Supply Chain Lessons Learned and Q&A

Joe Saad, MD, FCAP - College of American Pathologists
Matthew Pettengill, PhD, D(ABMM) - American Society for Microbiology

October 28, 2021
Agenda

• Introduction
  – Today’s Presenters
  – New/Featured OneLab Resources
  – Mentimeter Activity
• Supply Chain Lessons Learned – Part 1
• Mentimeter Activity
• Supply Chain Lessons Learned – Part 2
• Q&A
• Upcoming Events
Presenters

Matthew Pettengill, PhD
Diplomate, American Board of Medical Microbiology
Director of Clinical Microbiology, Thomas Jefferson University Hospital
Chair, American Society for Microbiology Professional Development Subcommittee

Joe Saad, MD, FCAP
Vice Chair, College of American Pathologists (CAP) Council on Professional and Government Affairs
Member, Board of Governors
Chief of Pathology, Methodist Health System
President-Elect of Medical Staff, Methodist Health System
Adjunct Associate Professor of Pathology, University of Texas Southwestern Medical Center
NEW RESOURCES
Introduction to Laboratory Risk Management

New CDC Laboratory Training
Lab Training VR: PPE Edition

Now Available!
cdc.gov/labtraining
New CDC Self-Testing Videos

How to Use a Self-Test
• Basics of COVID-19 self-tests
• Purchasing a test
• Specimen collection
• Performing the test
• Proper disposal

How to Interpret Self-Test Results
• What to do about a
  • Positive test result
  • Negative test result
  • Invalid result or test error
• False positive/negative results
SUPPLY CHAIN RELATED RESOURCES
Clinical Laboratory COVID-19 Response (CLCR) Calls

- Short Term Supply Readiness Approaches and Surge Response Capabilities – 8/23/21
  - Transcript | Slides

- How the Federal Government is Addressing Laboratory Supply Issues - 5/17/21
  - Transcript | Slides

- Managing Laboratory Supply Shortage Issues - 12/14/20
  - Transcript | Slides
Summary for Healthcare Facilities: Strategies for Optimizing the Supply of PPE during Shortages

- **Conventional Capacity**
  Strategies that should already be in place as a part of general infection prevention and control plans in healthcare settings

- **Contingency Capacity**
  Strategies that can be used during periods of anticipated PPR shortages

- **Crisis Capacity**
  Strategies that can be used when supplies cannot meet the facility’s current or anticipated PPE utilization rate.

- Summarizes [CDC Strategies to Optimize Personal Protective Equipment](https://www.cdc.gov) (PPE)
- [Optimizing Supply of PPE and Other Equipment during Shortages](#)
Supply Chain Disaster Preparedness Manual

- Hazardous scenarios likely to impact facility or systems
- Develop supply chain-related plans
- Develop an all-hazards cache of supplies

Supply Chain Disaster Preparedness Manual
Personal Protective Equipment (PPE) Burn Rate Calculator

- Spreadsheet-based model that will help healthcare facilities plan and optimize the use of PPE for response to COVID-19
- Non-healthcare facilities may also find this tool useful
Training of Trainers on Packing and Shipping Category B Infectious Substances and Dry Ice

To learn more email labtrainingneeds@cdc.gov
Communication strategies help simplify the process of translating complex information into meaningful messages for your audience.
Understanding sensitivity and specificity helps determine test selection and whether retesting might be necessary.
MENTIMETER ACTIVITY
Go to www.menti.com and use the code 4877 4703

My organization faced major supply chain issues throughout the COVID-19 Pandemic
Go to www.menti.com and use the code 4877 4703

My organization is still facing supply chain issues
I worry about future supply chain issues
SUPPLY CHAIN LESSONS LEARNED

MATTHEW PETTENGILL, PHD, D(ABMM)
AMERICAN SOCIETY FOR MICROBIOLOGY
Our COVID Experience: Clinical Microbiology at Thomas Jefferson University Hospital

Matthew A. Pettengill PhD, D(ABMM)
Outline

• Our COVID lab experience, TJUH/ Philadelphia
• Supply Chain – Shortages of reagents
• Shortages of Personnel
• Advocacy matters
Validation of a modified version of the CDC SARS-2CoV / COVID-19 PCR diagnostic assay:

