• Welcome
  – Jasmine Chaitram, CDC Division of Laboratory Systems

• Addressing Covid-19: Perspective From A Scientific Society
  – Robin Patel, President, the American Society for Microbiology (ASM)

• Testing Strategies and Priorities
  – Greg Armstrong, CDC Deputy Incident Manager for the COVID-19 Response

• Laboratory Testing Supply Chain Update
  – Brad Smith, Centers for Medicare and Medicaid Services (CMS)

• Expanding SARS-CoV-2 Testing in the District
  – Tony Tran, District of Columbia Public Health Laboratory

• Laboratory Biosafety Update
  – Bill Arndt, CDC Division of Laboratory Systems

• CLIA Updates
  – Karen Dyer, Centers for Medicare and Medicaid Services (CMS)
Help us improve these calls by taking a short 5-minute survey!

Questions?
Contact dlsqinquiries@cdc.gov

Take the survey here
www.surveymonkey.com/r/CLCRCall
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/

Interim Guidance for Collecting, Handling, and Testing Clinical Specimens

Diagnostic Tools and Virus

Emergency Preparedness for Laboratory Personnel
https://emergency.cdc.gov/labissues/index.asp

CDC's Laboratory Outreach Communication System (LOCS)
https://www.cdc.gov/csels/dls/locs/
“We want to hear from you!”

LabTrainingNeeds@cdc.gov
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
  ▪ Submit your question
  ▪ Please do not submit a question using the chat button

• For media questions, please contact CDC Media Relations at [media@cdc.gov](mailto:media@cdc.gov).
Addressing Covid-19: Perspective From A Scientific Society

Robin Patel, M.D., D(ABMM), FIDSA, FACP, F(AAM)
President, American Society for Microbiology

Elizabeth P. and Robert E. Allen Professor of Individualized Medicine,
Professor of Medicine and Professor of Microbiology, Co-Director of the Clinical Bacteriology Laboratory,
Director of the Infectious Diseases Research Laboratory, Mayo Clinic, Rochester, MN)
Supporting Clinical Microbiologists and Laboratories

Providing Information, Advocacy and Engagement

Supporting Microbial Research
Supporting Research

- COVID-19 International Summit
  - Held virtually on March 23
    https://asm.org/Articles/2020/March/ASM-COVID-19-International-Summit-Sets-Research-Pr
  - Paper published in mBio
    • “Value of Diagnostic Tests for SARS-CoV-2/COVID-19”

- ASM COVID-19 Research Registry
  - Curated by experts to provide timely access to top COVID-19 research
    https://asm.org/COVID/COVID-19-Research-Registry/Home

- Free access to journal articles related to coronaviruses and expedited peer review of COVID-19 studies
Supporting Clinical Microbiologists

• Connection of laboratory community – *ClinMicroNet, Div C Net*

• Development of Protocols and Guidelines
  – ASM Emergency Use Authorization verification protocol, April 3
  – COVID-19 Diagnostic Guidelines – ASM joining IDSA effort, early May

• Addressing regulatory issues & barriers faced by microbiology laboratories

• Supporting laboratory workforce – NY Times Op-ed
  – “*We Need a New Kind of National Guard*”
Advocacy and Engagement

- Coordination with White House Coronavirus Task Force

- Continued Dialogue with FDA and CDC
  - Testing challenges and concerns, shortages of supplies
  - Support for infrastructure, laboratory capacity, surveillance

- Ongoing Communications with House and Senate
  - Appropriations, including work to ensure ALL laboratories supported by emergency funding for testing capacity

To view all letters, statements: [http://asm.org/advocacy](http://asm.org/advocacy)
Resources

• ASM COVID-19 Resources Page

• COVID-19 FAQs with Graphics

• ASM COVID-19 Research Registry

• ASM Member Communications (listservs, newsletters)
  – https://asm.org/Forms/Listservs
Laboratory Testing Supply Chain Update

Brad Smith, Centers for Medicare and Medicaid Services (CMS)
Testing Technical Assistance Update

May 4, 2020
Testing Progress To Date

COVID-19 TESTING

- 788,000 tests on 28-Mar
- 1,620,000 tests on 4-Apr
- 2,960,000 tests on 11-Apr
- 4,170,000 tests on 18-Apr
- 5,230,000 tests on 25-Apr
- 6,830,000 tests on 2-May
COVID-19 TESTING

Four Types of Technical Assistance for States

✓ Specimen Collection Supplies: The federal government is directly procuring specimen collection supplies to supplement the specimen collection supplies states and healthcare providers are procuring from the private market. For May and June, FEMA will be distributing specimen collection supplies including swabs, transport media, and collection tubes directly to states.

