

# Clinical Laboratory COVID-19 Response Call

Monday, May 4<sup>th</sup>, 2020 at 3:00 PM EDT

- **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)

# Share Your Feedback

Help us improve these calls by taking a short 5-minute survey!



**Questions?**

Contact [dlsqinquiries@cdc.gov](mailto:dlsqinquiries@cdc.gov)

**Take the survey here**

[www.surveymonkey.com/r/CLCRCall](http://www.surveymonkey.com/r/CLCRCall)

# CDC Information 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/>

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's Laboratory Outreach Communication System (LOCS)

<https://www.cdc.gov/csels/dls/locs/>



“We want to hear from you!”

LabTrainingNeeds@cdc.gov

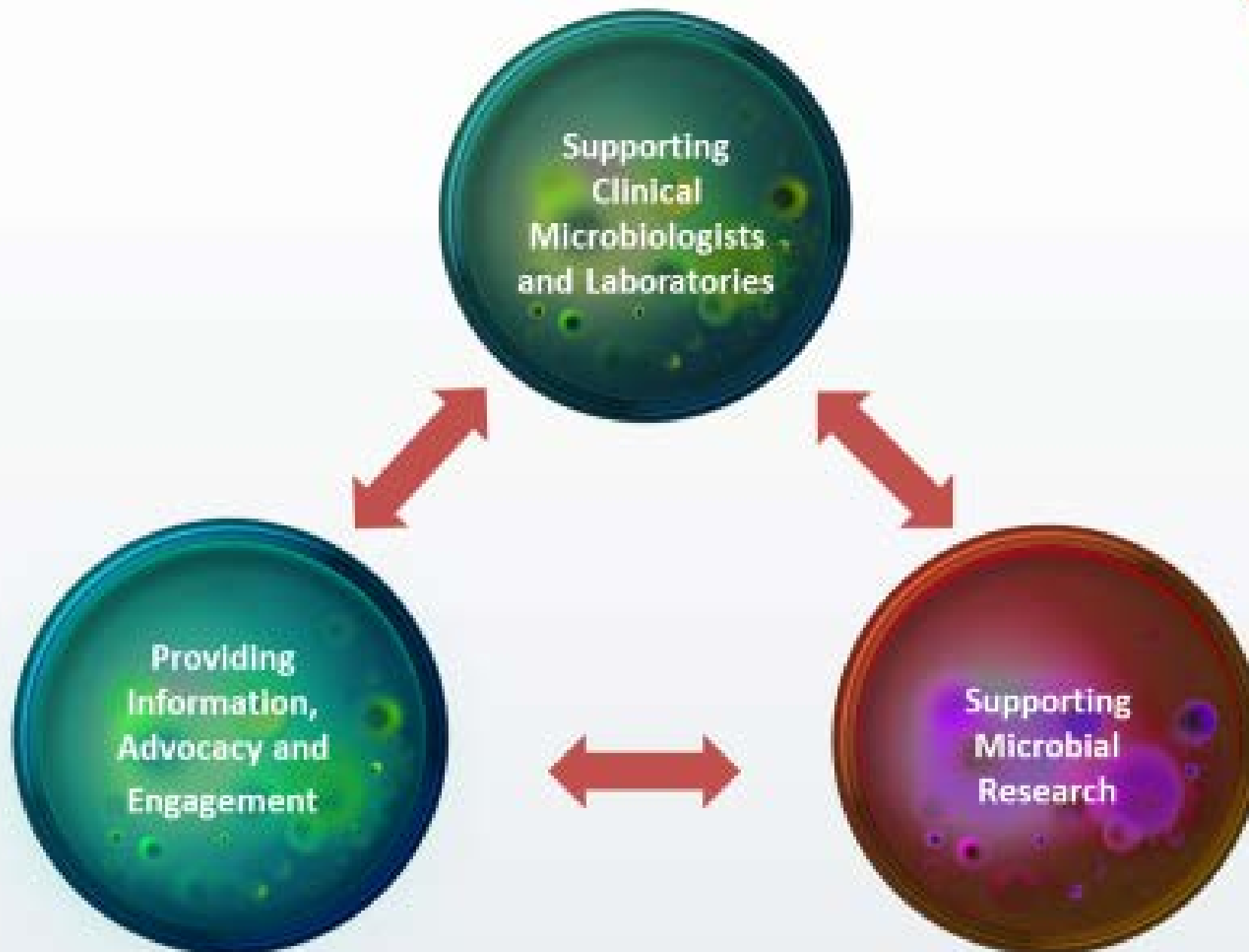
# To Ask a Question

- 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 Research



AMERICAN  
SOCIETY FOR  
MICROBIOLOGY

- **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



AMERICAN  
SOCIETY FOR  
MICROBIOLOGY

- **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>

# Resources

- **ASM COVID-19 Resources Page**
  - <https://asm.org/Articles/2020/April/COVID-19-Testing-FAQs>
- **COVID-19 FAQs with Graphics**
  - <https://asm.org/Articles/2020/April/COVID-19-Testing-FAQs>
- **ASM COVID-19 Research Registry**
  - <https://www.asm.org/COVID/COVID-19-Research-Registry/Home>
- **ASM Member Communications (listservs, newsletters)**
  - <https://asm.org/Forms/Listservs>

