Center for Surveillance, Epidemiology, and Laboratory Services



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



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

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

Division of Laboratory Systems

ntroduction to **Elaboratory** Risk Management **New CDC Laboratory Training**



is safety checklist:

Hazardous materials policy and safe

work procedures are in place

Products are labeled properly

Safety Data Sheets are available

ication and training provided to

íate control measures are ín

Products are stored properly



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

- <u>Short Term Supply Readiness Approaches and Surge Response Capabilities</u> 8/23/21
 <u>Transcript</u> | <u>Slides</u>
- How the Federal Government is Addressing Laboratory Supply Issues 5/17/21
 Transcript | Slides
- <u>Managing Laboratory Supply Shortage Issues</u> 12/14/20
 - <u>Transcript</u> | <u>Slides</u>

Summary for Healthcare Facilities: Strategies for Optimizing the Supply of PPE during Shortages

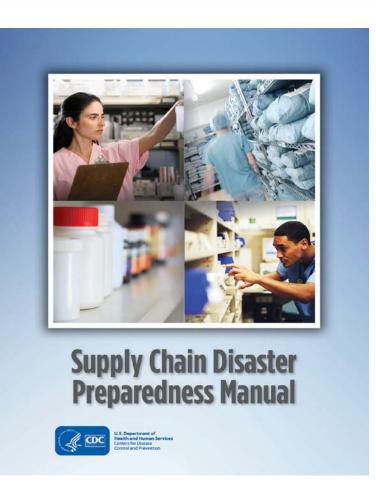
Conventional Capacity Strategies that should already be in place as a part of general infection prevention and control plans in healthcare settings **Contingency Capacity** Strategies that can be used during periods of anticipated PPR shortages Crisis Capacity Strategies that can be used when supplies cannot meet the facility's current or anticipated PPE utilization rate.

- Summarizes <u>CDC Strategies to Optimize Personal Protective</u> <u>Equipment (PPE)</u>
- 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

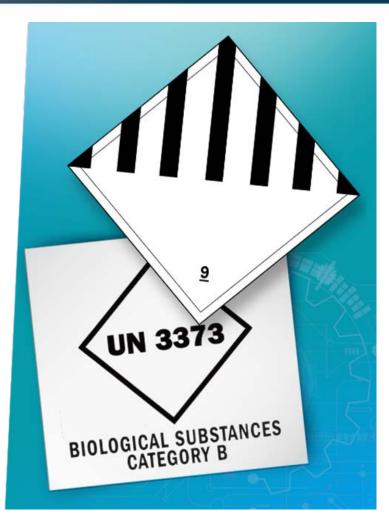
- Spreadsheet-based model that will help healthcare facilities plan and optimize the use of PPE for response to COVID-19
- Non-healthcare facilities may also find this tool useful



Personal Protective Equipment Burn Rate Calculator

COMING SOON RESOURCES

Training of Trainers on Packing and Shipping Category B Infectious Substances and Dry Ice



To learn more email <u>labtrainingneeds@cdc.gov</u>

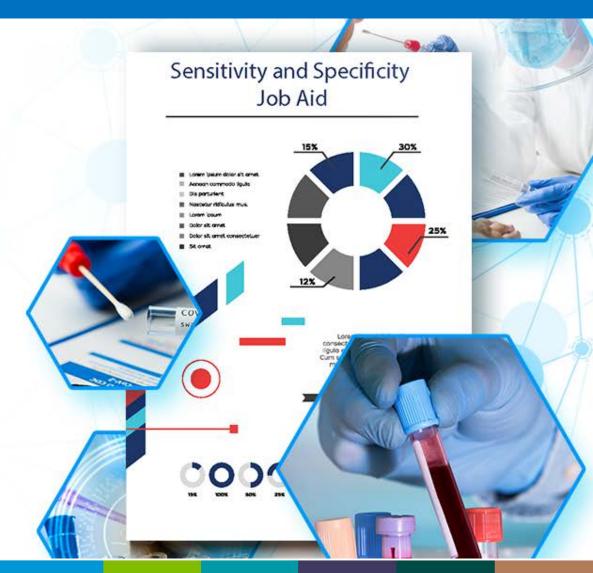
Laboratory Communications Toolkit

Communication strategies help simplify the process of translating complex information into meaningful messages for your audience.