To serve our patients and physicians at Thomas Jefferson University Hospital during the current COVID-19 pandemic, we sought to validate in house a modified version of the CDC SARS-2-CoV PCR assay. This was a collaboration between the clinical microbiology laboratory and the molecular pathology laboratory at TJUH. The following modifications were necessary due to inability to acquire the specified equipment or control material in a timely manner: PCR reactions and analysis were performed on an Applied Biosystems 7500 (software version 1.3.1), which necessitated also a slight modification to the specified annealing/extension time (from CDC protocol 30 seconds, to a modified 32 seconds). Human Specimen Control for daily external quality control was made in-house from pooled remnant nasopharyngeal swab viral transport media (4 pools made from 15-18 specimens each) and confirmed negative for N1 and N2 primer reactivity (positive for RNaseP), and whole genomic RNA from SARS-2-CoV was acquired as a kind gift from Dr. Scott Weaver with a material transfer agreement with the University of Texas Medical Branch (UTMB). We are extracting RNA using a BioMerieux Easy Mag, which was not included in the original CDC instructions for use but was included in the update to this document dated 15 March 2020. We are using CDC-validated lots of primers/probes acquired from Integrated DNA Technologies (IDT), with the exception that we are omitting use of the N3 target (we will use N1, N2, and RNaseP).

The whole genomic RNA from SARS-2-CoV from UTMB was quantified as to mass (total RNA, 10 uL received at 100 ng/uL), but not viral copies. We were informed by a representative from NIH who was coordinating viral RNA transfers for both UTMB and BEI that we should receive RNA from only one source so that this limited resource would be available to more labs (BEI’s material was quantified for viral
Understanding, Verifying, and Implementing Emergency Use Authorization Molecular Diagnostics for the Detection of SARS-CoV-2 RNA

Stephanie L. Mitchell,* Kirsten St. George, Daniel D. Rhoads, Susan M. Butler-Wu, Vaishali Dharmarha, Peggy McNult, Melissa B. Miller, on behalf of the American Society for Microbiology Clinical and Public Health Microbiology Committee

*Department of Pathology, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania, USA
Laboratory of Viral Diseases, Wadsworth Center, New York State Department of Health, Albany, New York, USA
University Hospitals Cleveland Medical Center, Cleveland, Ohio, USA
Department of Pathology, Keck School of Medicine of USC, Los Angeles, California, USA
American Society for Microbiology, Washington, DC, USA
University of North Carolina School of Medicine, Department of Pathology and Laboratory Medicine, Chapel Hill, North Carolina, USA
SARS-CoV-2 serologic testing was a hot topic in May/June 2020, but ultimately it has not been found to have much clinical utility.
3-Dimensional Printed Alternative to the Standard Synthetic Flocked Nasopharyngeal Swabs Used for Coronavirus Disease 2019 Testing


1University of South Florida, Morsani College of Medicine, Tampa, Florida, USA; 2Northwell Health System, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, New Hyde Park, New York, USA; 3Thomas Jefferson University, Philadelphia, Pennsylvania, USA; 4Tampa General Hospital, Tampa, Florida, USA

Table 5. Table of Agreement for All Methods

<table>
<thead>
<tr>
<th></th>
<th>3DP (+)</th>
<th>3DP (−)</th>
<th>3DP Inconclusive</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>FLNP</td>
<td>74</td>
<td>2</td>
<td>3</td>
<td>79</td>
</tr>
<tr>
<td>FLNP</td>
<td>4</td>
<td>203</td>
<td>1</td>
<td>208</td>
</tr>
<tr>
<td>FLNP Inconclusive</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>78</td>
<td>207</td>
<td>6</td>
<td>291</td>
</tr>
</tbody>
</table>

Bold indicates agreement. Abbreviations: 3DP, 3-dimensional printer; FLNP, flocked nasopharyngeal.

