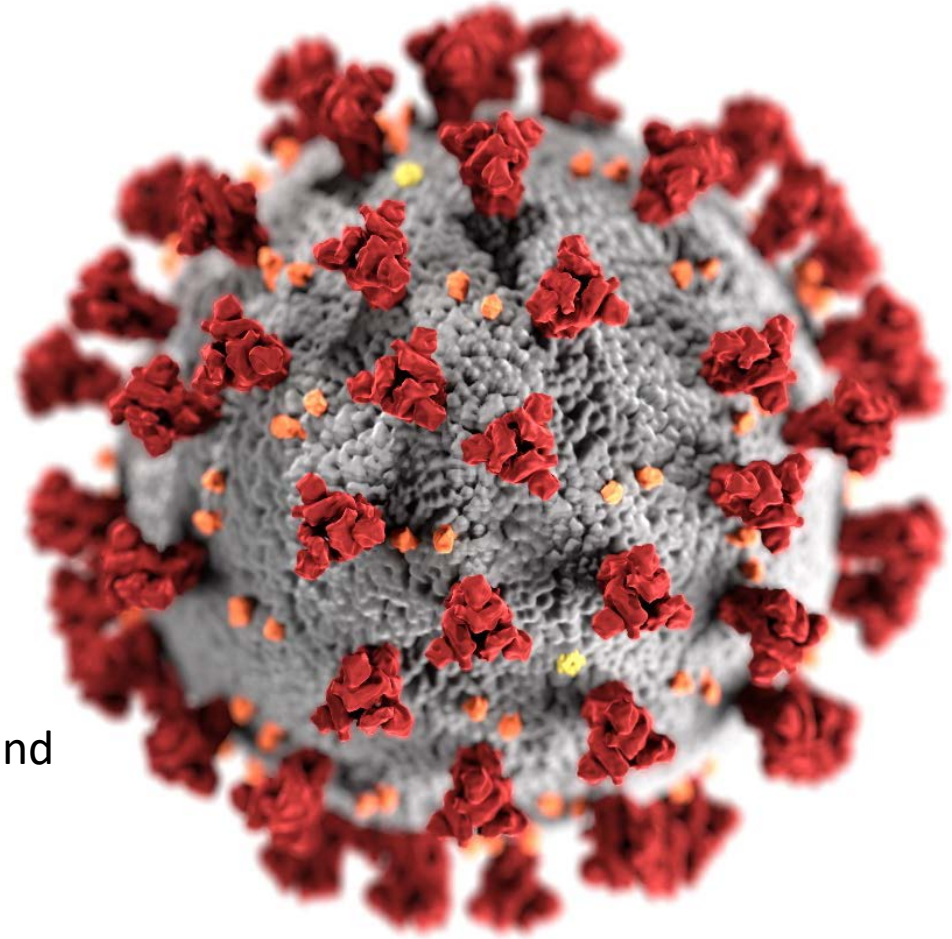
- For media questions, please contact CDC Media Relations at media@cdc.gov
- If you are a patient, please direct any questions to your healthcare provider

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.

SSEV Update

John R. Barnes, Ph.D.

SSEV Deputy Lead, COVID-19 Laboratory Task Force



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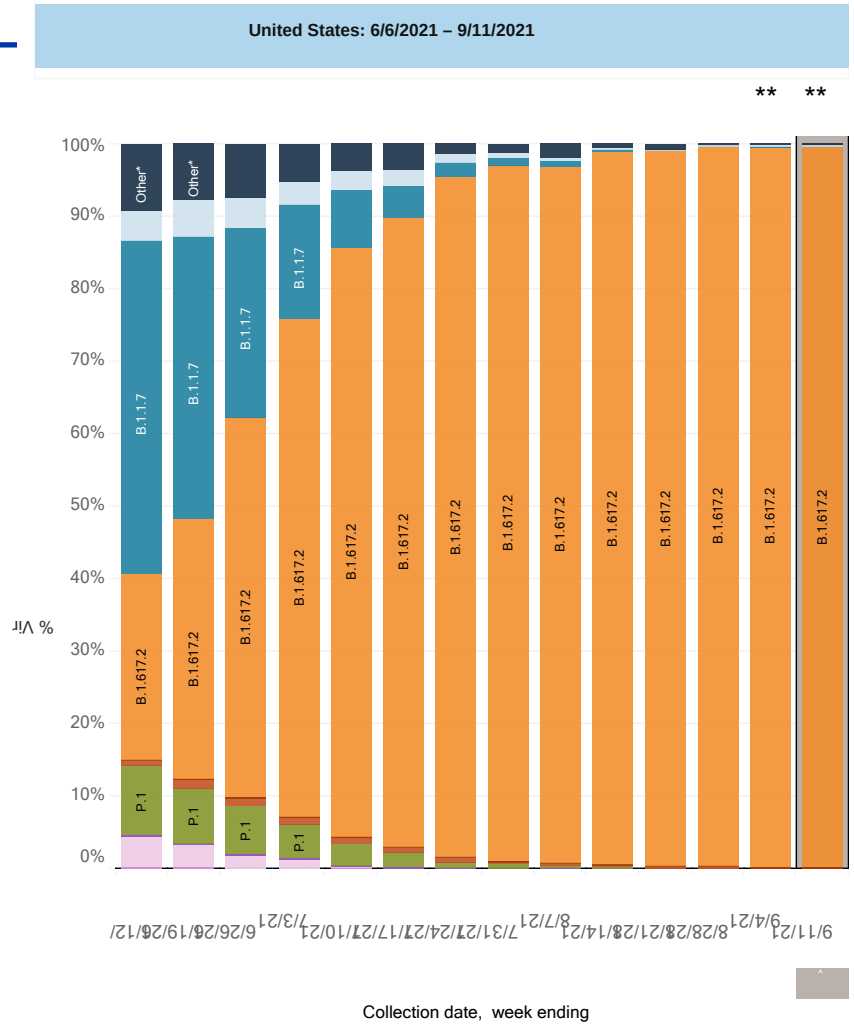
cdc.gov/coronavirus