# 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)



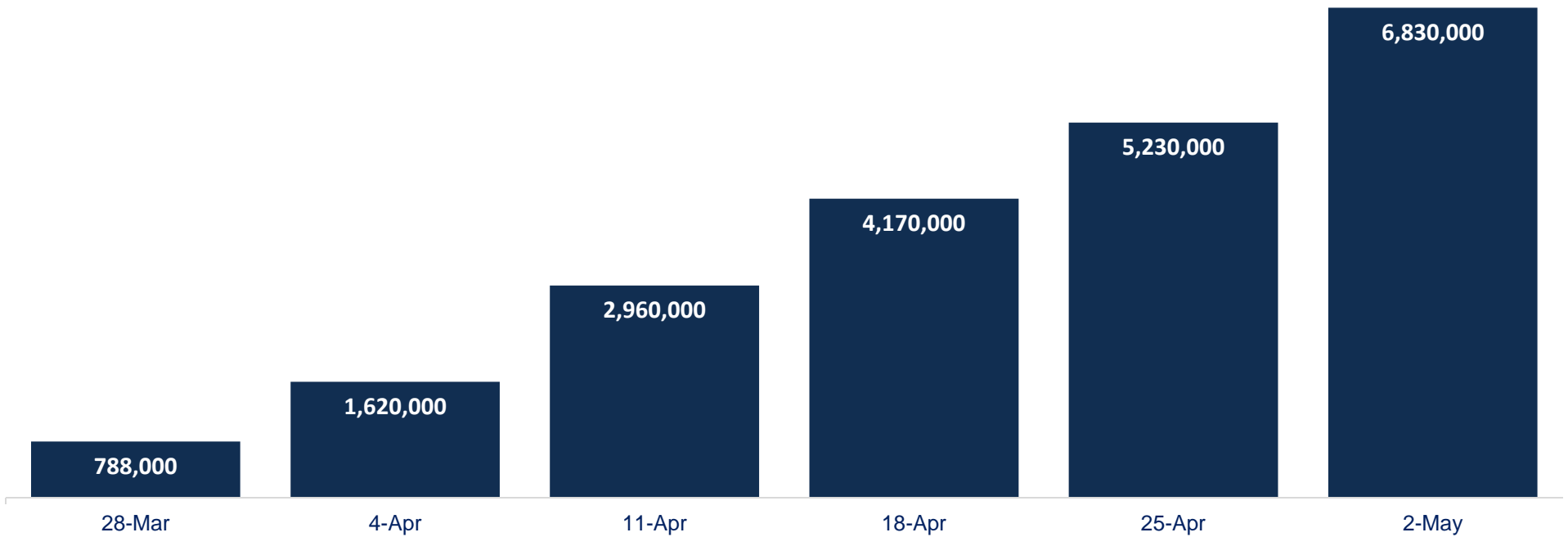
# Testing Technical Assistance Update

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May 4, 2020



## Testing Progress To Date





## Four Types of Technical Assistance for States

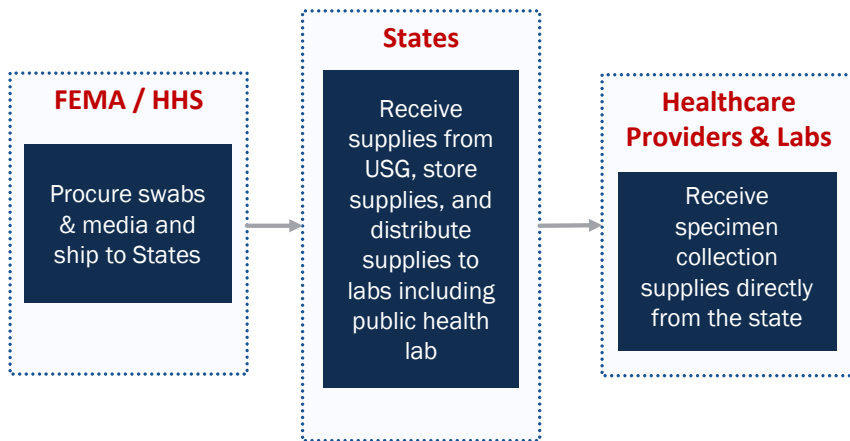
- ✓ **Specimen Collection Supplies:** The federal government is directly procuring specimen collection supplies to supplement the specimen collection supplies states and healthcare providers are procuring from the private market. For May and June, FEMA