Figure 1. 3-dimensional model of 3-dimensional printer swabs and 2 batches of 324 swabs.
In-house production of viral transport media, TJU Biotechnology Program under the leadership of Scott Gygax PhD, and Sean Chadwick: students generated ~ 30K VTM collection kits.
Extraction-Free Methods for the Detection of SARS-CoV-2 by Reverse Transcription-PCR: a Comparison with the Cepheid Xpert Xpress SARS-CoV-2 Assay across Two Medical Centers

Andrew Cameron, Nicole D. Pecora, Matthew A. Pettengill

*University of Rochester Medical Center, Clinical Microbiology, Department of Pathology and Laboratory Medicine, Rochester

*University of Rochester Medical Center, Department of Microbiology and Immunology, Rochester, New York, USA

Thomas Jefferson University Hospital, Department of Pathology, Anatomy, and Cell Biology, Philadelphia, Pennsylvania, USA

FIG 1 Extraction-free SARS-CoV-2 N2 screening. (A) Generalized direct PCR procedure. (B) The performance of the N2 primer/probe pair was most comparable to that seen with the Cepheid N2 target. (C) Optimization of sample volume in reaction mixture. (D) Direct N2 C<sub>T</sub> values compared to initial Cepheid N2 C<sub>T</sub> value (negative = C<sub>T</sub> value of 45). (E) Performance of Direct N2 screening by C<sub>T</sub> value and performing laboratory. (F) Shorter heat inactivation duration modestly increased performance.
Supply Shortages Impacting COVID-19 and Non-COVID Testing

Jan. 19, 2021

COVID-19 brought unprecedented challenges to clinical laboratories. While U.S. labs strove to provide quality and accurate test results in the face of 2020’s adversity, the uncertainty and lack of supplies were a significant hurdle, hindering day-to-day laboratory operations and the ability to increase testing capacity.

https://asm.org/Articles/2020/September/Clinical-Microbiology-Supply-Shortage-Collecti-1
Supply Shortages Impacting COVID-19 and Non-COVID Testing

COVID-19 brought unprecedented challenges to clinical laboratories. While U.S. labs strove to provide quality and accurate test results in the face of 2020’s adversity, the uncertainty and lack of supplies were a significant hurdle, hindering day-to-day laboratory operations and the ability to increase testing capacity.
COVID-19 brought unprecedented challenges to provide quality and accurate testing and lack of supplies were significant. The ability to increase testing was limited by shortages of supplies.

### COVID-19 Commercial Molecular Assay Testing Supplies Shortages

#### Non-COVID-19 Laboratory Testing Supplies Shortages

<table>
<thead>
<tr>
<th>Avg. % of Labs With a Shortage of Supplies</th>
<th>Week Of</th>
<th>Bacteria</th>
<th>Fungi</th>
<th>Myco</th>
<th>Parasite</th>
<th>STI</th>
</tr>
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<tr>
<td></td>
<td>Sep 11, 2020</td>
<td>94.0%</td>
<td>47.0%</td>
<td>14.0%</td>
<td>0.0%</td>
<td>88.9%</td>
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<tr>
<td></td>
<td>Sep 17, 2020</td>
<td>80.0%</td>
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<td>13.0%</td>
<td>9.0%</td>
<td>67.5%</td>
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<tr>
<td></td>
<td>Sep 24, 2020</td>
<td>67.0%</td>
<td>53.0%</td>
<td>21.0%</td>
<td>8.0%</td>
<td>77.8%</td>
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<tr>
<td></td>
<td>Oct 01, 2020</td>
<td>64.0%</td>
<td>33.0%</td>
<td>17.0%</td>
<td>0.0%</td>
<td>72.7%</td>
</tr>
<tr>
<td></td>
<td>Oct 08, 2020</td>
<td>67.0%</td>
<td>50.0%</td>
<td>19.0%</td>
<td>5.0%</td>
<td>69.6%</td>
</tr>
<tr>
<td></td>
<td>Oct 15, 2020</td>
<td>53.0%</td>
<td>39.0%</td>
<td>23.0%</td>
<td>8.0%</td>
<td>53.8%</td>
</tr>
<tr>
<td></td>
<td>Oct 22, 2020</td>
<td>47.0%</td>
<td>50.0%</td>
<td>15.0%</td>
<td>0.0%</td>
<td>57.1%</td>
</tr>
<tr>
<td></td>
<td>Nov 09, 2020</td>
<td>56.0%</td>
<td>12.0%</td>
<td>27.0%</td>
<td>14.0%</td>
<td>65.8%</td>
</tr>
<tr>
<td></td>
<td>Nov 20, 2020</td>
<td>39.0%</td>
<td>5.0%</td>
<td>35.0%</td>
<td>18.0%</td>
<td>70.0%</td>
</tr>
<tr>
<td></td>
<td>Dec 02, 2020</td>
<td>51.0%</td>
<td>29.0%</td>
<td>39.0%</td>
<td>16.0%</td>
<td>46.0%</td>
</tr>
<tr>
<td></td>
<td>Dec 09, 2020</td>
<td>58.0%</td>
<td>21.0%</td>
<td>26.0%</td>
<td>11.0%</td>
<td>59.0%</td>
</tr>
<tr>
<td></td>
<td>Jan 08, 2021</td>
<td>48.0%</td>
<td>19.0%</td>
<td>29.0%</td>
<td>9.0%</td>
<td>35.0%</td>
</tr>
</tbody>
</table>