National Nowcast Estimates of SARS-CoV-2 Lineages

- Delta is holding at 99%
  - B.1.617.2 major variant (99% contains AY.3-AY.25)
  - AY.2 (0.1%), AY.1 (0.2%)
- Alpha (B.1.1.7)
  - Estimated at 0.1%
- Beta (B.1.351)
  - Estimated at 0.0%
- Gamma (P.1)
  - 0.02%
- Mu (B.1.621)
  - 0.1%

[1]Weighted estimates from period ending 8/28/2021 (as of 9/10/2021) used for comparison with Nowcast (as of 09/11/2021)



United States: 9/5/2021 – 9/11/2021 NOWCAST

USA

Lineage		Type	%Total	95%PI
Alpha	B.1.1.7	VOC	0.0%	0.0-0.2%
Beta	B.1.351	VOC	0.0%	0.0-0.2%
Gamma	P.1	VOC	0.0%	0.0-0.2%
Delta	B.1.617.2	VOC	99.4%	98.6-100.0%
	AY.1	VOC	0.2%	0.0-0.7%
	AY.2	VOC	0.1%	0.0-0.5%
Eta	B.1.525	VOI	0.0%	0.0-0.2%
Iota	B.1.526	VOI	0.0%	0.0-0.2%
Kappa	B.1.617.1	VOI	0.0%	0.0-0.2%
Mu	B.1.621		0.1%	0.0-0.5%
N/A	B.1.617.3	VOI	0.0%	0.0-0.2%
Other	Other*		0.2%	0.0-0.7%

* Enumerated lineages are VOI/VOC or are circulating >1% in at least one HHS region during at least one two week period; remaining lineages are aggregated as "Other".

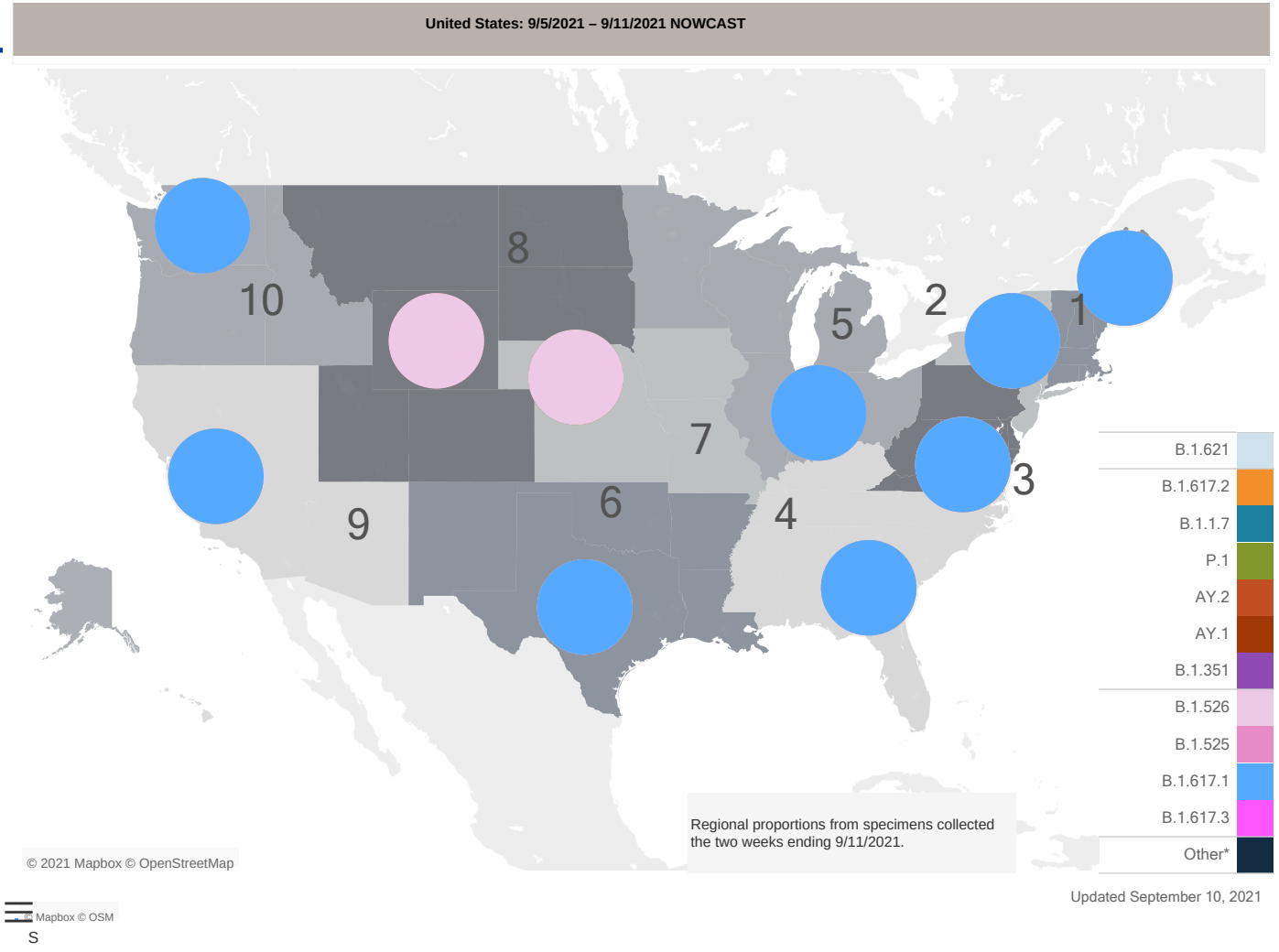
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