Sensitivity and Specificity Job Aid

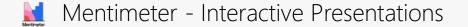
Understanding sensitivity and specificity helps determine test selection and whether retesting might be necessary.



MENTIMETER ACTIVITY

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Excellent Laboratories, Outstanding Health



Go to www.menti.com and use the code 4877 4703

My organization faced major supply chain issues throughout the COVID-19 Pandemic



ៅ Mentimeter

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SUPPLY CHAIN LESSONS LEARNED

MATTHEW PETTENGILL, PHD, D(ABMM) AMERICAN SOCIETY FOR MICROBIOLOGY

Center for Surveillance, Epidemiology, and Laboratory Services



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 RNÅseP), 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,^a ^(D) Kirsten St. George,^b Daniel D. Rhoads,^c Susan M. Butler-Wu,^d Vaishali Dharmarha,^e Peggy McNult,^e Melissa B. Miller,^f on behalf of the American Society for Microbiology Clinical and Public Health Microbiology Committee

^aDepartment of Pathology, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania, USA

^bLaboratory of Viral Diseases, Wadsworth Center, New York State Department of Health, Albany, New York, USA

^cUniversity Hospitals Cleveland Medical Center, Cleveland, Ohio, USA

^dDepartment of Pathology, Keck School of Medicine of USC, Los Angeles, California, USA

^eAmerican Society for Microbiology, Washington, DC, USA

fUniversity of North Carolina School of Medicine, Department of Pathology and Laboratory Medicine, Chapel Hill, North Carolina, USA



SARS-CoV-2 serologic test advertising on social media, June 2020



You can get tested for COVID-19 antibodies without a doctor's referral. Find a testing location near you.



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.



Clinical Infectious Diseases

MAJOR ARTICLE



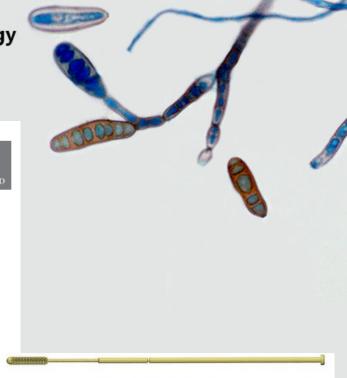
3-Dimensional Printed Alternative to the Standard Synthetic Flocked Nasopharyngeal Swabs Used for Coronavirus Disease 2019 Testing

Summer J. Decker,¹ Todd A. Goldstein,² Jonathan M. Ford,^{1,©} Michael N. Teng,¹ Robert S. Pugliese,³ Gregory J. Berry,² Matthew Pettengill,³ Suzane Silbert,⁴ Todd R. Hazelton,¹ Jason W. Wilson,¹ Kristy Shine,³ Zi-Xuan Wang,³ Morgan Hutchinson,³ Joseph Castagnaro,² Ona E. Bloom,² Dwayne A. Breining,² Barbara M. Goldsmith,³ John T. Sinnott,¹ Donna Gentile O'Donnell,³ James M. Crawford,² Charles J. Lockwood,¹ and Kami Kim¹

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				
		3DP	3DP	3DP	Total
		+	-	Inconclusive	
FLNP	+	74	2	3	79
FLNP	-	4	203	1	208
FLNP	Inconclusive	0	2	2	4
Total		78	207	6	291

Bold indicates agreement. Abbreviations: 3DP, 3-dimensional printer; FLNP, flocked nasopharyngeal. ^a95.88% Agreement, Kappa 0.901.