Legend:
- **0 - 5%**
- **5 - 20%**
- **20 - 100%**
Our local shortages:

- Haemophilus test media (agar)
- Chromogenic MRSA agar plates
- Mueller Hinton plates
- LJ and LJ Gruft slants
- Thioglycollate broth
- UTM/VTM
- eSwabs
- Automated ID and AST broth tubes – delays and allocations due to glass shortage
- Rapid Strep A antigen tests
- Syndromic panel backorders – GI Panel, ME Panel, BCID Panel
- C. difficile PCR
- Pipette tips
- AFB/mycobacteriology Probes – MTB, M. avium complex
- Biochemical bacterial and yeast identification panels
- Fecal lactoferrin immunochromatographic tests
- Glass slides
- Spreading loops / plasticware
- PEOPLE!!!
The American Society for Clinical Pathology's 2018 Vacancy Survey of Medical Laboratories in the United States

Edna Garcia, MPH,1 Iman Kundu, MPH,1 Melissa Kelly, PhD,2 and Ryan Soles, MS2

From the 1American Society for Clinical Pathology (ASCP) Institute of Science, Technology, and Policy, Washington, DC; and 2ASCP Evaluation, Measurement, and Assessment Department, Chicago, IL.
**Figure 2** Staff (nonsupervisory) vacancy rates by laboratory department. LIS/QA/PI, laboratory information system/quality assurance/performance improvement.
Figure 4: Overall retirement rates (anticipated in the next 5 years) by laboratory department. LIS/QA/PI, laboratory information system/quality assurance/performance improvement.
H. R. 5602

To amend the Public Health Service Act to establish a Bio-Preparedness and Infectious Diseases Workforce Loan Repayment Program.

IN THE HOUSE OF REPRESENTATIVES

October 15, 2021

Mrs. TRAHAH (for herself and Mr. MCKINLEY) introduced the following bill; which was referred to the Committee on Energy and Commerce
SEC. 2. ESTABLISHMENT OF A BIO-PREPAREDNESS AND INFECTIOUS DISEASES WORKFORCE LOAN REPAYMENT PROGRAM.

Subpart 3 of part E of title VII of the Public Health Service Act (42 U.S.C. 295f et seq.) is amended by inserting after section 776 (42 U.S.C. 295f–1) the following: “SEC. 776A BIO-PREPAREDNESS AND INFECTIOUS DISEASES WORKFORCE LOAN REPAYMENT PROGRAM.”
“(I) certification as a physician assistant;
“(J) a doctor of public health;
“(K) a master of public health;
“(L) a master of science in epidemiology;
“(M) a bachelor of science in medical technology;
“(N) certification in medical technology or as a medical lab scientist;
October 21, 2021

The Honorable Lori Trahan  
U.S. House of Representatives  
Rayburn House Office Building  
Washington, DC 20515

