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INTERNATIONAL FRANCHISE ASSOCIATION

WEBINAR SERIES

Testing, Testing, 1, 2, 3: Accuracy, Access and Policies Surrounding COVID-19 Testing

Speakers

- Mike Layman, Vice President, Federal Government Relations, International Franchise Association
- Bob Thompson, CEO, Clinical Reference Laboratory
- Liz Thomas, Director, Government Affairs for the American Clinical Laboratory Association

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Who is ACLA?

- National trade association at the forefront of driving diagnostic innovation.
- 35+ members including:
  - National reference labs
  - Hospitals, nursing homes, academic medical center labs
  - Cancer/genetics focused labs
- MOU with CDC developed after Zika to support emergency response.
- Over **55 million** COVID-19 PCR tests performed since early March.


ACULABS


Adaptive
biotechnologies


AEGIS


AGENDIA


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A Konica Minolta Company


ARUP
LABORATORIES


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DaVita
Kidney Care


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Dialysis Clinic, Inc.


eurofins
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Leading the Evolution of Mental Healthcare


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DIAGNOSTICS


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InterScience Institute


JVHL


LabCorp


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myriad


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NEO
GENOMICS


PACIFIC EDGE


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Early Challenges in Scaling Capacity

1. Supply shortages
   - Shortages of key supplies including pipettes, extraction kits, reagents, platforms, PPE.
   - Labor challenges including staffing, training, overtime.
2. Demand surges led to higher turnaround times
   - Increased Medicare rate helped more labs to stand up COVID-19 testing and meet high demand.
   - Average turnaround time for largest ACLA members is under 48 hours; even less for high priority patients.

ACLA Board Members at the White House on March 13, 2020.
Photo credit: Getty Images

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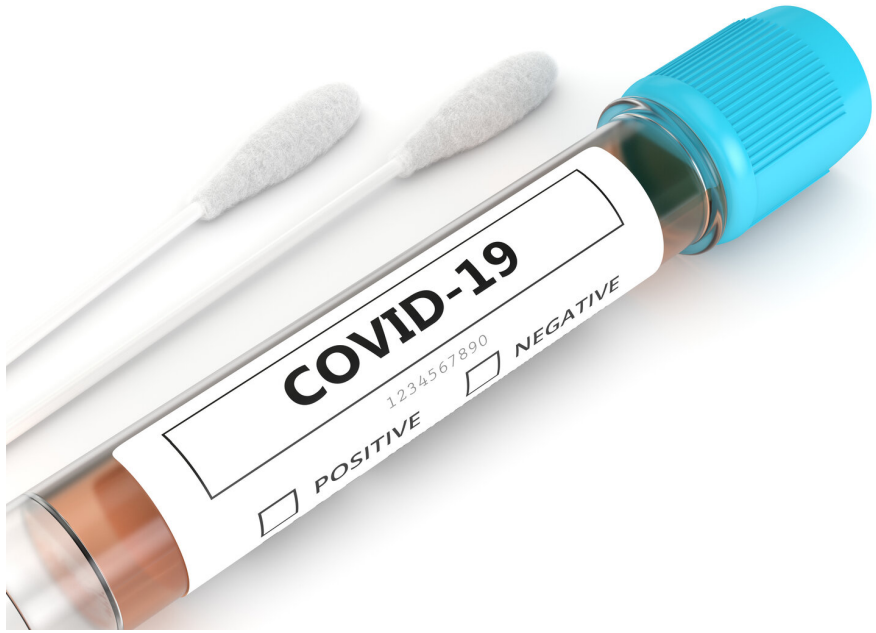
Remaining Challenges & Policy Priorities

1. Clear coverage and reimbursement policies for COVID-19 testing
2. Federal funding for workplace, school, and surveillance testing



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1) Coverage & Reimbursement

- **Problem:** Despite Congress' promise of "free" testing, a June 24 Tri-Agency Guidance created uncertainty regarding coverage requirements, leading to increased health plan denials for testing.
  - No patient who needs a test should ever have to question whether they can receive one without out-of-pocket costs.
  - Clear coverage and reimbursement is the #1 policy to bring more labs forward to test and innovate.