Sublineages of P.1, B.1.351 and B.1.621 are aggregated with the parent lineage and included in parent lineage's proportion. Q.1-Q.8 are aggregated with B.1.1.7. AY.3-AY.25 are aggregated with B.1.617.2.

https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Regional Nowcast Proportion of SARS-CoV-2 Lineages

- Delta (B.1.617.2) predominates in all HHS Regions
  - All 10 HHS regions >99%
  - AY.1 and AY.2 are <1% nationally, and for 9 out of 10 HHS
  - Region 9 AY.1 (0.8%) AY.2 (0.2%)
- Mu(B.1.621)
  - All HHS Regions <0.2%
    - There is no change >0.2% in this variant for any HHS Region from 8/28/21

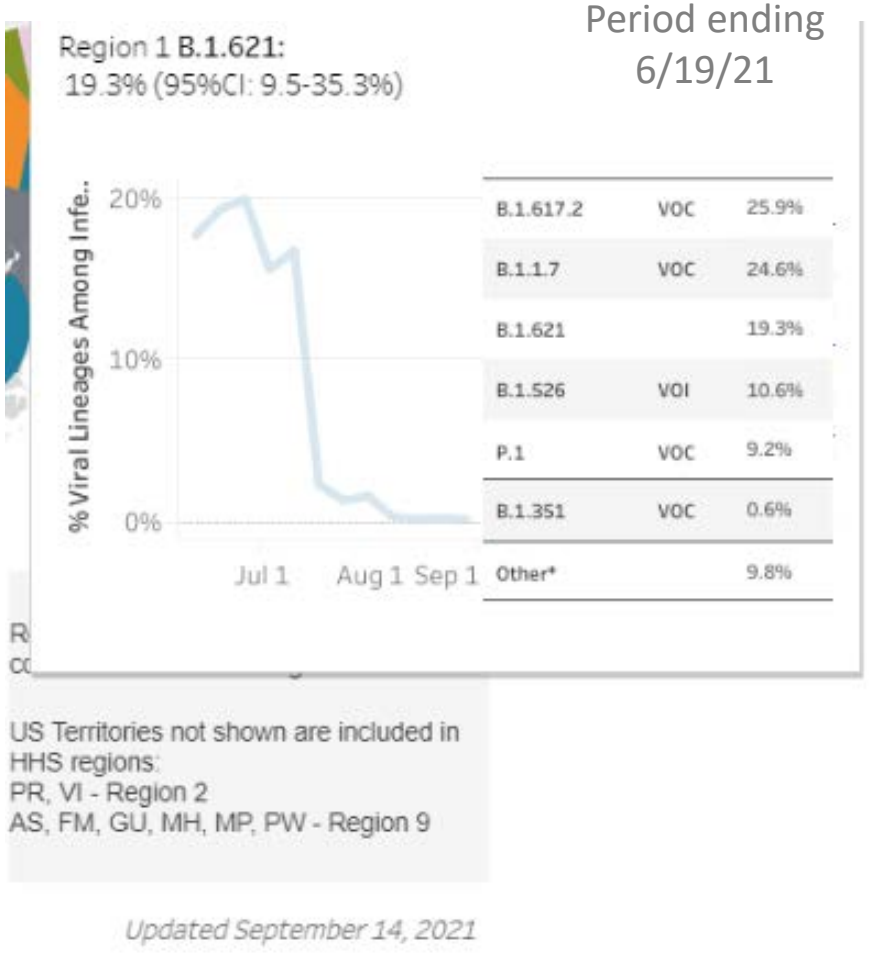


Updated 09/10/2021

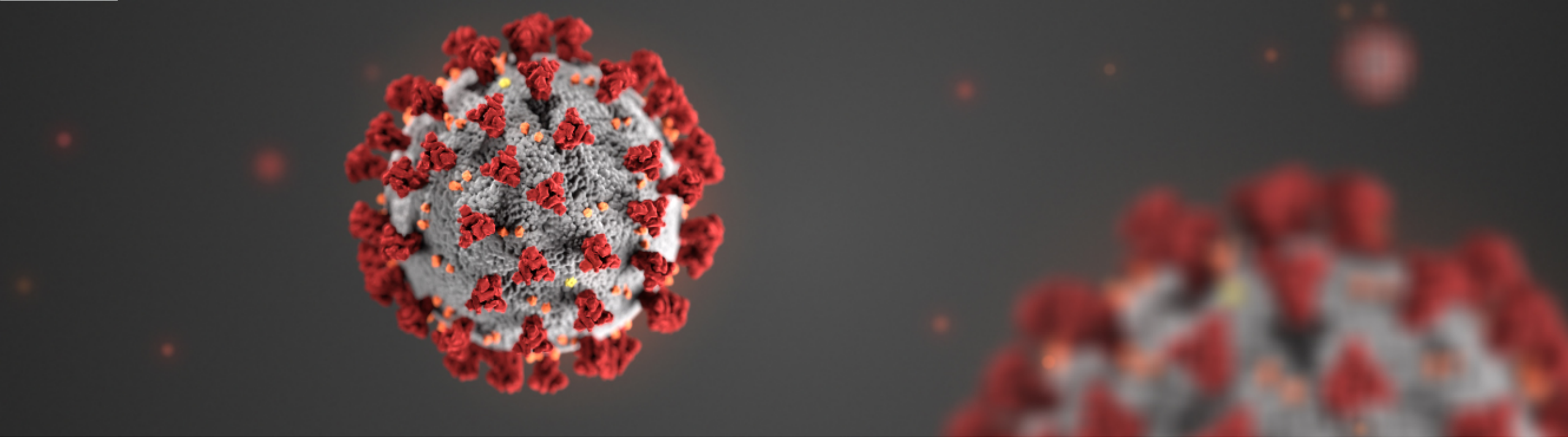
https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Proportions of Mu Lineage (B.1.621)

- Two lineages can be distinguished genetically
  - B.1.621 and B.1.621.1
  - Combined they currently represent <0.2%
  - Spikes typically share a few substitutions
    - T95I, Y144S, Y145N, **R346K**, **E484K**, **N501Y**, D614G, P681H, D950N
- B.1.621 and B.1.621.1 combined, peaked nationally at ~5% (period ending 6/19/2021)
  - Declining since that time
  - HHS Region 1 had largest proportion (~20%)
    - Period ending 6/26/2021
    - Chart on right shows B.1.621 (June-September)
- More interest in it since its designation as VOI by WHO
  - Those analyzing should be sure to check the collection dates of swabs rather than publication dates
  - We continue to track to identify any upturns



https://covid.cdc.gov/covid-data-tracker/#variant-proportions



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.