will be distributing specimen collection supplies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





# Specimen Collection Supplies

## Specimen Collection Supply Workflow

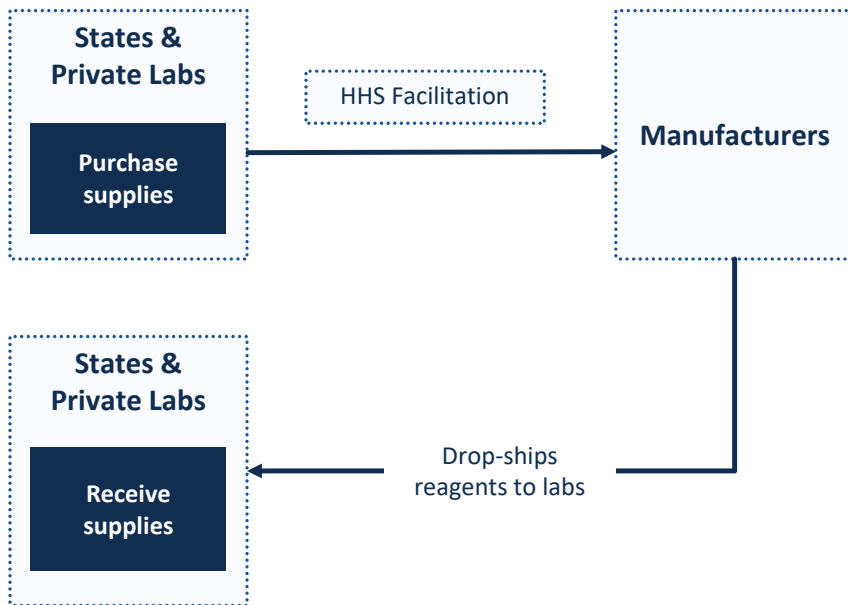


- ✓ Swabs and transport media will be shipped in weekly installments
- ✓ Supplies will be shipped to a single location within each state
- ✓ States will be in charge of distributing supplies within the state
- ✓ States will receive 75% of the transport media and collection tubes they receive in swabs (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



