# Clinical Laboratory COVID-19 Response Call

## Monday, October 19th, 2020 at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **National Healthcare Safety Network (NHSN) Point-of-Care Test Reporting Tool for COVID-19 in Long-Term Care Facilities**
  - Kathy Bridson, CDC Division of Healthcare Quality Promotion (DHQP)
- **2020-2021 Influenza Testing Issues**
  - Tim Uyeki, CDC Influenza Division (ID)
- **Effects of Increased SARS-CoV-2 Testing on Laboratory Services: An Emerging Infections Network (EIN) Survey**
  - Dan Diekema, University of Iowa
- **FDA Update**
  - Tim Stenzel, U.S. Food and Drug Administration (FDA)
- **How Does CDC Use COVID-19 Laboratory Testing Data?**
  - Jason Hall, CDC Division of Preparedness and Emerging Infections (DPEI)
  - Ed Lockhart, CDC Division of Laboratory Systems (DLS)

# Schedule for Clinical Laboratory COVID-19 Response Calls

The next call will be on **Monday, November 2nd** from **3:00 PM to 4:00 PM EDT**.

# We Want to Hear From You!

**Training and Workforce Development**

Questions about education and training?

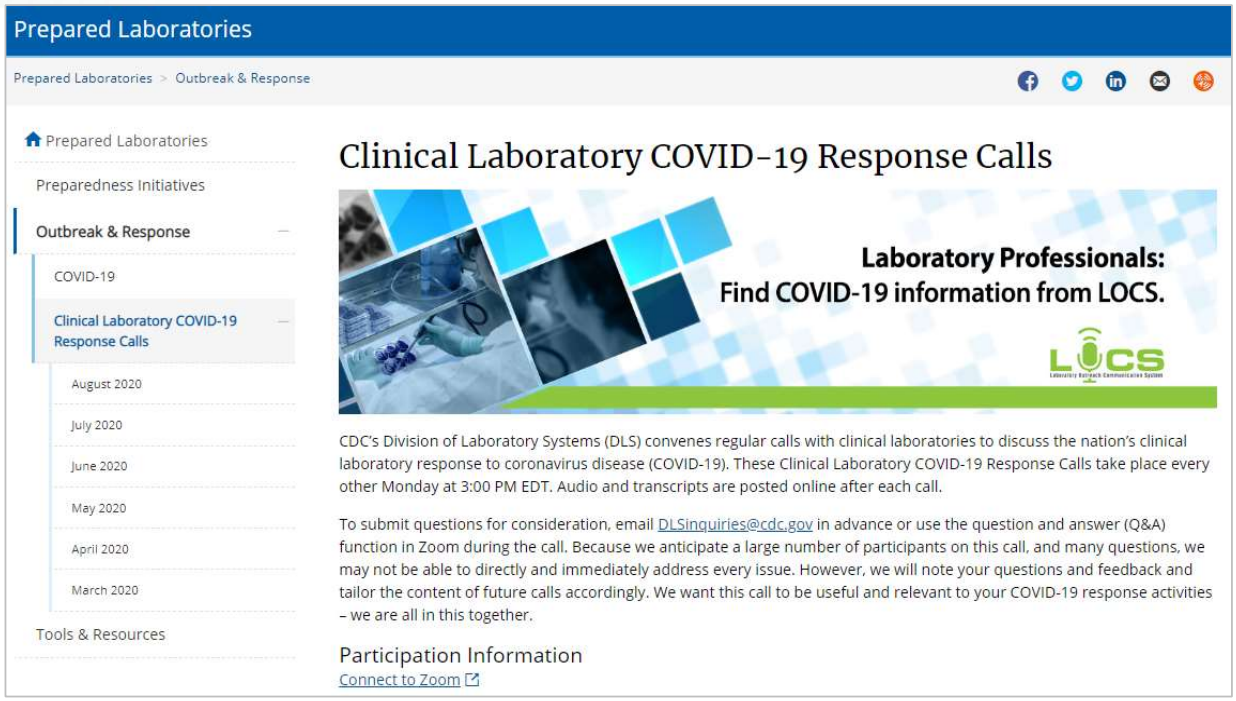
Contact LabTrainingNeeds@cdc.gov

# COVID-19 Resources for Laboratories

- **LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests**
  https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html
- **IVD Industry Connectivity Consortium**
  https://ivdconnectivity.org/livd/
- **Antigen Testing Guidance**
  https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html
- **Frequently Asked Questions about COVID-19 for Laboratories**
  https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html
- **Interim Guidance for Collecting, Handling, and Testing Clinical Specimens**
  https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
- **Diagnostic Tools and Virus**
  https://www.cdc.gov/coronavirus/2019-ncov/lab/tool-virus-requests.html
- **Emergency Preparedness for Laboratory Personnel**
  https://emergency.cdc.gov/labissues/index.asp
- **CDC Laboratory Outreach Communication System (LOCS)**
  https://www.cdc.gov/csels/dls/locs/

# CDC Preparedness Portal

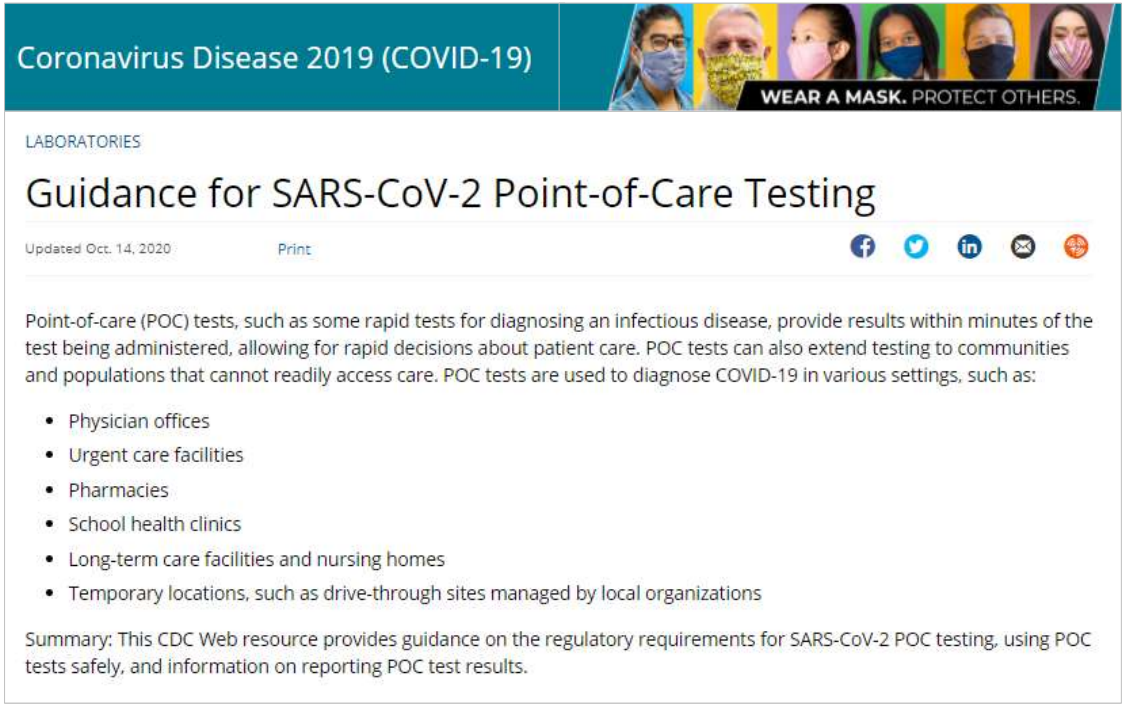
https://www.cdc.gov/csels/dls/preparedlabs/covid-19-clinical-calls.html