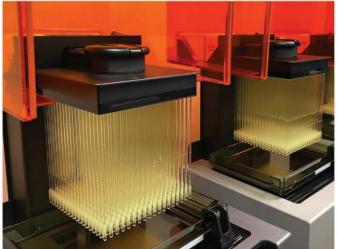


Figure 1. 3-dimensional model of 3-dimensional printer swabs and 2 batches of 324 swabs.





Sean Chadwick, an instructor in the biotechnology program, works on producing viral transport media for one of an estimated 10,000 testing kits. Also pictured: biotechnology student-volunteers and teaching assistants Ellen Robinson and Austin Pendergast.

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.

Jefferson Thomas Jefferson University

Department of Pathology, Anatomy, and Cell Biology Clinical Microbiology Laboratory



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,^a (D) Nicole D. Pecora,^{a,b} (D) Matthew A. Pettengill^c

^aUniversity of Rochester Medical Center, Clinical Microbiology, Department of Pathology and Laboratory Medicine, Rochester, ^bUniversity of Rochester Medical Center, Department of Microbiology and Immunology, Rochester, New York, USA ^cThomas Jefferson University Hospital, Department of Pathology, Anatomy, and Cell Biology, Philadelphia, Pennsylvania, USA



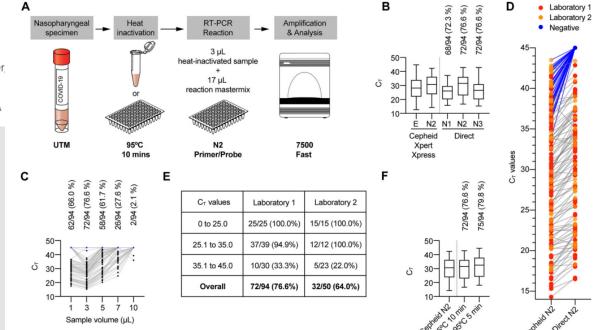


FIG 1 Extraction-free SARS-CoV-2 N2 screening. (A) Generalized direct PCR procedure. (B) The performance of the N2 primer/probe pair was most comparable to that seen with the Cepheid N2 target. (C) Optimization of sample volume in reaction mixture. (D) Direct N2 C_{τ} values compared to initial Cepheid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