The Honorable David McKinley  
U.S. House of Representatives  
Rayburn House Office Building  
Washington, DC 20515

Dear Representative Trahan and Representative McKinley:

On behalf of the American Society for Microbiology (ASM), we write to express our support for H.R. 5602, the Bolstering Infectious Outbreaks (BIO) Preparedness Workforce Act of 2021. Many of ASM’s 30,000 members work in clinical microbiology laboratories in a range of urban and rural settings; including, but not limited to, academic and university-based medical centers, large healthcare systems, private community hospitals, independent laboratories, and public health laboratories. This bill is an important step forward in addressing the clinical microbiology laboratory professional shortages that our field has experienced for several years now, coupled with the lack of federally-funded programs to address financial barriers to entering the field.
In addition to personnel challenges, laboratories continue to be stretched thin with supply shortages and increased demand from all angles (COVID-19 diagnostic and surveillance testing and routine clinical testing). Personnel and supply constraints are negatively affecting testing for infectious agents like strep, RSV, hepatitis C, TB, screening for antimicrobial resistance, and soon-possibly flu. Many labs cannot pivot easily due to lack of resources and diversity of testing platforms, and this is especially true in underserved areas. We are pleased that the legislation’s provisions aim to assist clinical laboratory professionals working in medically underserved areas and aim to boost the number of professionals working in biopreparedness from populations already underrepresented in healthcare.

We thank you for your leadership in sponsoring this legislation and recognizing the need to support a strong pipeline of clinical microbiologists, clinical laboratory scientists and other health care professionals. Supporting professionals working in biopreparedness will ensure a strong workforce to address the next pandemic or other health emergency our nation may face. If you have any questions, please contact Mary Lee Watts, ASM Director of Federal Affairs at mwatts@asmusa.org or 571-228-8345.

Sincerely,

Melissa B. Miller, PhD
Chair, ASM Clinical and Public Health Microbiology Committee

Stacey L. Schultz-Cherry, PhD
Chair, ASM Public and Scientific Affairs Committee
Jenna Meloni
Sara Goss
Mark Sterner Jr
Karishma Naik
Arpit Patel
Anjana John
Anna Alia Dela Cruz
Arvette Mitchell
Ashley Hudson
Ashley Clark
Bernice McLaughlin
Bonnie Roseman
Christine Slovik
Conrad Onuoha
David Wilds
Effimia Chatzimanoli
Eileen Andris
Heather Kelly
Hevikaben Patel
Jacqueline Mahney
Janki Patel
Jennifer DiCandilo
Jerome Brisbon
Jessica Morales
Joanne Hardesty
Kanyeba Ilunga
Kevin Moore Jr
Kwesi Morrison
Maria Kim
Michael Steiner
Michele McKenna
Niketa Patel
Olivia Truong
Payal Patel
Peggy Angelis
Preston Ball
Samantha Moses
Sandra Pierre
Somaly Sorn
Vijaykumar Patel
Yasmeen Jordan
Ivana Jones
Katarina Johnson
Simranjit Mehat
Elia Harmatz
Nicole Hartnett
Run Jin
Kairong Li
Carly Darnell
Valerie Williams
Shannon Mahoney
Robert Vander Meulen
Jedy Panjaitan
Ashley Anthony
Christopher Stein
Faisal Tabari
Lisa Joseph
Hannah Jenkinson
Gabrielle Pae
Dr. Stephen Peiper
Dr. Barbara Goldsmith
Dr. Zi-Xuan Wang
Dr. Doug Stickel
Dr. Scott Gygax
Laughlin Rice
Dr. Steve Gudowski
George Marrone
Kim Brown
Ramane Jones
Sharon Falasco
MENTIMETER ACTIVITY
Go to www.menti.com and use the code 4877 4703

What were your most challenging supply chain issues through 2020?

Press ENTER to pause scroll
Go to www.menti.com and use the code 4877 4703

What were/are your most challenging supply chain issues from January 2021 through now?
SUPPLY CHAIN LESSONS LEARNED

JOE SAAD, MD, FCAP
COLLEGE OF AMERICAN PATHOLOGISTS
Supply Chain Lessons Learned

A CAP Presentation for the OneLab Network

A. Joe Saad, MD, FCAP
Vice Chair, CAP Council on Government and Professional Affairs

October 28, 2021
About the CAP’s Surveys

• The CAP surveyed laboratories it accredits to evaluate the impact of the pandemic on pathologists and laboratories.