2020-2021 Influenza Testing Issues

Manish Patel MD
Influenza Division, CDC
September 20, 2021

Influenza Activity in the U.S. During 2021-2022

- Unpredictable, may vary by extent of COVID-19 control measures
  - Influenza activity can vary geographically over time
- Monitoring of viral co-circulation is essential
  - Public health surveillance (local, state, national)
    - SARS-CoV-2
    - Influenza A and B viruses
  - Local clinical laboratories, hospital testing results
- Prepare for viral co-circulation
  - Prevention and control strategies are needed for both SARS-CoV-2 and influenza viruses

Co-circulation of Influenza Viruses and SARS-CoV-2

- **Co-infection with influenza A or B viruses and SARS-CoV-2 might occur**
  - Documented in case reports, case series
  - Frequency, severity, and risk factors are unknown

- **Overlapping signs, symptoms, some differences with either infection**
  - Incubation period is shorter with influenza (1-3 days) than COVID-19 (2-14 days)
  - Viral shedding, period of viral RNA detection is generally shorter for influenza
  - Ageusia/dysgeusia, anosmia are more common with COVID-19 than influenza
  - Timing of onset of complications/severe disease is earlier with influenza

Cuadrado-Payan Lancet 2020; Azekawa ID Cases 2020; Ma Int J Infect Dis 2020; Ding J Med Virology 2020; Wu Emerg Inf Dis 2020; Beltran-Corellini Eur J Neurology 2020; Zayet Microbes and Infect 2020

Co-circulation of Influenza Viruses and SARS-CoV-2

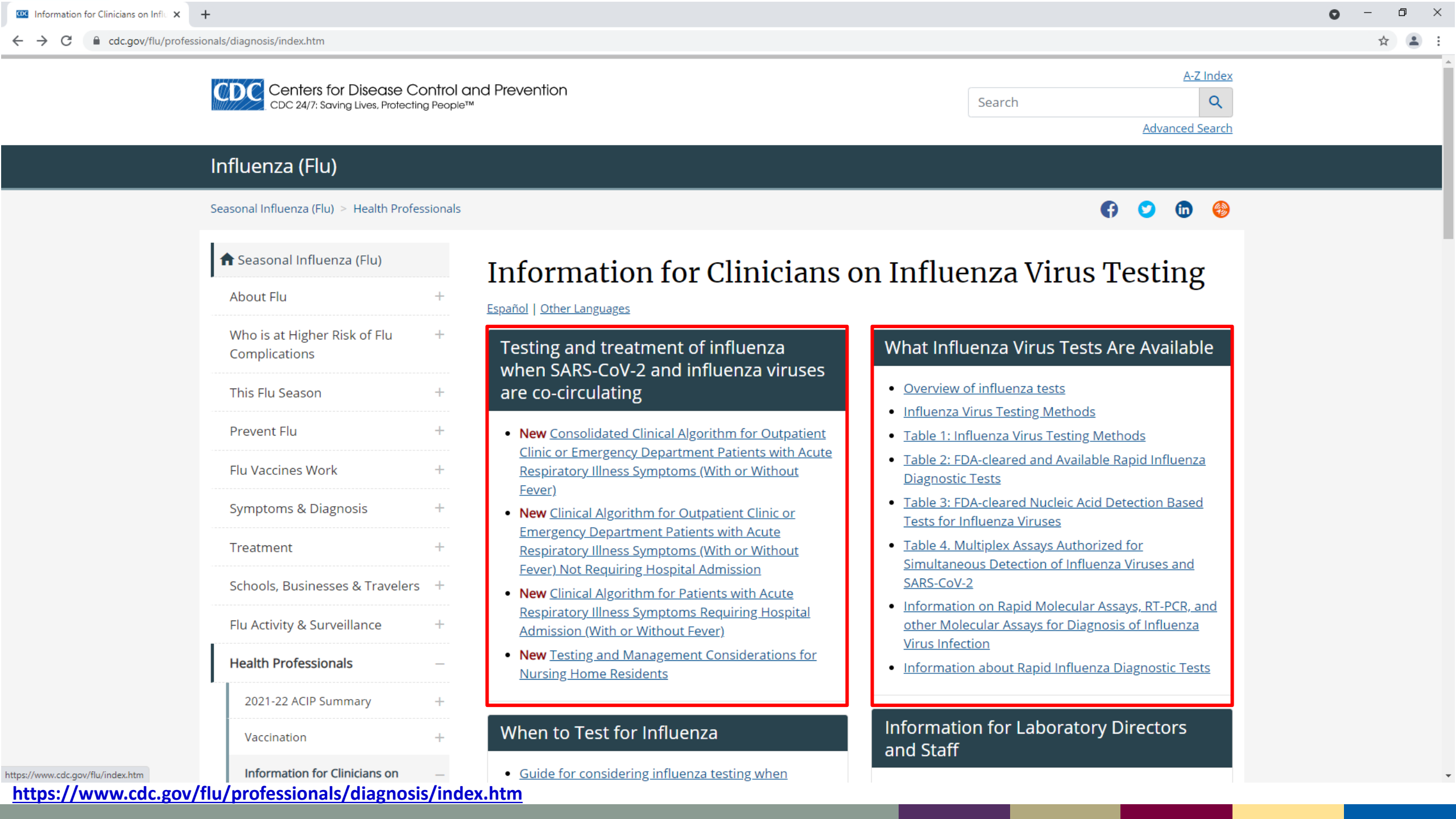
- **Implications**
  - **Testing is needed to distinguish influenza from COVID-19**
    - **Consider influenza virus infection, SARS-CoV-2 infection, co-infection**
- **Testing strategies (respiratory specimens) during co-circulation**
  - **Hospitalized patients with acute respiratory illness (nucleic acid detection assays are preferred):**
    - Test for SARS-CoV-2 and for influenza viruses by single-plex assays
    - Test for SARS-CoV-2 and influenza viruses by multiplex assay
  - **Outpatients with acute respiratory illness:**
    - Test for both SARS-CoV-2 and influenza viruses, **OR**
    - Test for SARS-CoV-2 and use judgement to clinically diagnose influenza and prescribe antiviral treatment of influenza