✓ Lab Testing Capacity Technical Assistance: The federal government is providing each state technical assistance to help states fully utilize their existing lab capacity. This includes providing states a map of their existing lab testing capacity as well as working with commercial manufacturers of lab testing supplies to ensure that states have the necessary lab testing supplies to meet the increased testing demand. States and healthcare providers will purchase lab testing supplies directly from commercial manufacturers, with the exception of public health labs who will still receive reagents through the IRR.

✓ Personnel: CDC has already deployed more than 650 personnel to states and is prepared to deploy additional personnel to states as needed, including individuals with expertise in epidemiology, public health, infection control and contact tracing.

✓ Guidance: CDC is providing states with guidance and technical assistance on a range of testing related topics including surveillance, specimen collection, testing in long-term care facilities, point-of-care testing, testing in outbreak settings, and serology.
COVID-19 TESTING

Specimen Collection Supplies

- Swabs and transport media will be shipped in weekly installments.
- Supplies will be shipped to a single location within each state.
- States will be in charge of distributing supplies within the state.
- States will receive 75% of the transport media and collection tubes they receive in swabs (as many states produce transport media locally).
- The federal government has additional swabs in reserve to meet the demand of states whose May testing is on pace to exceed their initial allotment of supplies.

Specimen Collection Supply Workflow

FEMA / HHS
- Procure swabs & media and ship to States

States
- Receive supplies from USG, store supplies, and distribute supplies to labs including public health lab

Healthcare Providers & Labs
- Receive specimen collection supplies directly from the state
Testing Capacity Maps: Each state has been provided a map and a spreadsheet of its testing capacity based on lab testing machines already present in the state.

One-on-One Technical Assistance: Each state has been assigned a federal technical expert to advise on strategies to ramp up testing capacity.

Manufacturers Introductions: The federal government is providing introductions for state leadership to the most senior level of lab testing supply manufacturers.

High-Demand Platforms: For the most in-demand lab testing platforms including Hologic Panther, Abbott ID Now, and Cepheid, the federal government is working with manufacturers to encourage appropriate distribution of supplies across the United States.
COVID-19 TESTING

**Personnel**

- CDC currently has more than 650 staff serving in all 50 states across the country.

- CDC will deploy an additional 5 or more staff to each state, as requested, to provide technical assistance and conduct outbreak investigations.

- Areas of expertise include:
  - Epidemiology
  - Public Health
  - Infection Control & Prevention
  - Contact Tracing

**665 Staff Currently Embedded or Deployed**
(as of May 2, 2020)
COVID-19 TESTING

Guidance

✓ Share, enhance and increase training around existing guidance including:
  ✓ Specimen Collection
  ✓ Surveillance
  ✓ Contact Tracing

✓ Issue new guidelines this week for:
  ✓ Serology
  ✓ How To Prioritize Point-of-Care Testing

✓ Share state best practices including at least:
  ✓ Continue weekly Monday calls with states
  ✓ Regular updates to CDC’s STLTS website/repository

✓ Continue to offer support from HRSA, IHS and the White House Opportunity and Revitalization Council to support sentinel surveillance and diagnostic testing in vulnerable populations and in underserved and distressed communities
Expanding SARS-CoV-2 Testing in the District

Anthony Tran, DrPH, MPH, D(ABMM), District of Columbia Public Health Laboratory
ONLINE MARCH 3rd

30 Extractions

3x per day = 180

2 hours

Capacity 50 samples per day

30 Extractions

25 Per Plate = 100

3 hours
WEEK OF MARCH 18TH

Staff

Extraction Options

8 at one time

16 Extractions
1 hour per run

6x per day = 96

8 at one time

25 Per Plate = 100 x 1 runs per day

3 hours

Capacity 100 samples per day
WEEK OF MARCH 25TH

Capacity 150 samples per day
Avg daily patients = 21

Staff

Extraction Option

48 at one time
2.5 hours per run
3x per day = 144
3 days

16 Extractions
1 hour per run
6x per day = 96
3 days

25 Per Plate = 150 x 1 runs per day
3 hours

Slides courtesy of Dr. Courtney
FULL AUTOMATION

Started March 30\textsuperscript{th} - Panther Fusion

Staff

Capacity 300-500 samples per day

Avg daily patients $= 75$

2:20 hours per sample
90 samples per run
$\sim$300 samples/8 hour
Ability to run overnight

Sample to Answer
No ABI 7500 needed
Much less staffing needed
Currently limited to certain VTM brands

Slides courtesy of Dr. Courtney

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WHY FULL AUTOMATION?
WHAT’S IT GOING TO TAKE TO REOPEN?

Coronavirus Testing Needs to Triple Before the U.S. Can Reopen, Experts Say
By Keith Collins  April 17, 2020

As some governors consider easing social distancing restrictions, new estimates by researchers at Harvard University suggest that the United States cannot safely reopen unless it conducts more than three times the number of coronavirus tests it is currently administering over the next month.

Average Daily Coronavirus Tests in the U.S.