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

# New Guidance for SARS-CoV-2 Point-of-Care Testing

https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html



Coronavirus Disease 2019 (COVID-19)



LABORATORIES

## Guidance for SARS-CoV-2 Point-of-Care Testing

Updated Oct. 14, 2020 Print

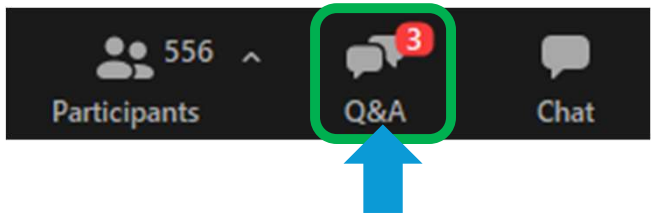
Point-of-care (POC) tests, such as some rapid tests for diagnosing an infectious disease, provide results within minutes of the test being administered, allowing for rapid decisions about patient care. POC tests can also extend testing to communities and populations that cannot readily access care. POC tests are used to diagnose COVID-19 in various settings, such as:

- Physician offices
- Urgent care facilities
- Pharmacies
- School health clinics
- Long-term care facilities and nursing homes
- Temporary locations, such as drive-through sites managed by local organizations

Summary: This CDC Web resource provides guidance on the regulatory requirements for SARS-CoV-2 POC testing, using POC tests safely, and information on reporting POC test results.

# How to Ask a Question

- **Using the 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

# National Healthcare Safety Network (NHSN) Point-of-Care Test Reporting Tool for COVID-19 in Long-Term Care Facilities

**Kathy Bridson**
CDC Division of Healthcare Quality Promotion (DHQP)



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

# 2020-2021 Influenza Testing Issues

Tim Uyeki MD, MPH, MPP, CAPT U.S. Public Health Service
Influenza Division, CDC
October 19, 2020

# Influenza Activity in the U.S. During 2020-2021

- 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 can 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
  - Diarrhea can occur in young children with influenza; at any age with COVID-19
  - Timing of onset of complications/severe disease is earlier with influenza
- High-risk groups for influenza and COVID-19 are similar
  - Young children, pregnant women are at high-risk for influenza complications

*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

# 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

## Multiplex Assays (nucleic acid detection) to Detect Influenza Viruses and SARS-CoV-2 in Respiratory Specimens (FDA EUA)

| Manufacturer | Assay | Viruses Detected | Result Time | Complexity |
|---|---|---|---|---|
| Biofire | Respiratory Panel 2.1 | Influenza A(H1), A(H1)pdm09, A(H3), B; SARS-CoV-2* | 1 hour | High, Moderate |
| Biofire | Respiratory Panel 2.1 -EZ | Influenza A(H1), A(H1)pdm09, A(H3), B; SARS-CoV-2* | 45 minutes | High, Moderate Waived |
| Genmark | ePlex Respiratory Pathogen Panel 2 | Influenza A(H1), A(H1)pdm09, A(H3), B; SARS-CoV-2* | <2 hours | High, Moderate |
| QIAGEN | QIAstat-Dx Respiratory SARS-CoV-2 Panel | Influenza A(H1), A(H1)pdm09, A(H3), B; SARS-CoV-2* | 1 hour | High, Moderate |
| Roche | cobas SARS-CoV-2 & Influenza A/B | Influenza A, B; SARS-CoV-2 | 3-8 hours | High, Moderate |
| Roche | cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test | Influenza A, B; SARS-CoV-2 | 20 minutes | High, Moderate Waived |
| Cepheid | Xpert Xpress SARS-CoV-2/ Flu/RSV | Influenza A, B; SARS-CoV-2 | <40 minutes | High, Moderate |
| Cepheid | Xpert Xpress SARS-CoV-2/ Flu/RSV | Influenza A, B; SARS-CoV-2 | <40 minutes | Waived |
| CDC | Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay | Influenza A, B; SARS-CoV-2 | 4 hours | High |

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-molecular;
https://www.cdc.gov/flu/professionals/diagnosis/table-flu-covid19-detection.html

***Also detect other respiratory viruses**

# 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
  - **Slower clearance of influenza viruses in severe disease**
  - **Influenza viral replication and viral RNA detection may be prolonged with corticosteroids, immunosuppression**
- **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**