What Influenza Tests Are Recommended?

- **Outpatients:**
  - **Rapid influenza molecular assays are recommended over rapid influenza antigen detection tests**
- **Hospitalized patients:**
  - **RT-PCR or other influenza molecular assays recommended (2020-2021: Influenza A/B, SARS-CoV-2)**
    - Rapid antigen detection tests and immunofluorescence assays are not recommended should not be used unless molecular assays are not available
  - **Immunocompromised patients: Multiplex RT-PCR assays targeting a panel of respiratory pathogens, including influenza viruses are recommended**

- ***Do not order viral culture for initial or primary diagnosis of influenza***
- ***Do not order serology for influenza***
  - **Results from a single serum specimen cannot be reliably interpreted, and collection of paired acute and convalescent sera 2-3 weeks apart are needed**

IDSA 2018 Influenza Clinical Practice Guidelines Clinical Infect Dis 2019



https://www.cdc.gov/flu/professionals/diagnosis/index.htm

Seasonal Influenza (Flu)
About Flu
Who is at Higher Risk of Flu Complications
This Flu Season
Prevent Flu
Flu Vaccines Work
Symptoms & Diagnosis
Treatment
Schools, Businesses & Travelers
Flu Activity & Surveillance
Health Professionals
Flu News & Spotlights
What's New

What CDC Does
FluVaxView
Communications Resource Center

Testing Guidance for Clinicians When SARS-CoV-2 and Influenza Viruses are Co-circulating

[Based upon local public health surveillance data and testing at local healthcare facilities]

Español | Other Languages

Outpatient Clinic or Emergency Department Patients with Acute Respiratory Illness Symptoms (With or Without Fever)*

Does the Patient Require Hospital Admission?

YES

1. **Specimen collection**

- **Implement recommended infection prevention and control measures and collect respiratory specimens for influenza and SARS-CoV-2 testing.**[1] (Two different specimens may need to be collected if multiplex testing is unavailable).

2. **SARS-CoV-2 and Influenza Testing**
   a) Order multiplex nucleic acid detection assay for influenza A/B/SARS-CoV-2.[2,3] ***OR***
   b) If multiplex nucleic acid detection assay is not available, order SARS-CoV-2 nucleic acid detection assay[3] ***and*** Influenza nucleic acid detection assay.[4]
   (If SARS-CoV-2 nucleic acid detection assay is not available on-site and SARS-CoV-2 antigen detection assay is used,[5] confirm negative SARS-CoV-2 antigen

NO

Follow recommended infection prevention and control measures[1]

1. **SARS-CoV-2 Testing**

Test for SARS-CoV-2 by nucleic acid detection[2,3]; *OR* if not available, by SARS-CoV-2 antigen detection assay.[5]

2. **Influenza Testing and Treatment**
   a) Test for influenza if results will change clinical management or for infection control decisions (e.g. long-term care facility resident returning to a facility, or a person of any age returning to a congregate setting): order rapid influenza nucleic acid detection assay[2,3,4,11]**;** if rapid influenza nucleic acid detection assay is not available on-site, order rapid influenza antigen assay[13]; prescribe antiviral treatment if

Testing Guidance for Clinicians When SARS-CoV-2 and Influenza Viruses are Co-circulating

[Based upon local public health surveillance data and testing at local healthcare facilities]

Outpatient Clinic or Emergency Department Patients with Acute Respiratory Illness Symptoms (With or Without Fever)*

Does the Patient Require Hospital Admission?

YES

1. Specimen collection

***Implement recommended infection prevention and control measures and collect respiratory specimens for influenza and SARS-CoV-2 testing.[1]** (Two different specimens may need to be collected if multiplex testing is unavailable).

2. SARS-CoV-2 and Influenza Testing

a) Order multiplex nucleic acid detection assay for influenza A/B/SARS-CoV-2.[2,3] ***OR***

b) If multiplex nucleic acid detection assay is not available, order SARS-CoV-2 nucleic acid detection assay[3] ***and*** Influenza nucleic acid detection assay.[4]
(If SARS-CoV-2 nucleic acid detection assay is not available on-site and SARS-CoV-2 antigen detection assay is used,[5] confirm negative SARS-CoV-2 antigen detection results by SARS-CoV-2 nucleic acid detection assay at an outside laboratory). (Note: Rapid influenza antigen detection assays are not recommended for hospitalized patients due to low sensitivities.)

(Note: Because SARS-CoV-2 and influenza virus co-infection can occur, a positive influenza test result without SARS-CoV-2 testing does not exclude COVID-19, and a positive SARS-CoV-2 test result without influenza testing does not exclude influenza.)