1) Coverage & Reimbursement

- **Solution:** Congress must clarify that individuals who need a test can receive one without cost-sharing, medical management, or prior authorization, and regardless of whether the individual is symptomatic.
  - With additional COVID-19 relief unlikely to pass until after the election, we have also called on the Administration to clarify coverage requirements.

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2) Federal Funding for Screening & Surveillance Testing

- **Problem:** Employers, schools, and state and local governments want more access to screening and surveillance testing, but it is not clear who is responsible for the costs.
  - Following the June 24 Tri-Agency guidance, insurers are denying coverage for screening and surveillance tests.
  - Current federal funding to support “testing” is overly broad; funds have largely been given to states or remain unallocated.

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2) Federal Funding for Screening & Surveillance Testing

- **Solution:** Congress should pass a federal fund specifically for surveillance, return-to-work, and return-to-school testing.
  - Insurers would still process payments for testing and seek reimbursement from a federal fund.
  - Medically necessary tests would still be covered by insurers.

Stakeholder & Congressional Advocacy

The New York Times

Coronavirus Tests Are Supposed to Be Free. The Surprise Bills Come Anyway.

PATIENTS, EMPLOYERS, LABS AND HEALTH INSURANCE PROVIDERS CALL ON CONGRESS TO DEDICATE FUNDING FOR COVID-19 TESTING TO GET AMERICA BACK TO WORK AND SCHOOL

LAWMAKERS RAISE CONCERN ABOUT COVID-19 TEST COVERAGE — A bipartisan group of 54 House lawmakers is calling on Azar to clarify federal guidance to ensure individuals do not get hit with out-of-pocket costs when seeking Covid-19 testing, POLITICO's David Lim reports.

REPS. REED & PETERS LEAD 28 HOUSE MEMBERS IN CALLING ON HHS TO ALLOCATE ADDITIONAL FEDERAL SUPPORT TO CLINICAL LABORATORIES FOR COVID-TESTING

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Legislative Landscape & Next Steps

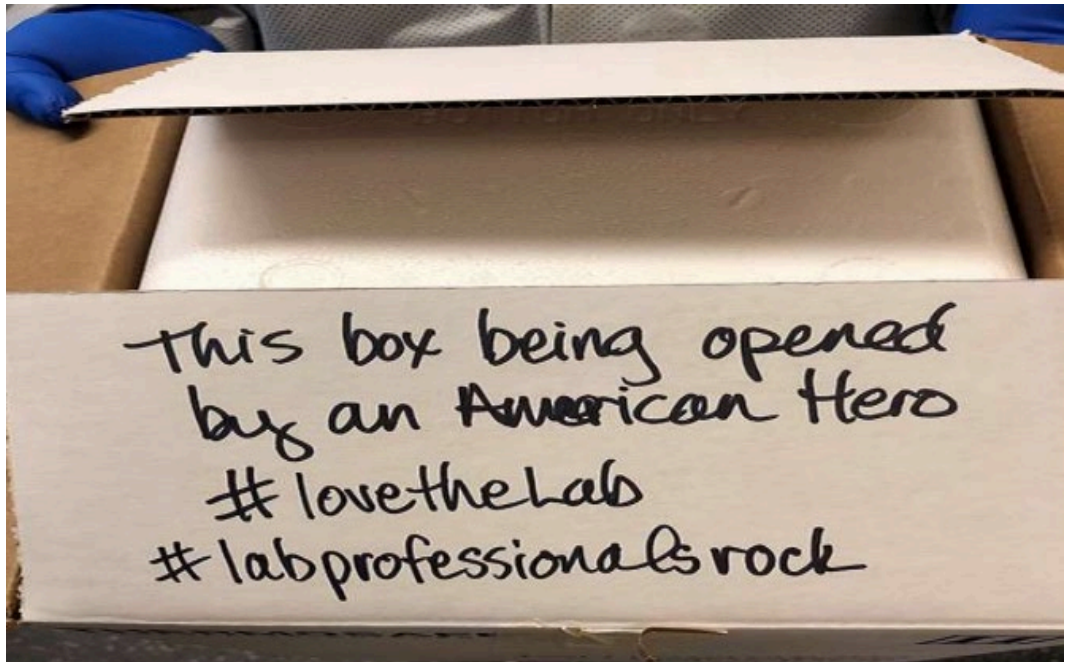

Photo courtesy of CDC and University of Pittsburgh Medical Center

- Post-election relief package?
- Potential for regulatory coverage clarification.
- In the meantime, testing remains a crucial component of our COVID-19 public health response *and* economic recovery.
- ACLA wants to be a resource!