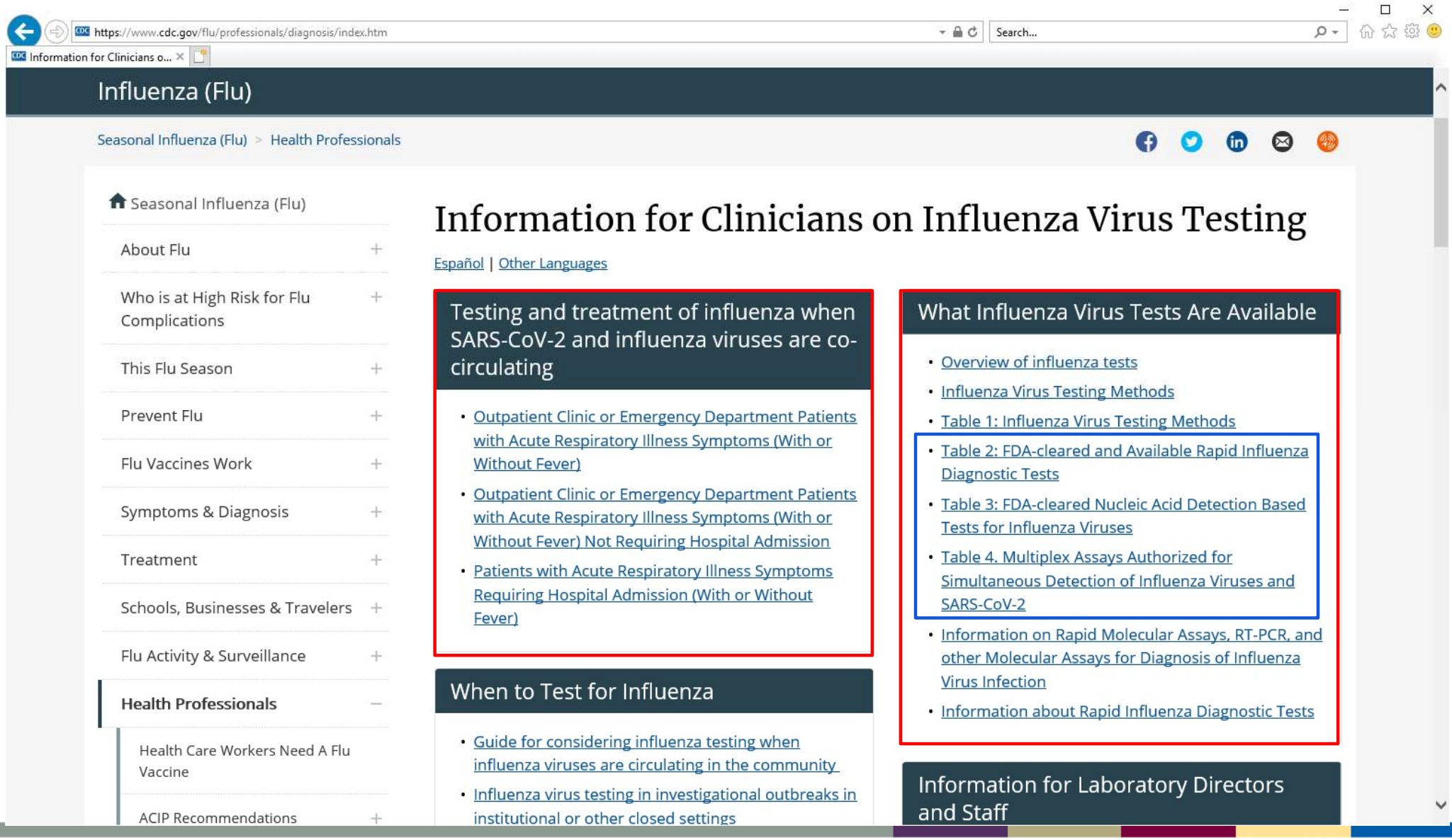
*Rello Crit Care 2009; Fleury Eurosurveillance 2009; Blyth NEJM 2009*

# 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
Search...
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Influenza (Flu)
Seasonal Influenza (Flu) > Health Professionals
Seasonal Influenza (Flu)
About Flu
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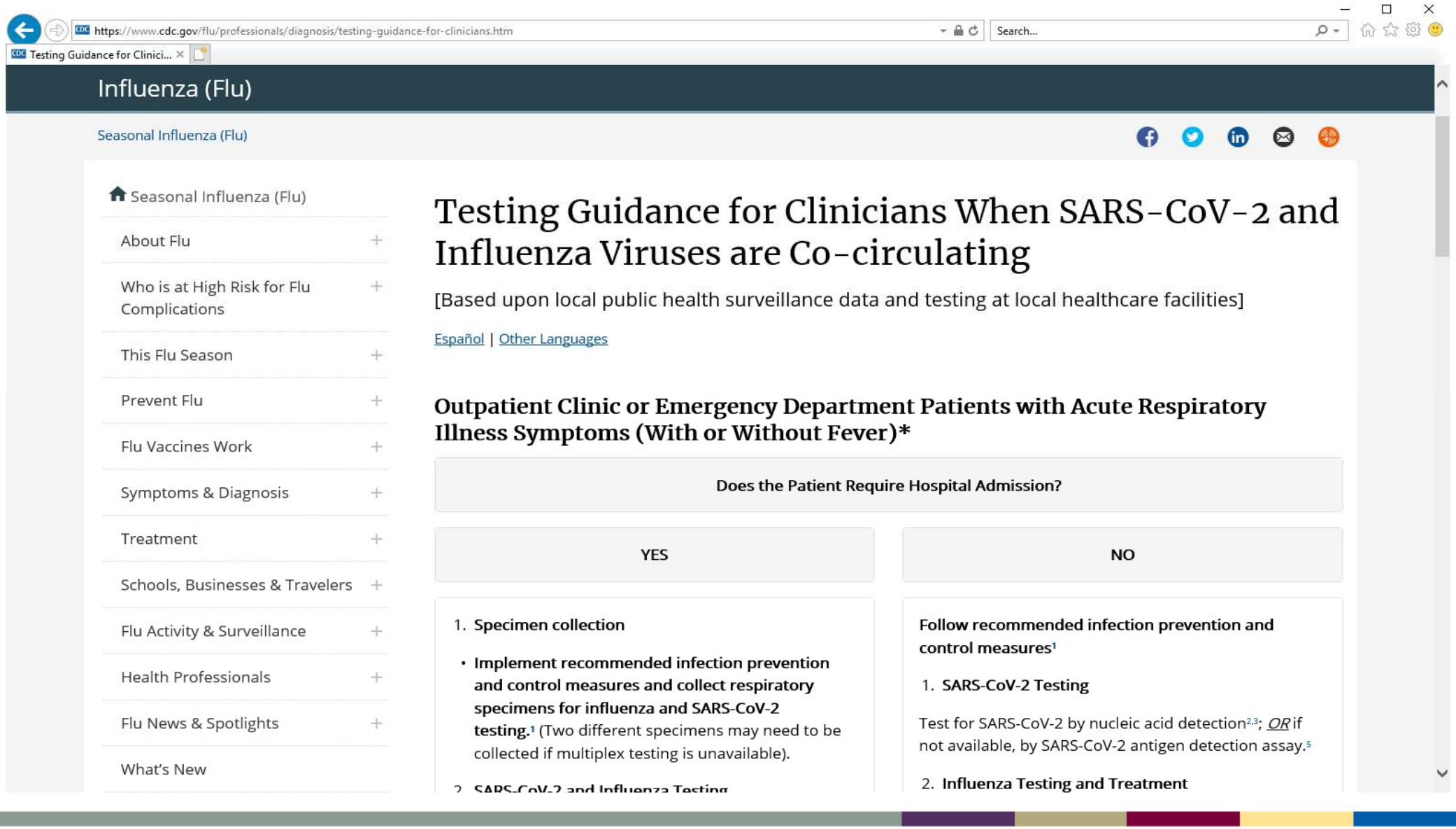
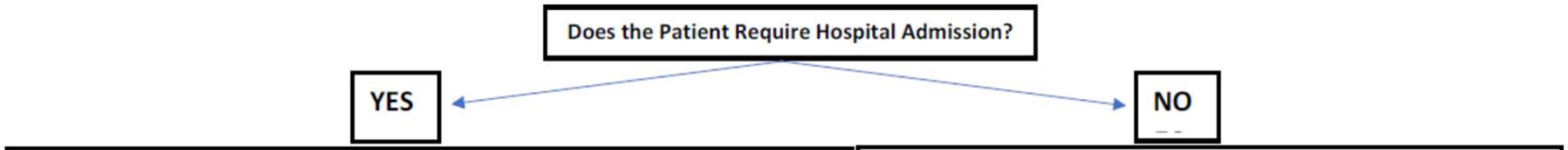
This Flu Season
Prevent Flu
Flu Vaccines Work
Symptoms & Diagnosis
Treatment
Schools, Businesses & Travelers
Flu Activity & Surveillance
Health Professionals
Health Care Workers Need A Flu Vaccine
ACIP Recommendations
Information for Clinicians on Influenza Virus Testing
Español | Other Languages
Testing and treatment of influenza when SARS-CoV-2 and influenza viruses are co-circulating
Outpatient Clinic or Emergency Department Patients with Acute Respiratory Illness Symptoms (With or Without Fever)
Outpatient Clinic or Emergency Department Patients with Acute Respiratory Illness Symptoms (With or Without Fever) Not Requiring Hospital Admission
Patients with Acute Respiratory Illness Symptoms Requiring Hospital Admission (With or Without Fever)
When to Test for Influenza
Guide for considering influenza testing when influenza viruses are circulating in the community
Influenza virus testing in investigational outbreaks in institutional or other closed settings
What Influenza Virus Tests Are Available
Overview of influenza tests
Influenza Virus Testing Methods
Table 1: Influenza Virus Testing Methods
Table 2: FDA-cleared and Available Rapid Influenza Diagnostic Tests
Table 3: FDA-cleared Nucleic Acid Detection Based Tests for Influenza Viruses
Table 4. Multiplex Assays Authorized for Simultaneous Detection of Influenza Viruses and SARS-CoV-2
Information on Rapid Molecular Assays, RT-PCR, and other Molecular Assays for Diagnosis of Influenza Virus Infection
Information about Rapid Influenza Diagnostic Tests
Information for Laboratory Directors and Staff