3. Treatment

*If bacterial pneumonia or sepsis is suspected, consider testing recommendations and empiric antibiotic treatment per American Thoracic Society-Infectious Diseases Society of America Adult Community-acquired Pneumonia Guidelines[6], and **administer supportive care and treatment for suspected or confirmed COVID-19 patients per NIH COVID-19 Treatment Guidelines.[7]** (Note: community-acquired bacterial co-infections can occur but appear to be uncommon with COVID-19,[8,9,10] and may be more common with influenza.[11])

*Start empiric oseltamivir treatment for suspected influenza as soon as possible regardless of illness duration, without waiting for influenza testing results, per Infectious Diseases Society of America Influenza Guidelines[11,12], and administer supportive care.

NO

Follow recommended infection prevention and control measures[1]

1. SARS-CoV-2 Testing

Test for SARS-CoV-2 by nucleic acid detection[2,3]; ***OR*** if not available, by SARS-CoV-2 antigen detection assay.[5]

2. Influenza Testing and Treatment

a) Test for influenza if results will change clinical management or for infection control decisions (e.g. long-term care facility resident returning to a facility, or a person of any age returning to a congregate setting): order rapid influenza nucleic acid detection assay[2,3,4,11]; if rapid influenza nucleic acid detection assay is not available on-site, order rapid influenza antigen assay[13]; prescribe antiviral treatment if positive.[11,12] ***OR***

b) Prescribe empiric antiviral treatment as soon as possible without influenza testing based on a clinical diagnosis of influenza for patients of any age with progressive disease of any duration, and for children and adults at high risk for influenza complications.[11,12,14]

*For adult patients with suspected community-acquired pneumonia who do not require admission, see American Thoracic Society-Infectious Diseases Society of America Adult Community-acquired Pneumonia Guidelines[6]

*For otherwise healthy non-high-risk persons with influenza-like illness (fever and either cough or sore throat) with illness ≤2 days, empiric antiviral treatment can be prescribed based upon clinical judgement.[11,12]

*For otherwise healthy non-high-risk persons without influenza-like illness or with illness duration >2 days, antiviral treatment of influenza is unlikely to provide significant clinical benefit.[11]

3. Follow isolation and quarantine recommendations for SARS-CoV-2[15]

https://www.cdc.gov/flu/professionals/diagnosis/index.htm

Testing Guidance for Clinicians When SARS-CoV-2 and Influenza Viruses are Co-circulating

[Based upon local public health surveillance data and testing at local healthcare facilities]

Español | Other Languages

Patients with Acute Respiratory Illness Symptoms Requiring Hospital Admission (With or Without Fever)

1. **Specimen collection**

- Implement recommended infection prevention and control measures and collect respiratory specimens for influenza and SARS-CoV-2 testing.[1] (Two different respiratory specimens may need to be collected if multiplex testing is unavailable).

2. **SARS-CoV-2 and Influenza Testing**

- Order multiplex nucleic acid detection assay for influenza A/B/SARS-CoV-2.[2,3] If not available, order SARS-CoV-2 nucleic acid detection assay[3] ***and*** influenza nucleic acid detection assay[4] (If a SARS-CoV-2 nucleic acid detection assay

Testing and Management Considerations for Nursing Home Residents with Acute Respiratory Illness Symptoms when SARS-CoV-2 and Influenza Viruses are Co-circulating

Español | Other Languages

The following practices should be considered when SARS-CoV-2 and Influenza viruses are found to be co-circulating based upon local public health surveillance data and testing at local healthcare facilities. While these considerations are specific to care of residents residing in nursing homes, some practices could be adapted for use in other long-term care settings (e.g. assisted living facilities).

1. **Place symptomatic residents in Transmission-Based Precautions using all recommended PPE for care of a resident with suspected SARS-CoV-2 infection**[1]

   Because some of the symptoms of influenza and COVID-19 are similar, it may be difficult to tell the difference between these two infections based on symptoms alone. Residents in the facility who develop symptoms of acute illness consistent with influenza or COVID-19 should be moved to a single room, if available, or remain in current room, pending results of viral testing. They should not be placed in a room with new roommates nor should they be moved to the COVID-19 care unit unless they are confirmed to have COVID-19 by SARS-CoV-2 testing.

   Nursing home residents, including older adults, those who are medically fragile and those with neurological or neurocognitive conditions, may manifest atypical signs and symptoms of influenza virus infection and may not have fever.

https://www.cdc.gov/flu/professionals/diagnosis/testing-management-considerations-nursinghomes.htm

QUESTIONS?

Non-hospitalize patients

Testing Guidance for Clinicians When SARS-CoV-2 and Influenza Viruses are Co-circulating
[Based upon local public health surveillance data and testing at local healthcare facilities]

Outpatient Clinic or Emergency Department Patients with Acute Respiratory Illness Symptoms (With or Without Fever) Not Requiring Hospital Admission

Follow recommended infection prevention and control measures[1]

1. Specimen Collection

***Implement recommended infection prevention and control measures and collect respiratory specimens for influenza and SARS-CoV-2 testing.[1]**
(Two different specimens may need to be collected if multiplex testing for influenza viruses and SARS-CoV-2 is unavailable on-site.[2,3])

2. SARS-CoV-2 and Influenza Testing

A) Test for SARS-CoV-2 by nucleic acid detection[2,3]; *OR* if not available, by SARS-CoV-2 antigen detection assay.[4]
(Note: Because antigen detection assays have lower sensitivity than nucleic acid detection assays, a negative SARS-CoV-2 antigen detection assay result does not necessarily exclude SARS-CoV-2 infection and should be confirmed by SARS-CoV-2 nucleic acid detection assay, especially if suspicion for COVID-19 is high – such as high SARS-CoV-2 community prevalence or recent close exposure to a person with COVID-19.)