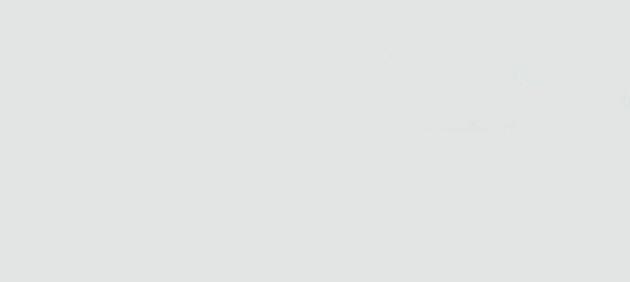


Supply Shortages Impacting COVID-19 and Non-COVID Testing

Jan. 19, 2021

SHARE THIS 🕝

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





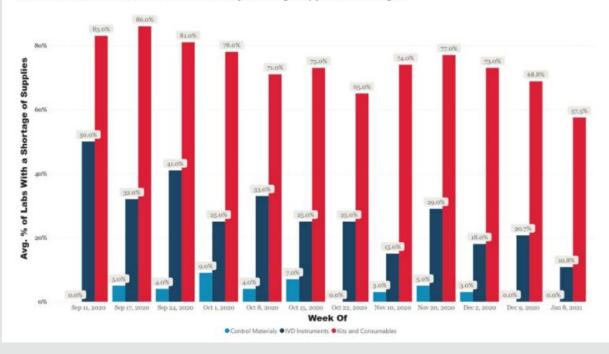
AMERICAN SOCIETY FOR MICROBIOLOGY

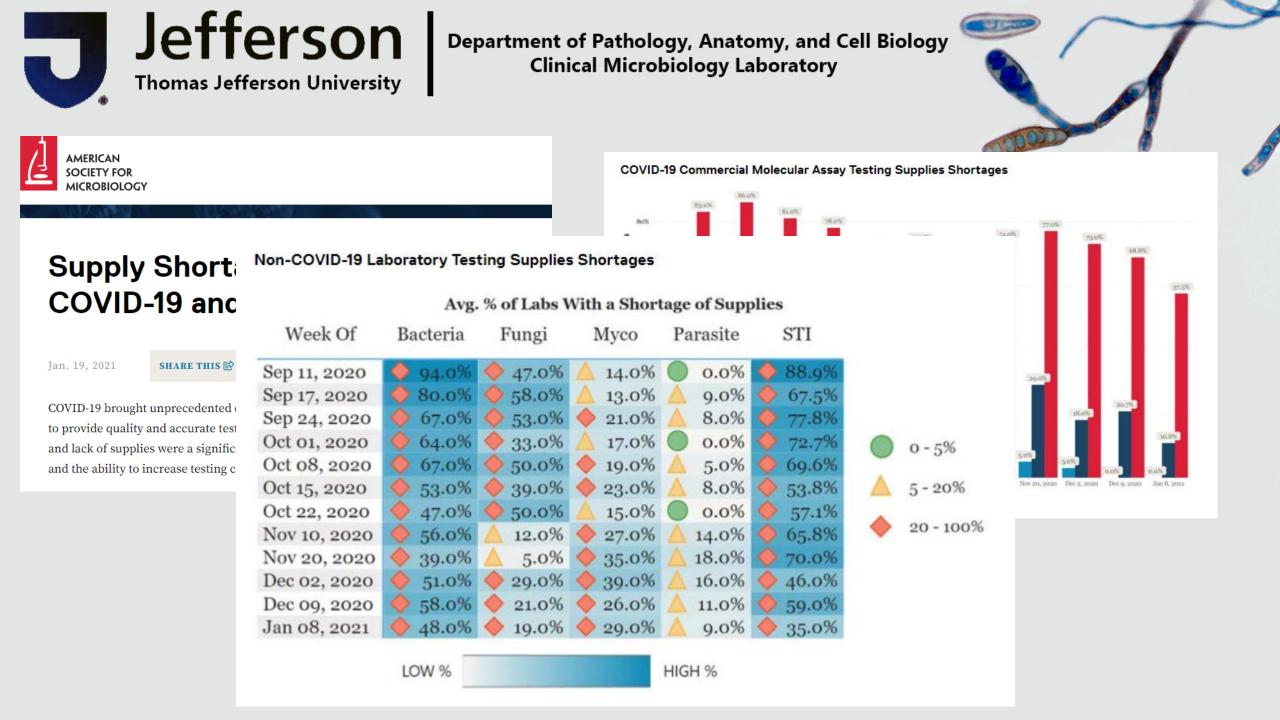
Supply Shortages Impacting COVID-19 and Non-COVID Testing

Jan. 19, 2021

SHARE THIS 🕼

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 Commercial Molecular Assay Testing Supplies Shortages







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!!!



AJCP / ORIGINAL ARTICLE

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.