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Robert Thompson, *President & CEO*
Clinical Reference Laboratory

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Key Decision Points on Returning to Work

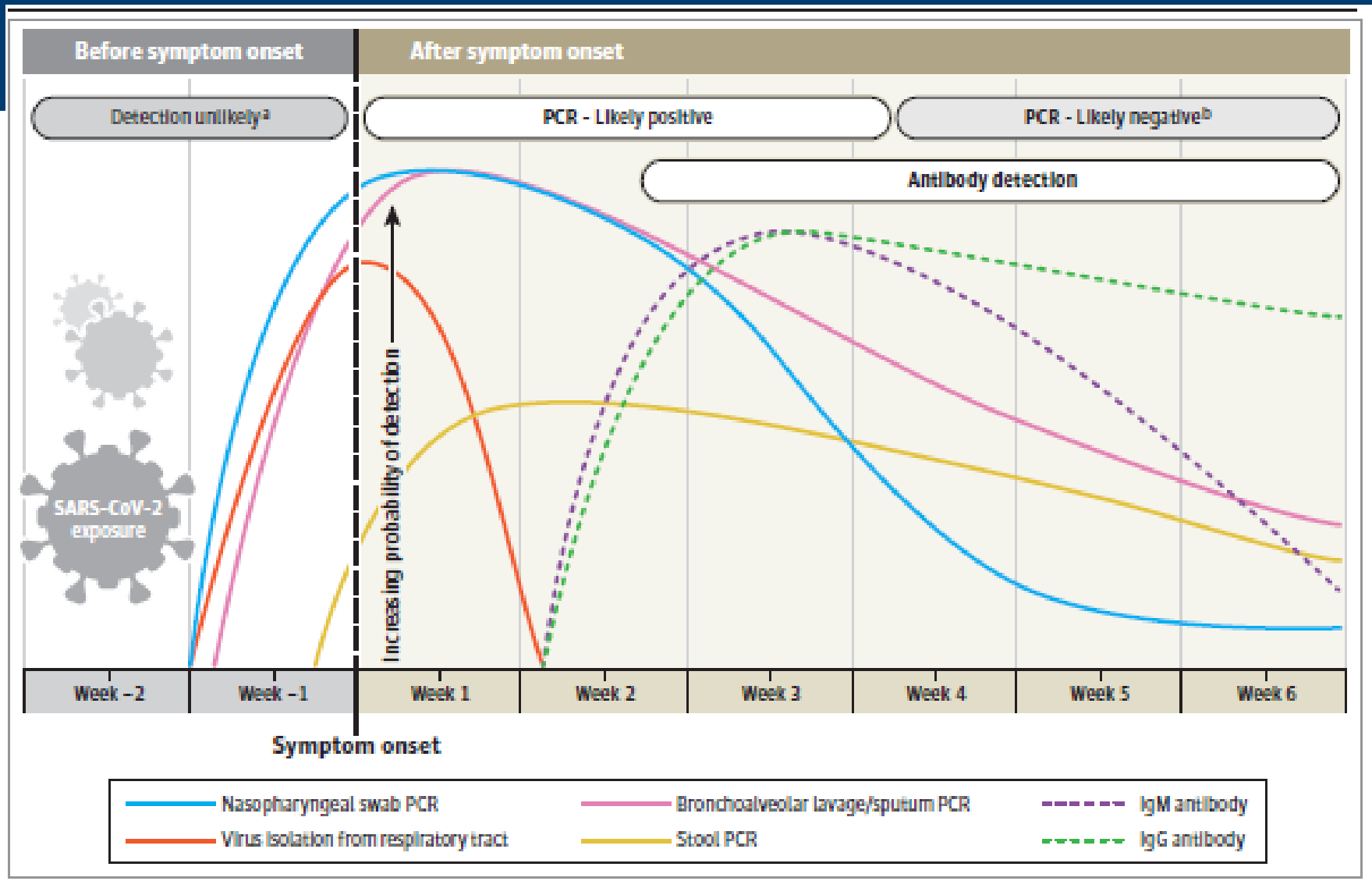
- Type of test
- Frequency of testing
- Voluntary vs Required and Collecting consents
- Reporting to employee and employer
- Cost ranges