# Lab Testing Capacity

## Lab Testing Supply Workflow



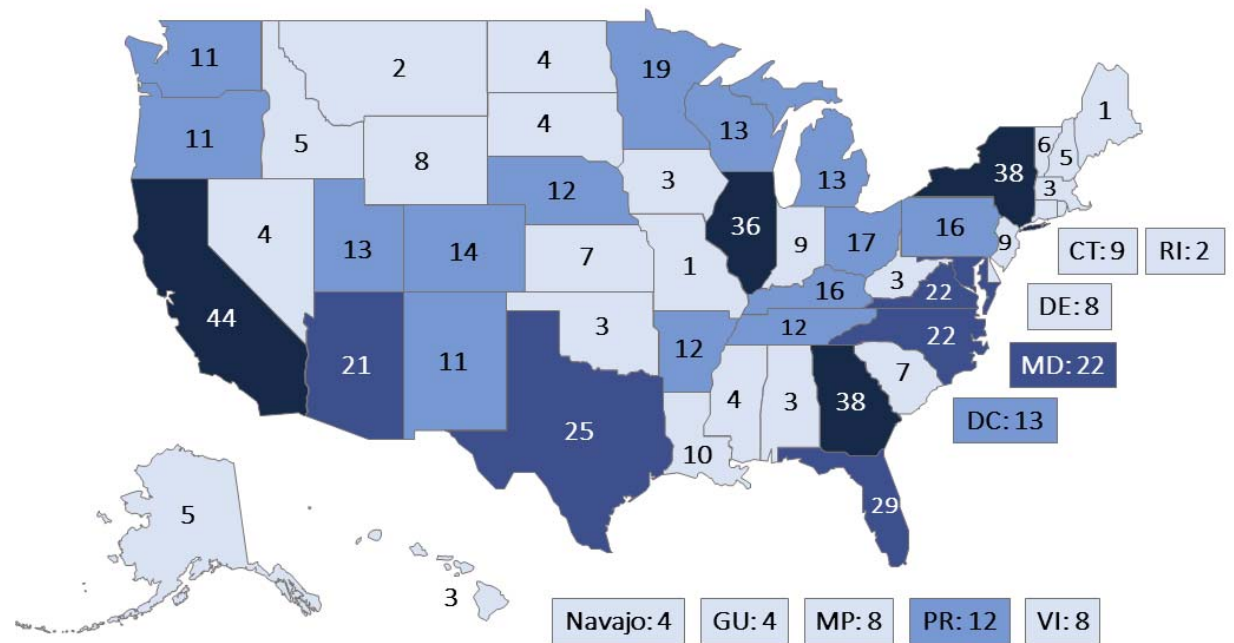
- ✓ **Testing Capacity Maps:** Each state has been provided a map and a spreadsheet of its testing capacity based on lab testing machines already present in the state.
- ✓ **One-on-One Technical Assistance:** Each state has been assigned a federal technical expert to advise on strategies to ramp up testing 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.



# 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)





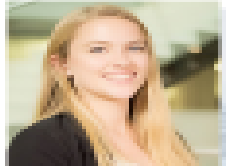
## Guidance

- ✓ 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 3<sup>RD</sup>



3x per day=180

30 Extractions



30 Extractions



25 Per Plate= 100



2 hours Capacity 50 samples per day 3 hours

Slides courtesy of Dr. Courtney

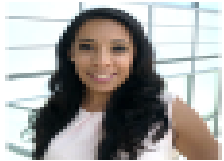


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# WEEK OF MARCH 18<sup>TH</sup>

## Staff



## Extraction Options



8 at one time    8 at one time

16 Extractions  
1 hour per run

6x per day=96



25 Per Plate= 100 x 1 runs per day

3 hours



## Capacity 100 samples per day

Slides courtesy of Dr. Courtney



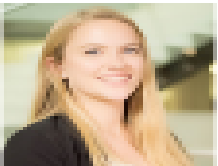
**DFS**  
DEPARTMENT OF  
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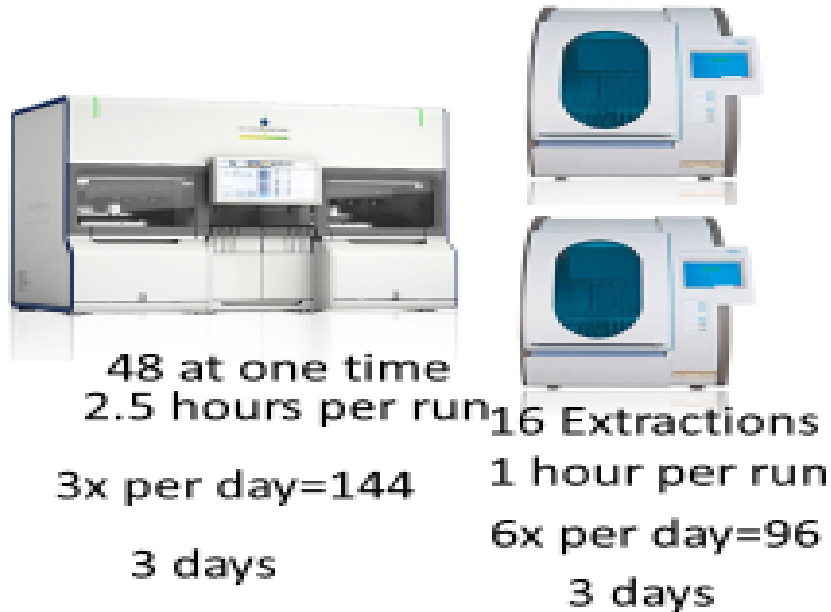
**WE ARE DC**  
GOVERNMENT OF THE  
DISTRICT OF COLUMBIA  
MURIEL BOWSER, MAYOR