https://www.cdc.gov/flu/professionals/diagnosis/testing-guidance-for-clinicians.htm
Search...
Testing Guidance for Clinici...
Influenza (Flu)
Seasonal Influenza (Flu)
Seasonal Influenza (Flu)
About Flu
Who is at High Risk for 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
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
NO
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
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

## 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)*




**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.

**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

## 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-

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

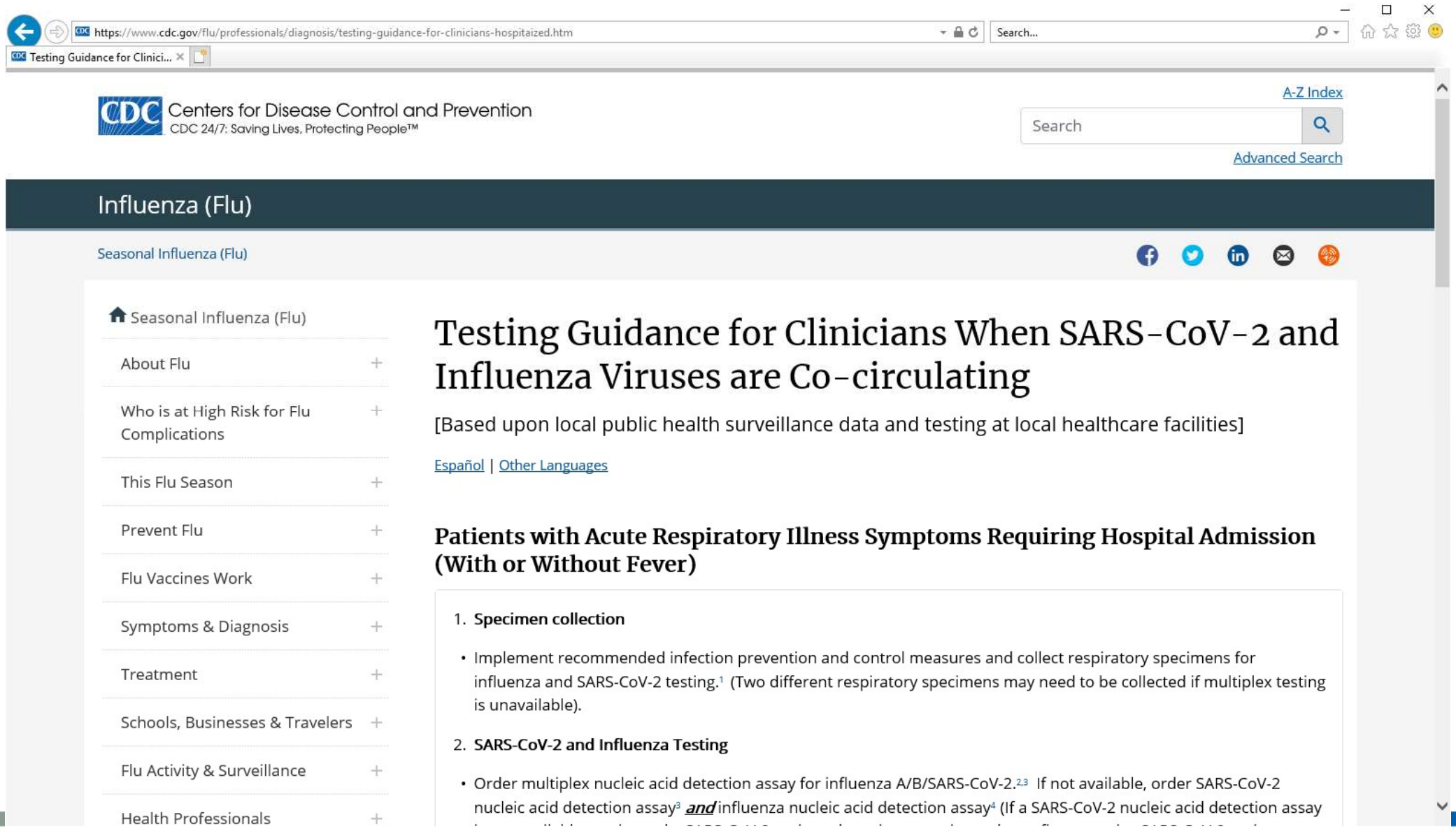
***For adult patients with suspected community-acquired pneumonia who do not require hospitalization, see antibiotic treatment recommendations from the American Thoracic Society-Infectious Diseases Society of America Adult Community-acquired Pneumonia Guidelines.[10]**

*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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Seasonal Influenza (Flu)
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Flu Vaccines Work
Symptoms & Diagnosis
Treatment
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Flu Activity & Surveillance
Health Professionals
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 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