• These studies were fielded over the course of a year:
  o April 2020
  o June 2020
  o February 2021

• The data that follow are taken from these surveys and focus on the issue of laboratory shortages.

• These data have informed the CAP’s advocacy and engagement with Congress and the Administration.
More than half of respondents are in practices that offer PCR tests

February 2021: Which of the following COVID-19 testing does your laboratory currently perform on-site? (select all that apply)

<table>
<thead>
<tr>
<th>Test Type</th>
<th>All Respondents</th>
<th>CLIA Laboratory Directors only</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>n</td>
</tr>
<tr>
<td>Molecular (PCR) high throughput testing</td>
<td>52%</td>
<td>50%</td>
</tr>
<tr>
<td></td>
<td>307</td>
<td>74</td>
</tr>
<tr>
<td>Molecular (PCR) non-high throughput testing</td>
<td>53%</td>
<td>62%</td>
</tr>
<tr>
<td></td>
<td>316</td>
<td>91</td>
</tr>
<tr>
<td>Antigen testing</td>
<td>37%</td>
<td>39%</td>
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<tr>
<td></td>
<td>221</td>
<td>57</td>
</tr>
<tr>
<td>Antibody testing</td>
<td>49%</td>
<td>57%</td>
</tr>
<tr>
<td></td>
<td>292</td>
<td>83</td>
</tr>
<tr>
<td>None, COVID-19 testing is not performed on-site</td>
<td>11%</td>
<td>13%</td>
</tr>
<tr>
<td></td>
<td>66</td>
<td>19</td>
</tr>
<tr>
<td>Unsure</td>
<td>7%</td>
<td>1%</td>
</tr>
<tr>
<td></td>
<td>41</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>595</td>
<td>147</td>
</tr>
</tbody>
</table>
## Academic, Community Hospitals, and Larger Practices are All Likely to Offer PCR Testing

<table>
<thead>
<tr>
<th>Setting</th>
<th>Practice Size (# of FTEs)</th>
<th>Academic medical center (n=219)</th>
<th>Non-academic hospital (n=235)</th>
<th>Independent Laboratory (n=56)</th>
<th>&lt;6 (n=150)</th>
<th>6-10 (n=91)</th>
<th>11-20 (n=80)</th>
<th>21-50 (n=79)</th>
<th>&gt;50 (n=22)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular (PCR) high throughput testing</td>
<td></td>
<td>71.7%</td>
<td>39.6%</td>
<td>41.1%</td>
<td>25.3%</td>
<td>66.3%</td>
<td>73.4%</td>
<td>90.9%</td>
<td>54.9%</td>
</tr>
<tr>
<td>Molecular (PCR) non-high throughput testing</td>
<td></td>
<td>51.6%</td>
<td>64.7%</td>
<td>19.6%</td>
<td>56.0%</td>
<td>50.0%</td>
<td>57.0%</td>
<td>59.1%</td>
<td>52.7%</td>
</tr>
<tr>
<td>Antigen testing</td>
<td></td>
<td>34.7%</td>
<td>46.8%</td>
<td>23.2%</td>
<td>43.3%</td>
<td>32.5%</td>
<td>45.6%</td>
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<td>51.9%</td>
<td>37.5%</td>
<td>48.7%</td>
<td>56.3%</td>
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<td>40.9%</td>
<td>48.4%</td>
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<tr>
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<td>2.5%</td>
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<td>12.1%</td>
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<tr>
<td>Unsure</td>
<td></td>
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<td>5.5%</td>
<td>3.6%</td>
<td>3.3%</td>
<td>10.0%</td>
<td>6.3%</td>
<td>4.5%</td>
<td>5.5%</td>
</tr>
</tbody>
</table>
Nearly 80% of laboratories providing COVID-19 testing have more than one testing platform; nearly half have 3 or more platforms