Different Types of Coronavirus Tests

	Molecular Test	Antigen Test	Antibody Test
Also known as:	Diagnostic test, viral test, molecular test, nucleic acid amplification test (NAAT), RT-PCR test, LAMP test	Rapid diagnostic test (Some molecular tests are also rapid tests.)	Serological test, serology, blood test, serology test
How the sample is taken:	Nasal or throat swab (most tests) Saliva (a few tests)	Nasal or throat swab	Finger stick or blood draw
How long it takes to get results:	Same day (some locations)	One hour or less	Same day (many locations) Or 1-3 days
Is another test needed:	This test is typically highly accurate and usually does not need to be repeated.	Positive results are usually highly accurate but negative results may need to be confirmed with a molecular test.	Sometimes a second antibody test is needed for accurate results.
What it shows:	Diagnoses active coronavirus infection	Diagnoses active coronavirus infection	Shows if you've been infected by coronavirus in the past

Source: FDA (https://www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics)

Estimated detection windows for COVID test types



https://jamanetwork.com/journals/jama/fullarticle/2765837

Sample Types for Molecular COVID tests

- NP swab: considered the “gold standard” by the FDA, but uncomfortable and generally not used for employer testing
- Saliva: Easier to collect. Research has shown they provide similar, if not better, sensitivity compared to NP swabs1
- Nasal Swab: Accuracy compared to NP swab varies highly

Clinical Specimen	Positive Rate
Bronchoalveolar lavage fluid	93% (14/15)
Sputum	72% (72/104)
Nasal swabs	63% (5/8)
Fibrobronchoscope brush biopsy	46% (6/13)
Pharyngeal swabs	32% (126/398)
Feces	29% (44/153)
Blood	1% (3/307)
Urine	0% (0/72)

1. https://www.nejm.org/doi/full/10.1056/NEJMc2016359
2. https://jamanetwork.com/journals/jama/article-abstract/2762997

Accuracy of COVID tests

- Dependent on when the test is administered. False negatives likely if testing occurs too close to exposure.

- Dependent on how the test is administered. False negatives possible with improper sample collection. NP and nasal swab collection highly technique dependent.

Frequency of Testing

- Most testing on re-entry, if applicable
- Regular testing, frequency based on work situation (spacing, degree of public interface)
- Data driven – most start weekly, or every other week, then decrease/increase as data indicates

Voluntary vs Mandatory and Collecting Consents

- Many are requiring it, allowed under federal and state rules
- White collar tends to be voluntary, blue collar tends to be mandatory
- Consent collected during testing process for release to employer, ordering physician, and state/local health agencies

Reporting

- Most deliver result back through a web portal to both the employee and the employer.

- It is the laboratory's responsibility to report to the state

Costs

- **PCR testing is dropping in price**
  - Available online for $110-150, but employer-focused labs are well below $100 now
  - Delivery model matters, with bulk shipping lowering costs by $20 or more

- Antigen testing, if available, is around $15-20. Needs to be performed more frequently, so cost per employee is several times that figure.

Vaccine Progress

- **The Process**
  - **Preclinical:** Test on animals, looking for immune response
  - **Phase 1** (Safety): Test on a small number of people
  - **Phase 2** (Expanded): Test on hundreds of people of different ages to verify safety and determine immune responsiveness
  - **Phase 3** (Efficacy): Thousands of people – actually determine rate of infection among vaccinated vs. placebo recipients
  - **Early or limited approval**
  - **Final approval**

Vaccines: Where we are

Vaccines

- **“Limited Approval”**
  - 2 Russian vaccines
- **Phase 3**
  - Oxford-Astra-Zeneca vaccine
    - September 8 – one case of transverse myelitis
    - May have some results as early as December
  - Biontech-Pfizer mRNA vaccine
    - Fairly promising
    - May have some results as early as November
  - Johnson and Johnson
  - Moderna
    - May have some results as early as December

Questions?

Thank you for attending!