B) Test for influenza if results will change clinical management or for infection control decisions (e.g. long-term care facility resident returning to a facility, or a person of any age returning to a congregate setting): order rapid influenza nucleic acid detection assay[5,6]; if rapid influenza nucleic acid detection assay is not available on-site, order rapid influenza antigen detection assay.[7] (If available, multiplex nucleic acid detection assay for SARS-CoV-2, influenza A and B viruses can be performed on-site, or at an offsite clinical laboratory.[2,3])

(Note: Because SARS-CoV-2 and influenza virus co-infection can occur, a positive influenza test result without SARS-CoV-2 testing does not exclude SARS-CoV-2 infection, and a positive SARS-CoV-2 test result without influenza testing does not exclude influenza virus infection.

3. Treatment

***Prescribe antiviral treatment if on-site influenza testing is positive *OR* prescribe empiric antiviral treatment without influenza testing based upon a clinical diagnosis of influenza for patients of any age with progressive disease of any duration, and for children and adults at high risk for influenza complications with illness.[6,8,9]** (encourage patients to start antiviral treatment as soon as possible)

***For adult patients with suspected community-acquired pneumonia who do not require hospitalization, see antibiotic treatment recommendations from the American Thoracic Society-Infectious Diseases Society of America Adult Community-acquired Pneumonia Guidelines.[10]**

*For otherwise healthy non-high-risk persons with influenza-like illness (fever and either cough or sore throat) with illness ≤2 days, empiric antiviral treatment of suspected influenza can be prescribed based upon clinical judgement.[6,8]

*For otherwise healthy non-high-risk persons without influenza-like illness or with illness duration >2 days, antiviral treatment of influenza is unlikely to provide significant clinical benefit.[6]

4. Follow isolation and quarantine recommendations for SARS-CoV-2,[11] and arrange follow-up for any pending testing results.

https://www.cdc.gov/flu/professionals/diagnosis/index.htm

Hospitaliz patients

Testing Guidance for Clinicians When SARS-CoV-2 and Influenza Viruses are Co-circulating
[Based upon local public health surveillance data and testing at local healthcare facilities]

Patients with Acute Respiratory Illness Symptoms Requiring Hospital Admission (With or Without Fever)

1. Specimen collection

*Implement recommended infection prevention and control measures and collect respiratory specimens for influenza and SARS-CoV-2 testing.[1] (Two different respiratory specimens may need to be collected if multiplex testing is unavailable).

2. SARS-CoV-2 and Influenza Testing

*Order multiplex nucleic acid detection assay for influenza A/B/SARS-CoV-2.[2,3] If not available, order SARS-CoV-2 nucleic acid detection assay[3] ***and*** influenza nucleic acid detection assay[4] (If a SARS-CoV-2 nucleic acid detection assay is not available on-site and a SARS-CoV-2 antigen detection assay is used,[5] confirm negative SARS-CoV-2 antigen detection assay results by SARS-CoV-2 nucleic acid detection assay at an outside laboratory). (Note: Rapid influenza antigen detection assays are not recommended due to lower sensitivities compared with rapid influenza nucleic acid detection assays.)

(Note: Because SARS-CoV-2 and influenza virus co-infection can occur, a positive influenza test result without SARS-CoV-2 testing does not exclude COVID-19, and a positive SARS-CoV-2 test result without influenza testing does not exclude influenza.)

*In critically ill intubated and mechanically ventilated patients who are suspected to have COVID-19 or influenza without a confirmed diagnosis, including when upper respiratory tract specimens are negative, lower respiratory tract (e.g. endotracheal aspirate) specimens should be collected for SARS-CoV-2 and influenza virus testing by nucleic acid detection assay per NIH COVID-19 Treatment Guidelines,[6] and Infectious Diseases Society of America Influenza Clinical Practice Guidelines.[7]

3. Treatment

*If bacterial pneumonia or sepsis is suspected, consider testing recommendations and empiric antibiotic treatment per American Thoracic Society-Infectious Diseases Society of America Adult Community-acquired Pneumonia Guidelines,[8] and administer supportive care and treatment for suspected or confirmed COVID-19 patients per NIH COVID-19 Treatment Guidelines.[6] (Note: community-acquired bacterial co-infections can occur with COVID-19 but appear to be uncommon,[9,10,11] and may be more common with influenza.[7])

*Start empiric oseltamivir treatment for suspected influenza as soon as possible regardless of illness duration, without waiting for influenza testing results, per Infectious Diseases Society of America Influenza Clinical Practice Guidelines,[7,12] and administer supportive care.

https://www.cdc.gov/flu/professionals/diagnosis/index.htm

Influenza Testing and Specimen Source

- **Upper respiratory tract**
  - **Influenza viruses are generally detectable for 3-4 days by antigen detection; and 5-6 days by nucleic acid detection in uncomplicated disease, longer in infants and immunosuppressed**
    - ***Highest yield: Nasopharyngeal (NP) swabs (ideally collected within 3-4 days of illness onset)***
      - Other acceptable specimens: nasal swabs, NP aspirates, nasal aspirates, combined nasal and throat swabs

- **Lower respiratory tract**
  - **Higher, prolonged viral replication in severe lower respiratory tract disease**
    - **Influenza viruses may be detectable when cleared from the upper respiratory tract**
      - **RT-PCR was negative in 10-19% of patients in upper respiratory tract specimens versus lower respiratory tract (BAL specimens) for influenza A(H1N1)pdm09 viral RNA**

Rello Crit Care 2009; Fleury Eurosurveillance 2009; Blyth NEJM 2009

Influenza Tests in Clinical Settings

- **Variety of diagnostic tests available to clinicians to detect influenza viruses in respiratory specimens**
  - Differ by time to produce results, information provided, approved respiratory specimens, approved clinical settings, and **accuracy**
    - **Antigen detection** (FDA-cleared single-plex, multiplex)
      - One multiplex assay (detects SARS-CoV-2 & influenza viruses) received FDA EUA
    - **Nucleic acid detection** (FDA-cleared single-plex, multiplex)
      - 9 multiplex assays (detect SARS-CoV-2 & influenza viruses) received FDA EUA
    - Point-of-care assays (CLIA-waived)
    - Moderately complex (requires clinical laboratory)
    - Highly complex (large clinical laboratories, public health labs)