# Effects of Increased SARS-CoV-2 Testing on Laboratory Services: An Emerging Infections Network (EIN) Survey

**Dan Diekema**
University of Iowa

# Background

- COVID-19 emergence has resulted in massive demand for diagnostic testing for SARS-CoV-2
- Major stress on clinical laboratories
- Has led to laboratory supply shortages
- Both COVID-19 and non-COVID-19 tests affected
- Need to better understand scope of the problem to bring to policy makers and other stakeholders

# Emerging Infections Network

- Clinician-based sentinel network funded by CDC and Infectious Disease Society of America
- Over 2,800 participants, most in the U.S.
- Designed to detect new or unusual clinical events, clusters, outbreaks, clinical aspects of emerging infections, & connect members to public health

# Survey on SARS-CoV-2 test impact

- Sent 8/25, 9/3 & 9/10 to EIN members
- Also sent separately to clinical microbiology laboratory directors via ClinMicroNet and the ASM Division C listserv
- EIN response rate 34% (613/1795)
- CMN/Div C: 85 lab directors responded

# Where is SARS-CoV-2 PCR performed?

| | 426 ID physicians | 85 Lab Directors |
|---|---|---|
| Onsite only | 253 (60%) | 55 (65%) |
| Offsite only | 34 (8%) | 0 |
| Both onsite+offsite | 133 (31%) | 29 (34%) |

Are you aware of any delays in results or unavailable tests (non-SARS-CoV-2) due to the demand for SARS-CoV-2 testing?

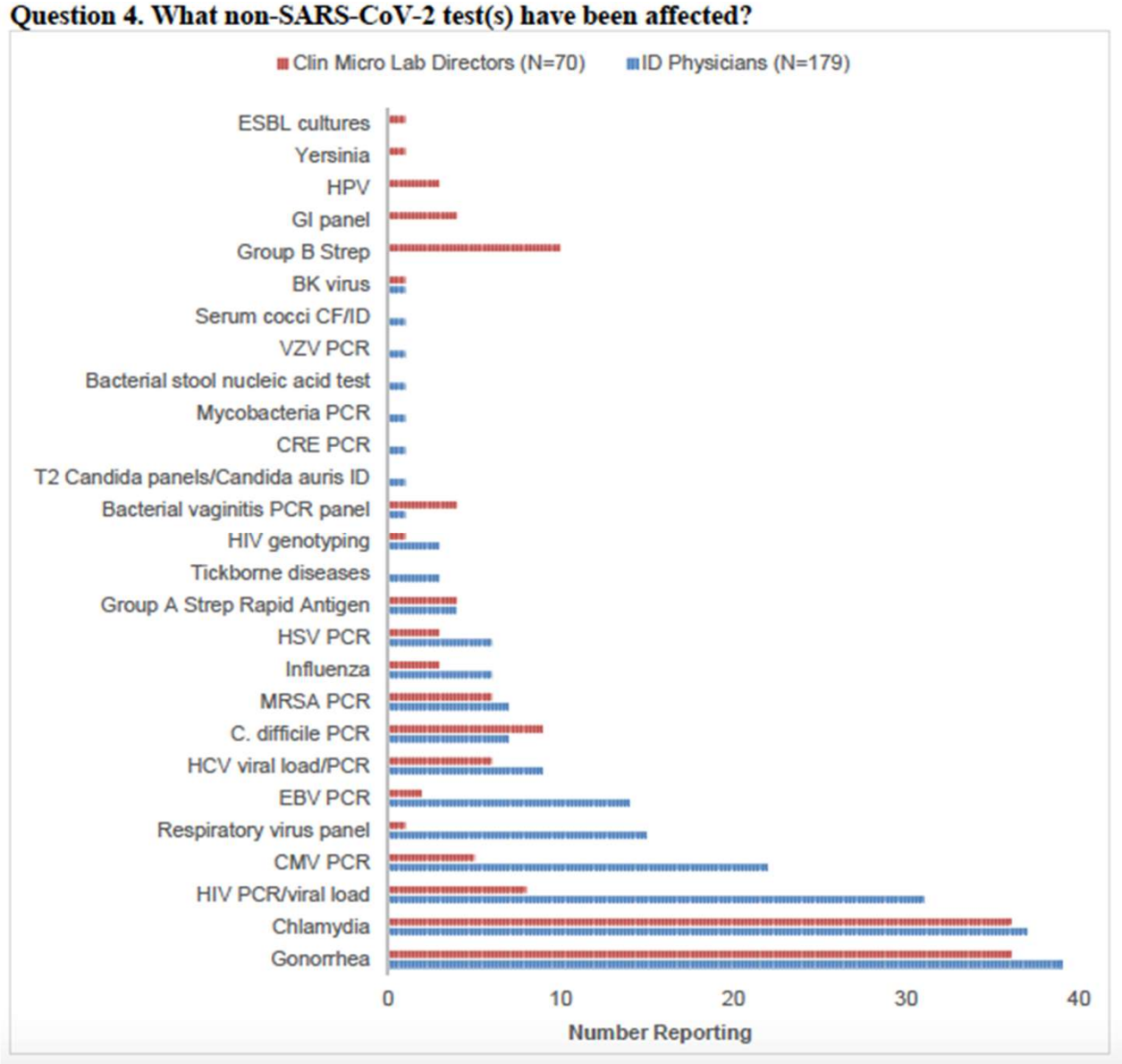
| | ID physicians | Lab directors |
|---|---|---|
| YES | 196 (32%) | 73 (86%) |
| NO | 417 (68%) | 12 (14%) |

Was the testing:

| | ID physicians | Lab Directors |
|---|---|---|
| Delayed | 133 (68%) | 36 (49%) |
| Not available | 34 (17%) | 12 (17%) |
| Both delayed & not available | 24 (12%) | 24 (33%) |

Most often affected:

MRSA PCR
*C difficile* PCR
HCV viral load PCR
EBV PCR
Resp virus panel
CMV PCR
HIV viral load PCR
**Chlamydia**
**Gonorrhea**



# Specific shortage comments:

- Media (MH, SBA, CNA, Mycocel, T-M, etc)
- Reagents, many for extraction steps
- Swabs
- Cartridges for major molecular platforms
- Personnel

# How did SARS-CoV-2 testing cause delays or unavailability?

| | ID physicians | Lab Directors |
|---|---|---|
| Reagent shortage | 107 (55%) | 62 (85%) |
| Personnel shortage | 68 (35%) | 28 (38%) |
| Device shortage | 49 (25%) | 31 (42%) |
| Supply shortage | 41 (21%) | 48 (66%) |