# WEEK OF MARCH 25<sup>TH</sup>

## Staff



## Extraction Option



Capacity 150 samples per day  
Avg daily patients = 21

Slides courtesy of Dr. Courtney



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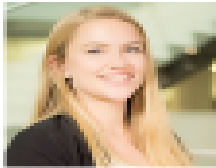


# FULL AUTOMATION

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Started March 30<sup>th</sup> - Panther Fusion

## Staff



Capacity 300-500 samples per day

Avg daily patients = 75

2:20 hours per sample  
90 samples per run  
~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?

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# WHAT'S IT GOING TO TAKE TO REOPEN?

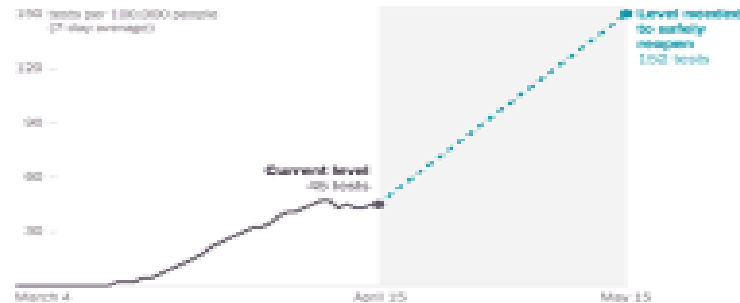
The New York Times

## Coronavirus Testing Needs to Triple Before the U.S. Can Reopen, Experts Say

By Keith Collins · April 17, 2020

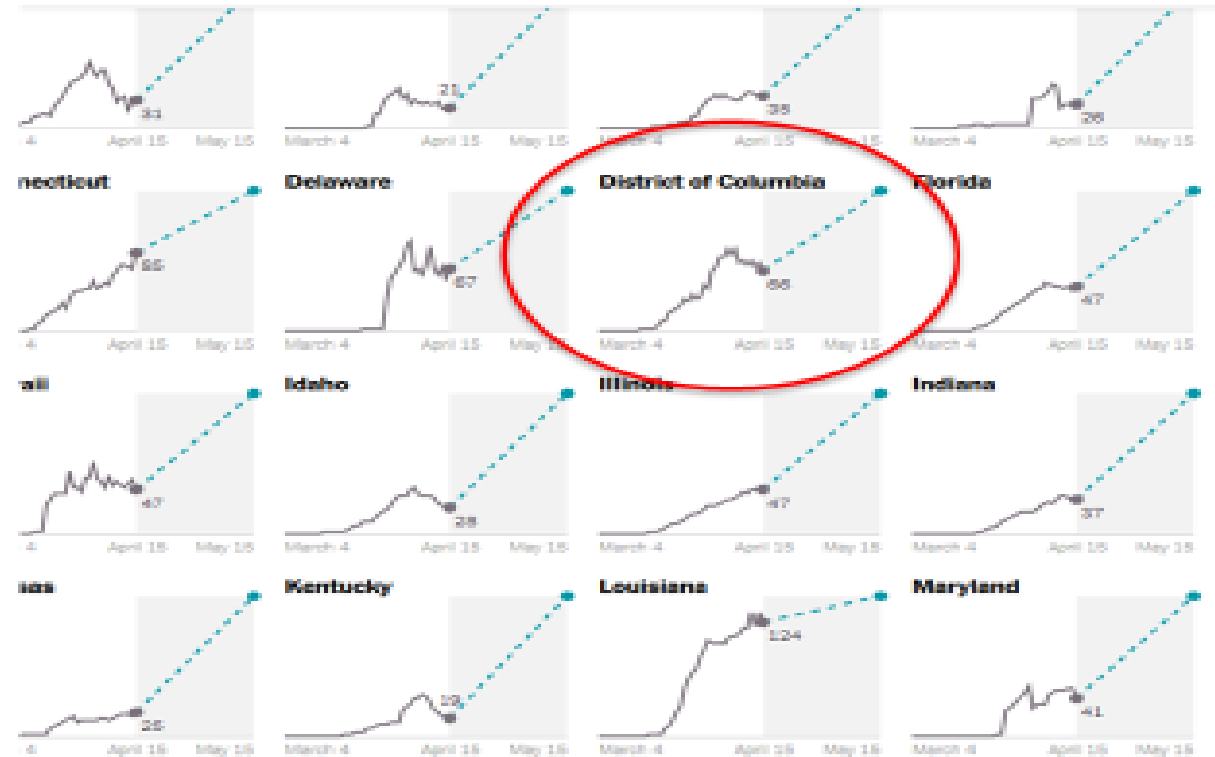
As some governors [consider easing social distancing restrictions](#), new estimates by researchers at Harvard University suggest that the United States cannot safely reopen unless it conducts more than three times the number of coronavirus tests it is currently administering over the next month.