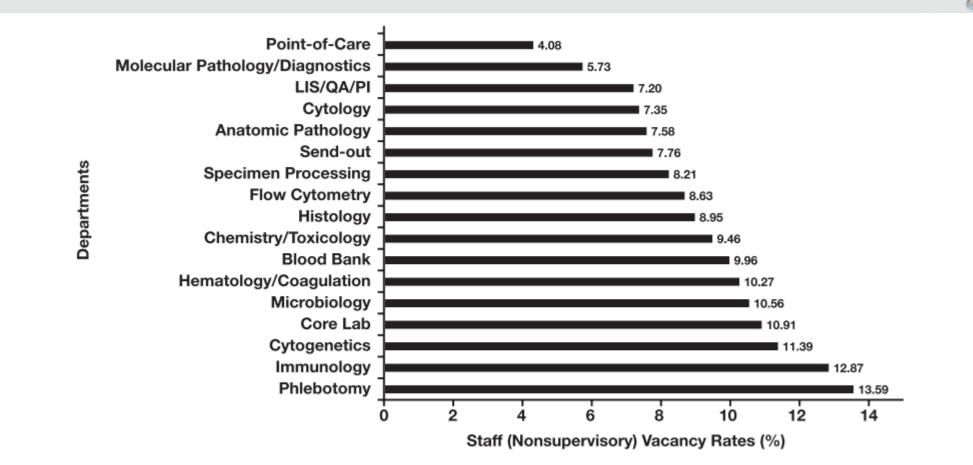
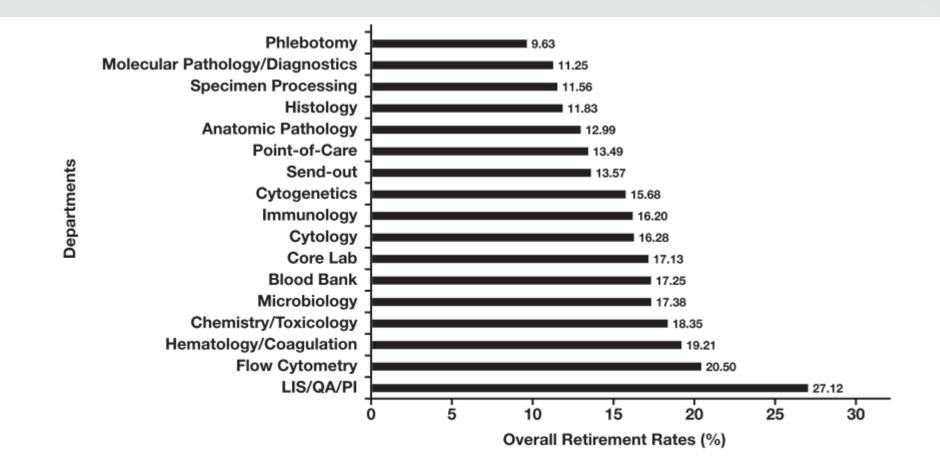


Figure 2 Staff (nonsupervisory) vacancy rates by laboratory department. LIS/QA/PI, laboratory information system/quality assurance/performance improvement.





IFigure 4 Overall retirement rates (anticipated in the next 5 years) by laboratory department. LIS/QA/PI, laboratory information system/quality assurance/performance improvement.



^{117th CONGRESS} 1st Session 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. TRAHAN (for herself and Mr. MCKINLEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

https://www.govinfo.gov/content/pkg/BILLS-117hr5602ih/pdf/BILLS-117hr5602ih.pdf



SEC. 2. ESTABLISHMENT OF A BIO-PREPAREDNESS AND IN-

FECTIOUS DISEASES WORKFORCE LOAN RE-

PAYMENT 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 DIS-EASES WORKFORCE LOAN REPAYMENT PRO-

GRAM.



.....

"(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.

Jefferson Thomas Jefferson University

Department of Pathology, Anatomy, and Cell Biology Clinical Microbiology Laboratory

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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,

nelissa Bruin

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

Stacy Schult-Cheny

Stacey L. Schultz-Cherry, PhD Chair, ASM Public and Scientific Affairs Committee





TJUH Clinical Microbiology Staff

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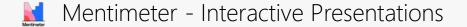
Nicole Hartnett Run Jin Kairong Li Carly Darnell Valerie Williams Shannon Mahoney Robert Vander Meulen Jedy Panjaitan Ashley Anthony Christopher Stein Faisal Tabari Lisa Joseph Hannah Jenkinson Gabrielle Pae

TJUH Administrative/Support

Dr. Stephen Peiper Dr. Barbara Goldsmith Dr. Zi-Xuan Wang Dr. Doug Stickle Dr. Scott Gygax Laughlin Rice Steve Gudowski George Marrone Kim Brown Ramane Jones Sharon Falasco

MENTIMETER ACTIVITY

Center for Surveillance, Epidemiology, and Laboratory Services



Go to www.menti.com and use the code 4877 4703

What were your most challenging supply chain ** Mentimeter issues through 2020?