Percent reporting that the following “deteriorated” as a result of SARS-CoV-2 testing demand:

| | ID physicians | Lab Directors |
|---|---|---|
| Communication | 44 (22%) | 24 (33%) |
| Turnaround times | 122 (62%) | 51 (70%) |
| Special req testing | 34 (17%) | 16 (22%) |
| Overall availability | 77 (39%) | 44 (60%) |

*"We've had to re-design our lab to adjust to the new workflow from the high SARS-CoV-2 test volumes, new instrumentation and new personnel. We've had to send some molecular tests to a reference lab to free up thermocyclers for testing. We've also had to send other molecular tests to our reference lab due to reagent shortage. Currently, we've run low on several different agar plates in micro and having to source them from other vendors."*

*"It's been non-stop juggling and trouble-shooting"*

*“SARS-CoV-2 has left us scrambling in ways that were previously unimaginable for a clinical lab in the US”*

*“question wisdom of pre-OP testing”*

*“very dissatisfied lab staff who do not see ourselves as needing to do public health testing”*

*“the situation is unacceptable for the most wealthy country in the world”*

# Summary

- SARS-CoV-2 testing has been a major stressor for US clinical laboratories
- Supply chain and personnel issues have led to delays and unavailability of tests, greatest impact on STI (chlamydia/GC) testing
- Concern remains for ongoing adverse impact on patient care and public health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

September 8, 2020

Dear Colleagues,

There is a current shortage of STI test kits and laboratory supplies, most notably for chlamydia and gonorrhea nucleic acid amplification tests (CT/GC NAAT). The shortages affect multiple diagnostic companies, public health and commercial laboratories, and impact several components of the specimen collection and testing process. CDC is working with state, local and territorial STD programs, the Association of Public Health Laboratories (APHL) and other laboratories, manufacturers of STI diagnostic supplies, and the U.S. Food and Drug Administration (FDA) to understand the scope of the shortages and determine possible solutions.