### 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 Tracking Project](#), which on Friday reported 3.1 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 700,000, according to [the Harvard estimates](#), which is a daily minimum of about 152 tests per 100,000 people.

### U.S. | Coronavirus Testing Needs to Triple Before the U.S. Can Reopen, Experts Say



$$7 \times 152 = 1064 \text{ samples/day}$$

Keith Collins, NY Times April 17, 2020 <https://www.nytimes.com/interactive/2020/04/17/us/coronavirus-testing-states.html>



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# TESTING SNAPSHOT (4/28/2020)

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## 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%

<https://coronavirus.dc.gov/page/coronavirus-data>



# POCT DEPLOYMENT (PLAN)

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## 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 skilled nursing facilities (>100 beds)
  - Transitions (Pilot facility) = 1
- DFS Mobile Testing Truck = 3



Slides courtesy of Dr. Chastain-Potts

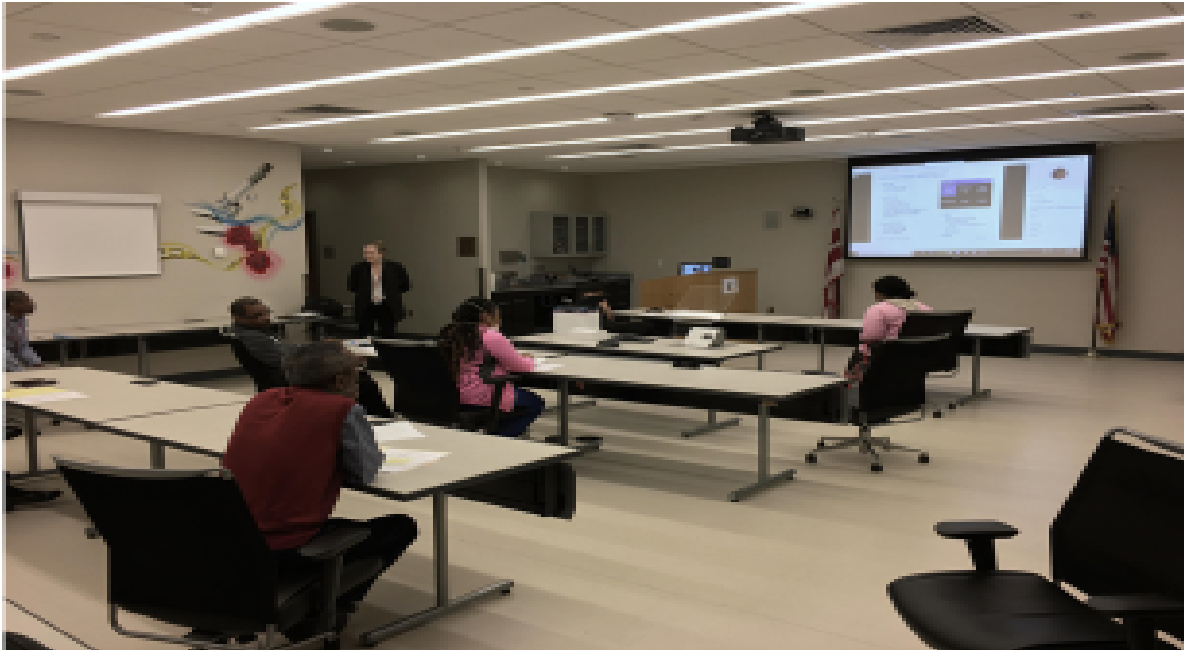
# REQUIREMENTS FOR TESTING

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- 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

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- 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...