An average of 146,000 people per day have been tested for the coronavirus nationally so far this month, according to the COVID Tracker Project. The daily reported 2.2 million total tests across the country. To reopen the United States by mid-May, the number of tests performed every day should be 500,000 to 750,000, according to the Harvard estimates, which is a daily minimum of about 152 tests per 100,000 people.

7 x 152 = 1064 samples/day

TESTING SNAPSHOT (4/28/2020)

District of Columbia Testing Picture
- Overall Tested = 19,229 / 702,455 = 2.73% of DC population
- Overall Positivity = 4,106/19,229 = 21.4%
- PHL Testing = 2,595 patients
- PHL Positivity = 34.8%
- Drive-Thru/Walk-Up Testing
  - Tested = 1,401 (and growing)
  - Positivity = 23.7%
- Vulnerable Populations
  - Tested = 1,194
  - Positivity = 47.8%

POCT DEPLOYMENT (PLAN)

ABBOTT ID NOW™ Distribution Plan (15)
- Unity Health (Homeless Shelters) = 6
- Unity Health (DOC) = 2
- St. Elizabeth’s Hospital = 2
- Mary’s Center = 1
- Long-term, acute care or skill nursing facilities (>100 beds)
  - Transitions (Pilot facility) = 1
- DFS Mobile Testing Truck = 3

Slides courtesy of Dr. Chastain-Potts
REQUIREMENTS FOR TESTING

- Initial site assessment
- Complete site specific risk assessment
- Identify 1-2 staff to be trained
- Training conducted by DFS PHL staff
- Competency assessment documented
- Proficiency testing conducted twice annually
DC PHL TRAINING

- DC PHL Hosted Training for deployment
- Hand-outs for Quality System
- Provide Site Survey
- Provide Competency Assessments
- Provide Proficiency Testing
IF THEY WON’T COME TO YOU...
THE NATIONAL HEALTH & NUTRITION EXAMINATION SURVEY (NHANES) TRUCK

- Lab area with bio hood
- Space for Cepheid & Abbott equipment
- Refrigerator and Freezer
- Sink
- Patient sampling area
- Bathroom facility

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PROCESS FLOW

Specimen Receipt

STAT?

YES

NO

3 Units
(3 Units x 12 runs/shift = 36 runs total)

ID NOW™

• Result in 5 – 15 min
• 1 per run

GeneXpert

1 Unit
(1 Unit x 14 runs/shift = 14 runs total)

Total Throughput: 50 per 4-hr shift (36 STAT, 14 routine)
DFS PHL MOBILE TESTING SETUP

Abbott ID NOW™

Cepheid GeneXpert

Photos courtesy of Dr. Kiehlbauch

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DFS PHL MOBILE TESTING
SETUP

Photos courtesy of Dr. Kiehlbauch

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SPECIAL THANKS TO PHL COVID-19 RESPONSE TEAM

- Accessioning
  - Katie Morris
  - Lesley Krien
  - Brittany Hamilton
  - Tamla Mings
  - Andrew Alviar
  - Donovan Bialose
- Microbiology/BT
  - Michael Adjei
  - Denise Edwards
  - Sosina Merid
- Chemistry
  - Michael Krause
  - Justin Jacob
  - Olin Jackson
- Molecular Diagnostics
  - Rakeiya McKnight
  - Connie Maza
  - Elizabeth Zelaya
  - Melodie Nasr
  - Monica Mann
  - Channyn Williams
- BioWatch Surge
  - Yolis Begazo
  - Matt Hedin
  - Glory Umoh
  - Maria Medina
  - Maikan Kone
  - Rico Duncan
- Sr. Leadership
  - Jenifer Smith
  - Colleen Courtney
  - Pushker Raj
  - Matt McCarron
  - Berihun Taye
  - Julie Kiehlbauch
  - Kimary Harmon
  - Luke Short
- Immunology/Virology
  - Jessie Lowry
  - Brandon Williams
  - Cleveland Weeden
- Communications
  - Richard Jordan
  - Darrell Pressley
- Admin/Ops
  - Nia Deot
  - Hana Asnake
  - Tatiana Schrader
  - Shayla Montalvo
  - David Payne
- CDC
  - Shelby Chastain-Potts
- Health & Safety
  - Rachel Mando
  - Regina Geter

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Laboratory Biosafety Update for COVID-19

Bill Arndt, PhD
CDC Division of Laboratory Systems
COVID-19 Information for Laboratories page:

Interim Laboratory Biosafety Guidelines:

Laboratory Biosafety Frequently Asked Questions:

Send Inquiries to: DLSInquiries@cdc.gov
CLIA Updates

Karen Dyer, Centers for Medicare and Medicaid Services (CMS)
CDC Social Media

Facebook: https://www.facebook.com/CDC

Twitter: https://twitter.com/cdcgov

LinkedIn: https://www.linkedin.com/company/cdc
Thank You For Your Time!

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

This box being opened by an American Hero
#lovetheLab
#labprofessionalsrock