# Acknowledgements


- Susan Beekmann
- Phil Polgreen
- Tom File
- Cliff McDonald
- John T. Brooks

# FDA Update

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

# 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

# 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 (*)

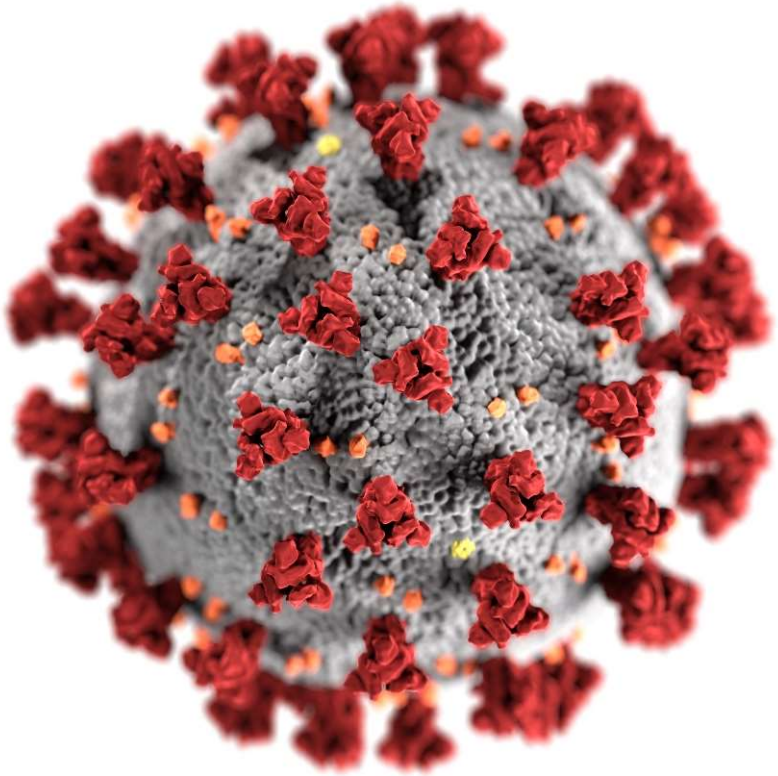
U.S. FOOD & DRUG ADMINISTRATION

# How Does CDC Use COVID-19 Laboratory Testing Data?

**Edward Lockhart, Lead, Laboratory Testing Data**

**Jason Hall, Lead, Laboratory Reporting**

DLS COVID-19 Response Call
October 19, 2020



**cdc.gov/coronavirus**

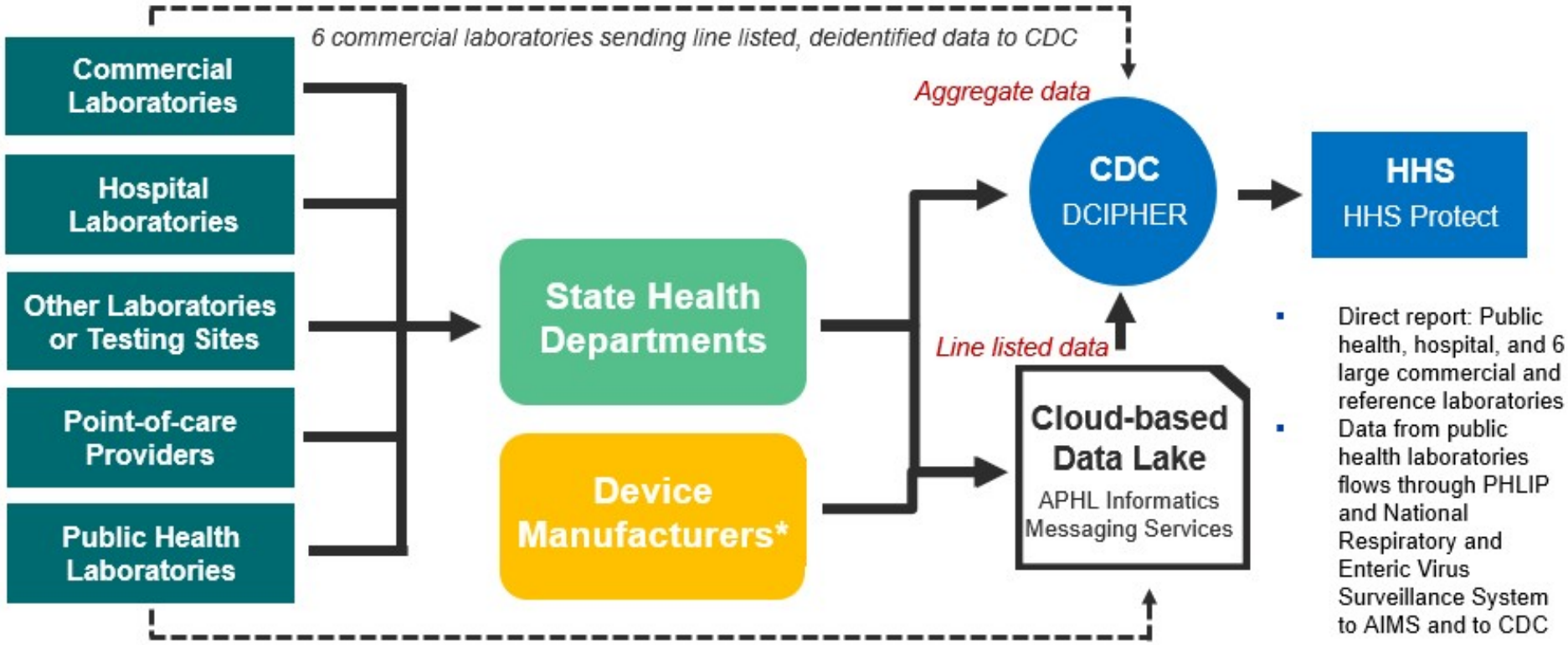
# Agenda

- COVID-19 Electronic Laboratory Reporting (CELR)
- How do laboratory test data transition through CDC?
- How does CDC use laboratory test data to inform the public?
- Answering follow-up questions from previous clicker calls

# COVID-19 Electronic Laboratory Reporting (CELR)

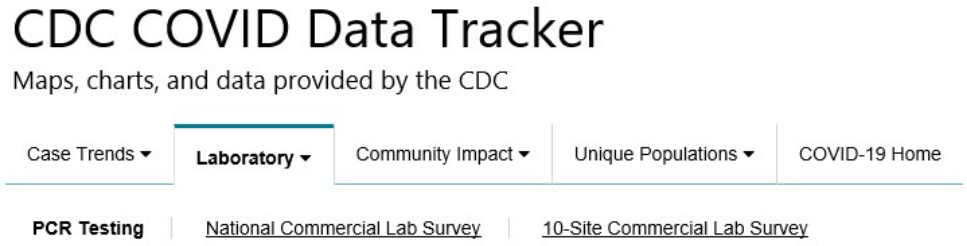
- Data are reported in accordance with the CARES Act (CARES Act Section 18115). Data for each state or jurisdiction are either:
  - Submitted directly by the state health department via COVID-19 electronic laboratory reporting (CELR)
  - From a combination of commercial, public health, and in-house hospital laboratories.

# How do laboratory test data transition through CDC?

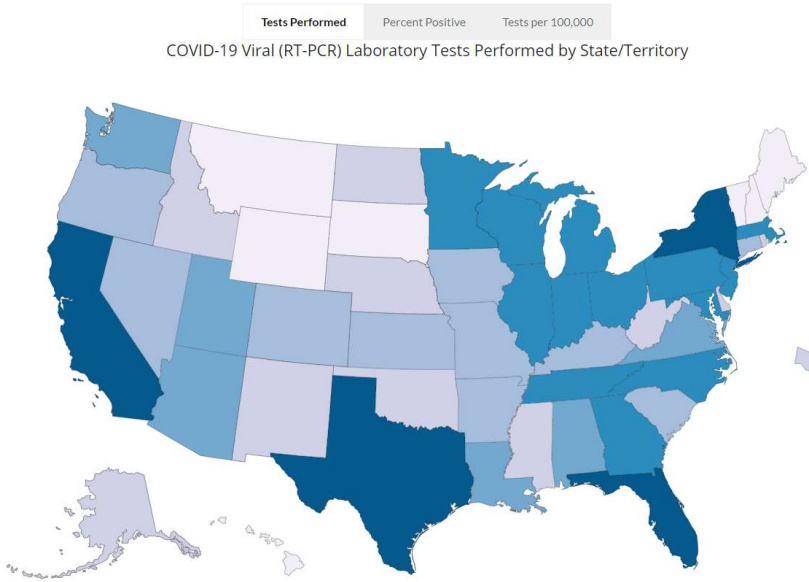



*CDC beginning to work with device manufacturers to support direct reporting

# How does CDC use laboratory data to inform the public?





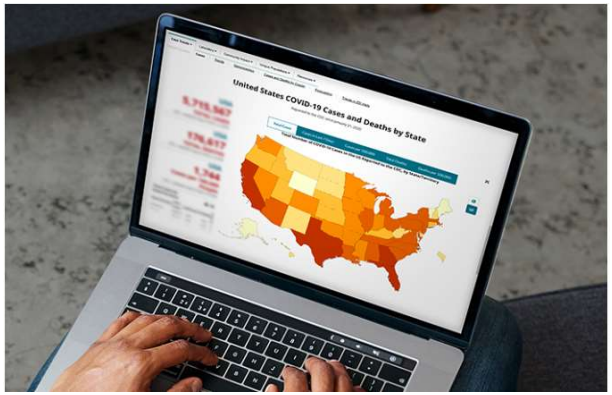


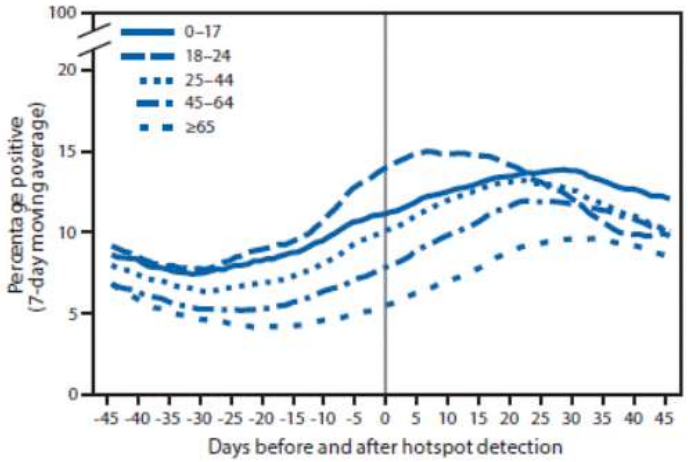

- Lab test data CDC receives are used to populate CDC COVID-19 Data Tracker
- COVID-19 Data Tracker reports out viral RT-PCR test results
  - Percent positivity
  - Test per 100k
- Seroprevalence survey data
- Monitoring trends and magnitude of disease
- Over 77 Million views and counting

https://covid.cdc.gov/covid-data-tracker/

# Secondary use of laboratory testing data

- Provide information to policy  makers
- Creation of guidance documents and recommendations
  - Percent positivity from lab testing data is being used to inform CMS nursing home testing
  - School reopening's
- Incident Manager (IM) presentations
- HHS and WH briefings
- Publications to inform healthcare and the public (MMWR, journals)
- Address media inquiries




Source: Oster AM, Caruso E, DeVies J, Hartnett KP, Boehmer TK. Transmission Dynamics by Age Group in COVID-19 Hotspot Counties — United States, April–September 2020. MMWR Morb Mortal Wkly Rep. ePub: 9 October 2020. DOI: http://dx.doi.org/10.15585/mmwr.mm6941e1.