CDC. Information for Clinicians on Influenza Virus Testing: https://www.cdc.gov/flu/professionals/diagnosis/index.htm
CDC. Rapid Influenza Diagnostic Tests (RIDTs): https://www.cdc.gov/flu/professionals/diagnosis/table-ridt.html
CDC. Nucleic Acid Detection Based Tests for Influenza Viruses: https://www.cdc.gov/flu/professionals/diagnosis/table-nucleic-acid-detection.html

FDA Update

Tim Stenzel
U.S. Food and Drug Administration (FDA)

U.S. Food and Drug Administration (FDA)

- **COVID-19 Emergency Use Authorization (EUA) Information for Medical Devices**
  https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations
- **COVID-19 In Vitro Diagnostic EUAs**
  https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
- **COVID-19 Frequently Asked Questions**
  https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions
- **COVID-19 Updates**
  https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov
- **FDA Townhall Meetings**
  https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-immediately-effect-guidance-coronavirus-covid-19-diagnostic-tests-06032020
- **Independent Evaluations of COVID-19 Serological Tests**
  https://open.fda.gov/apis/device/covid19serology/

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration (FDA)

- **COVID-19 Diagnostic Development**
  CDRH-EUA-Templates@fda.hhs.gov

- **Spot Shortages of Testing Supplies: 24-Hour Support Available**
  1. Call 1-888-INFO-FDA (1-888-463-6332)
  2. Then press star (*)

- **FDA MedWatch**
  https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

U.S. FOOD & DRUG ADMINISTRATION

CDC Social Media

https://www.facebook.com/CDC

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Thank You For Your Time!

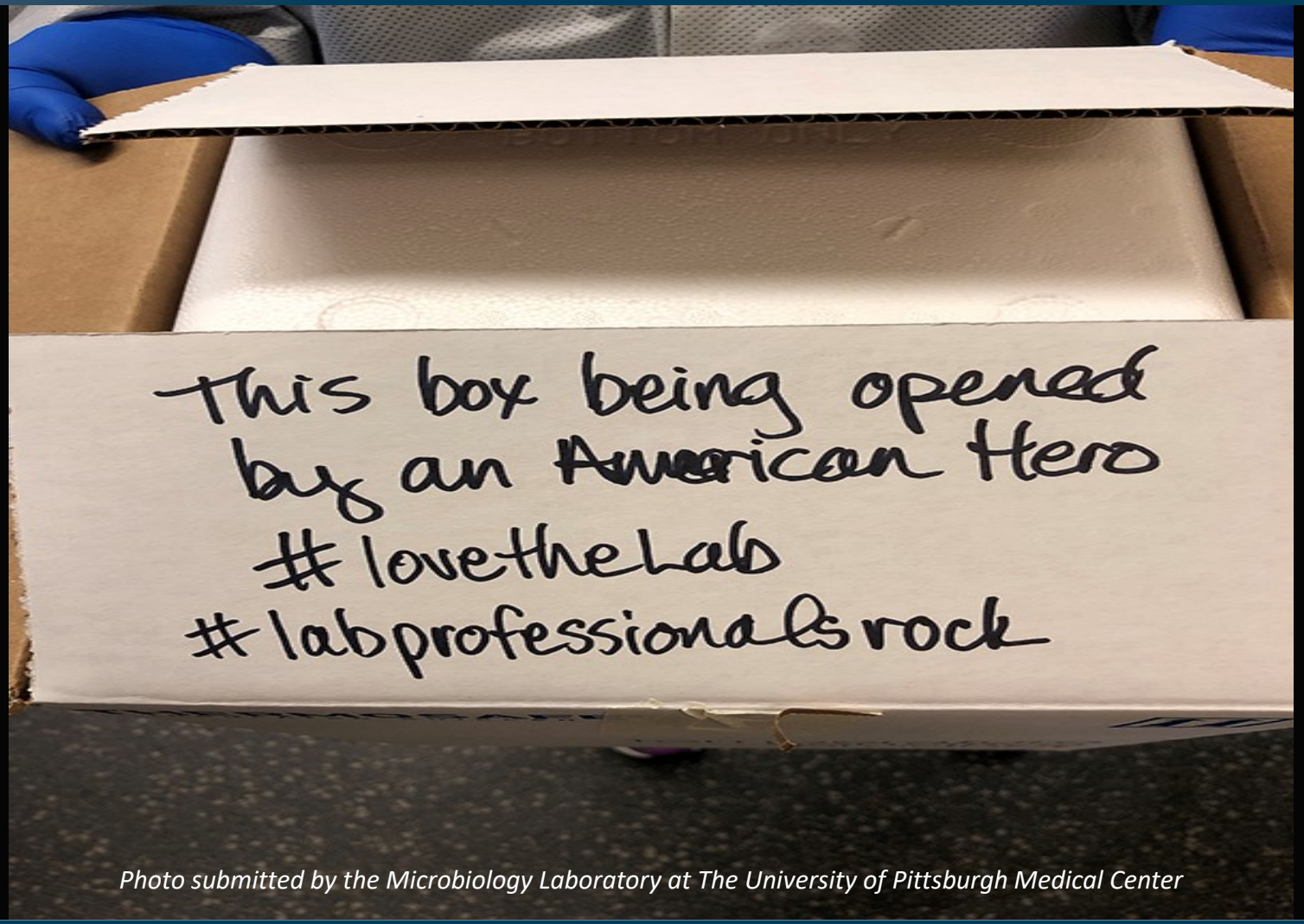

Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center