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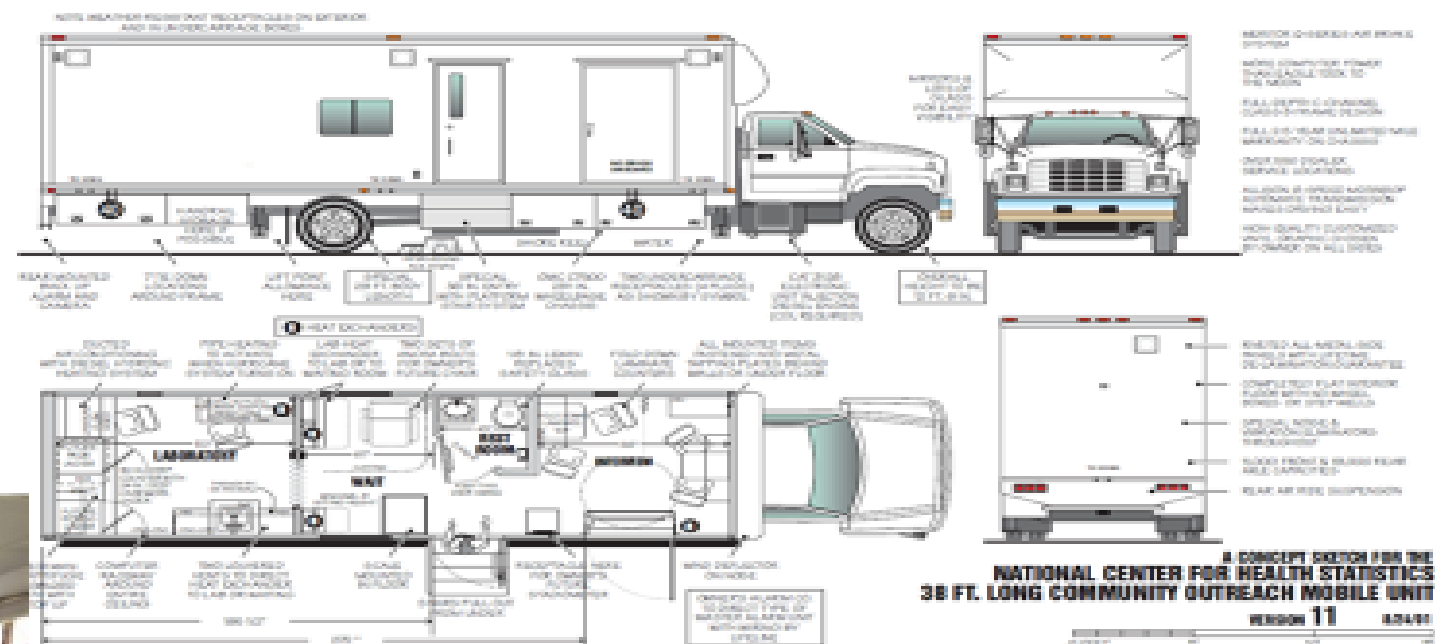
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GOVERNMENT OF THE  
DISTRICT OF COLUMBIA  
MURIEL BOWSER, MAYOR