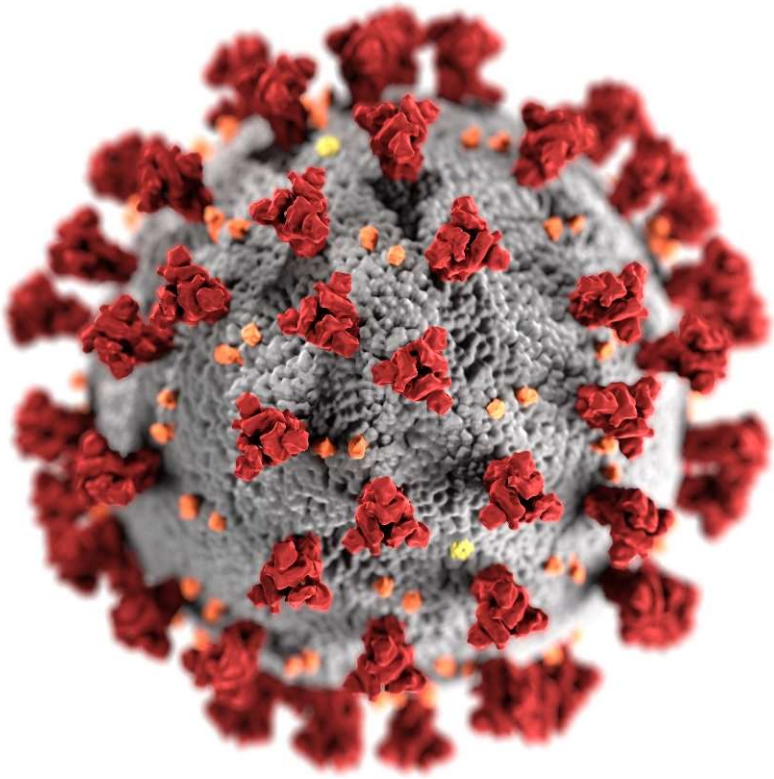
# Recent follow-up questions on reporting

- Should test results be reported to the local or state health department where the lab is located, or where the patient lives?
- If the reference lab sending samples to another state, are they required to send results?

- SAMSHA 42CFR Part 2 indicates that patients seeking alcohol/drug treatment are exempt from public health reporting unless the patient provides written approval to do so. Are labs now required to report these patients seeking alcohol/drug treatment without written permission? Does COVID-19 test reporting now constitute a Medical Emergency and thus override the public health notification exemption?

- If a patient is a student on a college campus, will they need to report locally or to their home address?
- What if your lab serves patients from all 50 states. Is it required to setup interfaces with all 50 states?

# Thank You!!



For any questions please contact:
chall@cdc.gov or
elockhart@cdc.gov

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

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# Thank You For Your Time!

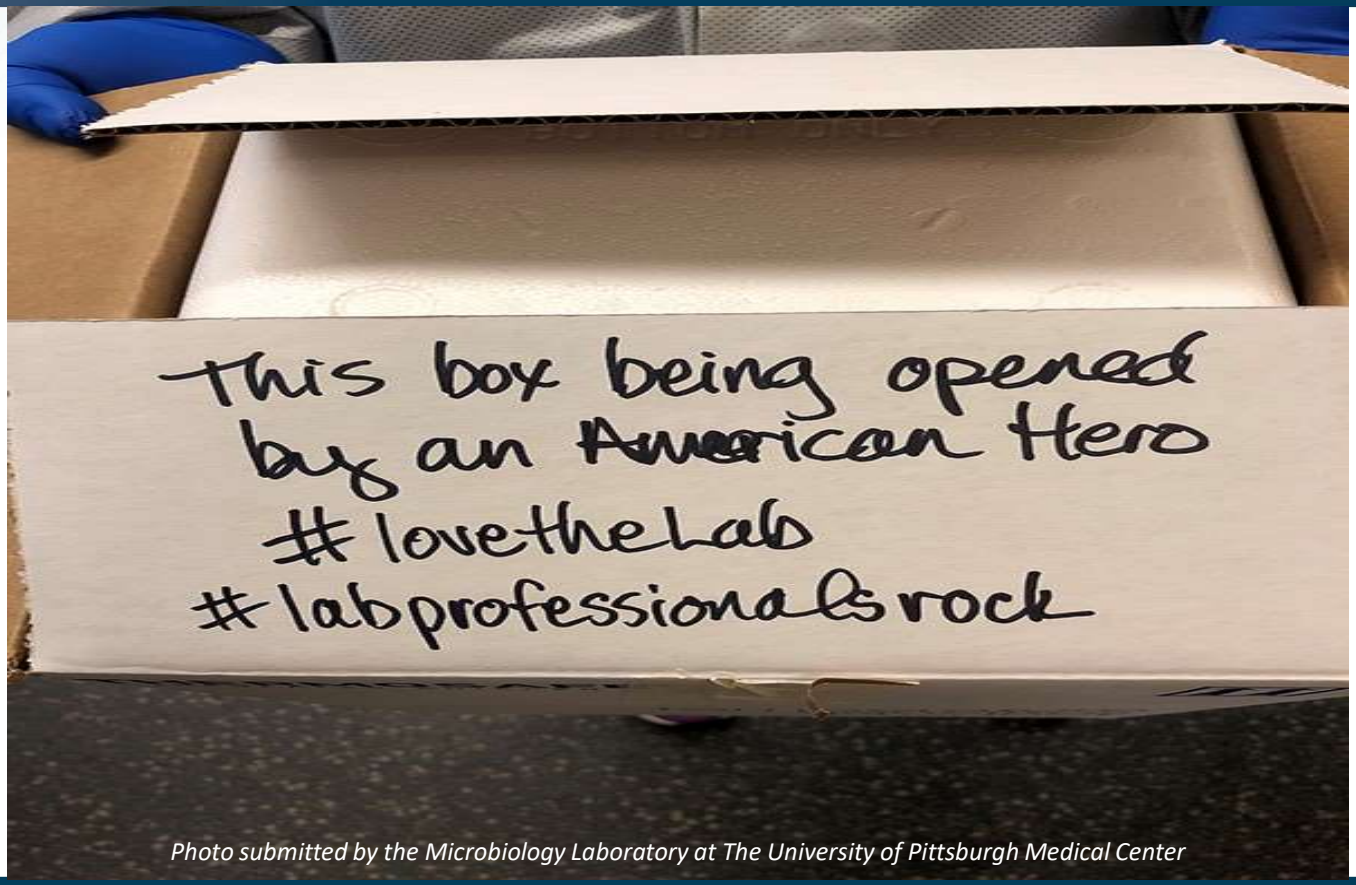


*Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center*