On how many different (unique) platforms does your laboratory perform molecular (PCR) COVID-19 testing? (Includes only respondents whose practices provide PCR or antigen COVID-19 testing)

*Note: Excludes one observation of 80 High Throughput PCR platforms and one observation of 100 High Throughput PCR platforms
Many laboratories have multiple versions of the same type of testing platform (high throughput vs. non-high throughput)

On how many different (unique) platforms does your laboratory perform molecular (PCR) COVID-19 testing? (Includes only respondents whose practices provide PCR or antigen COVID-19 testing)

*Note: Excludes one observation of 80 High Throughput PCR platforms and one observation of 100 High Throughput PCR platforms
Laboratory directors reported problems acquiring reagents, pipette tips for COVID-19 testing; other supplies still difficult to acquire for some laboratories

<table>
<thead>
<tr>
<th>Testing item</th>
<th>February 2021</th>
<th>June 2020</th>
<th>April 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagents for platforms/test kits</td>
<td>45%</td>
<td>64%</td>
<td>69%</td>
</tr>
<tr>
<td>Pipette tips</td>
<td>30%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>SARS-COV-2 instruments</td>
<td>19%</td>
<td>43%</td>
<td>42%</td>
</tr>
<tr>
<td>Flocked nasopharyngeal swab</td>
<td>18%</td>
<td>60%</td>
<td>66%</td>
</tr>
<tr>
<td>Viral transport media/universal transport media</td>
<td>17%</td>
<td>55%</td>
<td>62%</td>
</tr>
<tr>
<td>Personal protective equipment (PPE)</td>
<td>16%</td>
<td>30%</td>
<td>42%</td>
</tr>
<tr>
<td>Assay positive control material</td>
<td>15%</td>
<td>25%</td>
<td>24%</td>
</tr>
<tr>
<td>Extraction control material</td>
<td>14%</td>
<td>34%</td>
<td>30%</td>
</tr>
<tr>
<td>Extraction platform</td>
<td>13%</td>
<td>42%</td>
<td>40%</td>
</tr>
</tbody>
</table>
Many laboratory directors report difficulties in acquiring adequate staffing for COVID-19 testing

<table>
<thead>
<tr>
<th>Staffing Item</th>
<th>CLIA Laboratory Directors (n= 129)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen collection personnel (nurses, physicians, phlebotomists, etc.)</td>
<td>35.7%</td>
</tr>
<tr>
<td>COVID-19 testing personnel</td>
<td>43.4%</td>
</tr>
<tr>
<td>Accessioners</td>
<td>23.3%</td>
</tr>
<tr>
<td>Other staffing difficulties</td>
<td>17.1%</td>
</tr>
<tr>
<td>No staffing difficulties</td>
<td>38.8%</td>
</tr>
<tr>
<td>n</td>
<td>129</td>
</tr>
</tbody>
</table>
Lessons Learned
Lessons Learned

• Testing supplies will be strained as laboratories ramp up capacity and meet demands for testing in their communities during health crises.
• Our health care system needs a reliable supply source for testing materials during pandemics.
  o Laboratories will compete for the same resources.
  o Supplies need to be targeted to “hot spots.”
• We can improve the monitoring and communication of shortages of testing supplies when they occur.
• We need to address the workforce pipeline for laboratory professionals.
• We must have testing available close to the patient.
Recent Actions to Address Future Shortages

• The CAP has engaged with Congress and the Administration to support various efforts to mitigate supply shortages.
• The FDA’s 2022 budget included $21.6 million for the new Resilient Supply Chain and Shortages Prevention Program.
• At the CAP, we continue to serve as a resource for federal agencies by providing them with additional information and expertise.
Resources

- CAP Laboratory COVID-19 Impact Study May 2020
- CAP Laboratory COVID-19 Impact Study June 2020
MENTIMETER ACTIVITY
Go to www.menti.com and use the code 4877 4703

What questions do you still have regarding supply chain issues?
Next OneLab Network Event

Collaborative Education Event: Point of Care Testing

Registration coming soon!
For more information, contact CDC
1-800-CDC-INFO (232-4636)

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