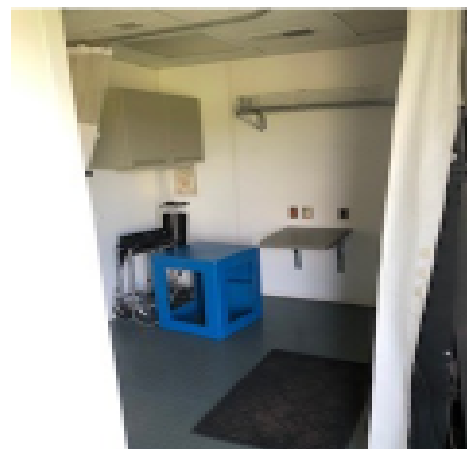


# THE NATIONAL HEALTH & NUTRITION EXAMINATION SURVEY (NHANES) TRUCK

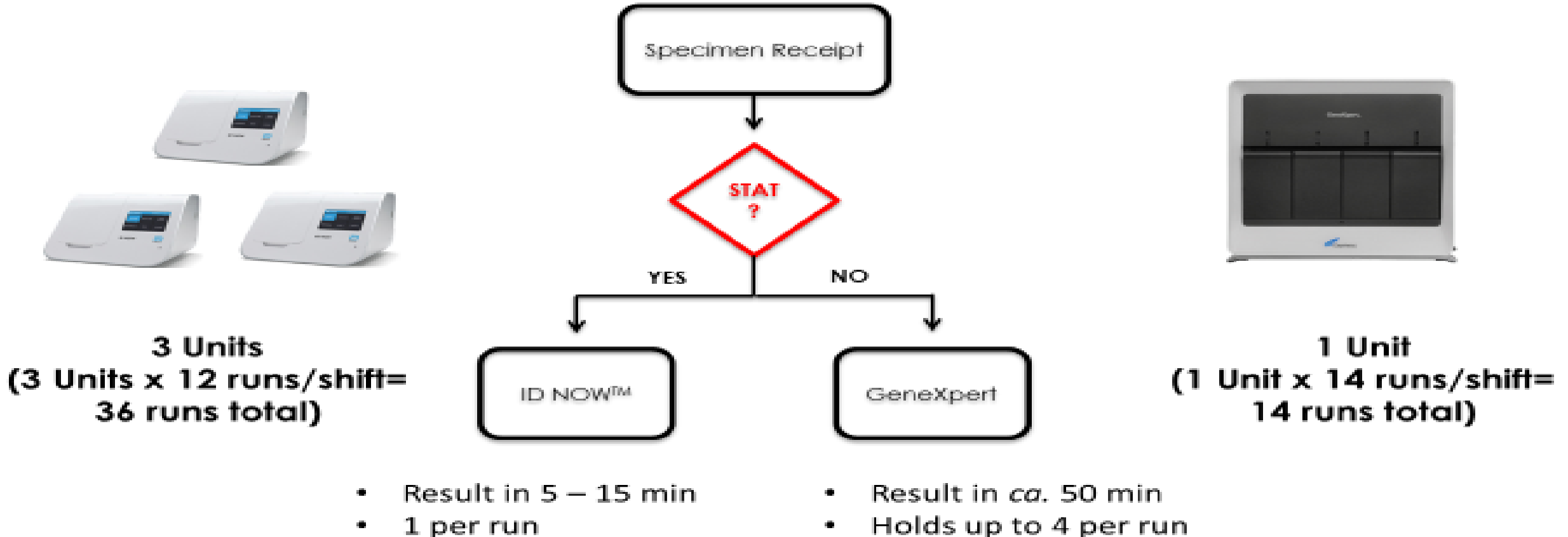


A CONCEPT SKETCH FOR THE NATIONAL CENTER FOR HEALTH STATISTICS 38 FT. LONG COMMUNITY OUTREACH MOBILE UNIT  
VERSION 11 AD2111

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



# PROCESS FLOW



**Total Throughput : 50 per 4-hr shift (36 STAT, 14 routine)**

# DFS PHL MOBILE TESTING SETUP

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## Abbott ID NOW™



## Cepheid GeneXpert



Photos courtesy of Dr. Kiehlbauch



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# DFS PHL MOBILE TESTING SETUP

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Photos courtesy of Dr. Kiehlbauch



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# SPECIAL THANKS TO PHL COVID-19 RESPONSE TEAM

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



# Laboratory Biosafety Update for COVID-19

Bill Arndt, PhD  
CDC Division of Laboratory Systems



# Biosafety Resources

COVID-19 Information for Laboratories page:

<https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html>

Interim Laboratory Biosafety Guidelines:

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>

Laboratory Biosafety Frequently Asked Questions:

<https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html>

Send Inquiries to: [DLSInquiries@cdc.gov](mailto: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.*