Press ENTER to pouse scro

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

🛛 🛃 Mentimeter

SUPPLY CHAIN LESSONS LEARNED

JOE SAAD, MD, FCAP COLLEGE OF AMERICAN PATHOLOGISTS

Center for Surveillance, Epidemiology, and Laboratory Services

Excellent Laboratories, Outstanding Health



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)

	All Respondents		CLIA Laboratory Directors only	
	%	n	%	n
Molecular (PCR) high throughput testing	52%	307	50%	74
Molecular (PCR) non-high throughput testing	53%	316	62%	91
Antigen testing	37%	221	39%	57
Antibody testing	49%	292	57%	83
None, COVID-19 testing is not performed on-site	11%	66	13%	19
Unsure	7%	41	1%	2
Total	595		147	

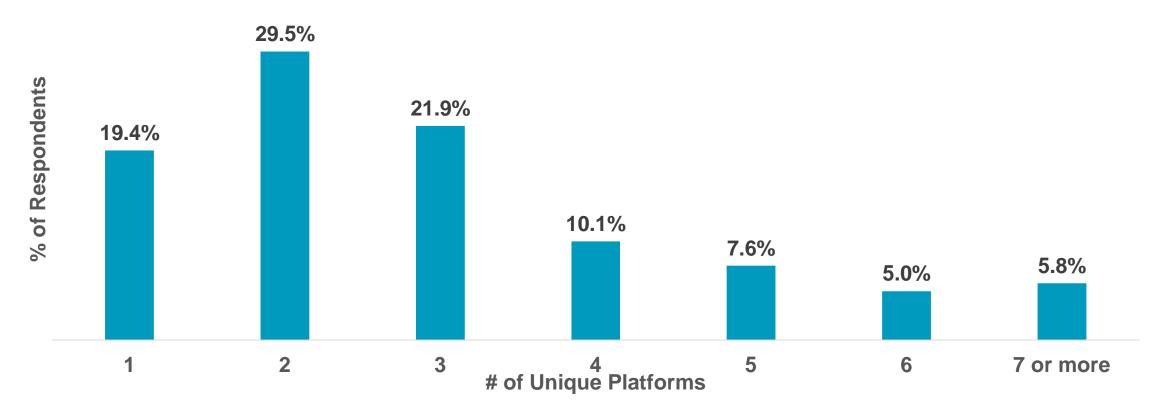
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Academic, Community Hospitals, and Larger Practices are All Likely to Offer PCR Testing

	Setting			Practice Size (# of FTEs)				
	Academic medical center (n=219)	Non- academic hospital (n=235)	Independent Laboratory (n=56)	<6 (n=150)	6-10 (n=91)	11-20 (n=80)	21-50 (n=79)	>50 (n=22)
Molecular (PCR) high throughput testing	71.7%	39.6%	41.1%	25.3%	66.3%	73.4%	90.9%	54.9%
Molecular (PCR) non- high throughput testing	51.6%	64.7%	19.6%	56.0%	50.0%	57.0%	59.1%	52.7%
Antigen testing	34.7%	46.8%	23.2%	43.3%	32.5%	45.6%	22.7%	35.2%
Antibody testing	52.5%	51.9%	37.5%	48.7%	56.3%	65.8%	40.9%	48.4%
None	1.4%	3.4%	46.4%	19.3%	6.3%	2.5%	0.0%	12.1%
Unsure	10.5%	5.5%	3.6%	3.3%	10.0%	6.3%	4.5%	5.5%

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)



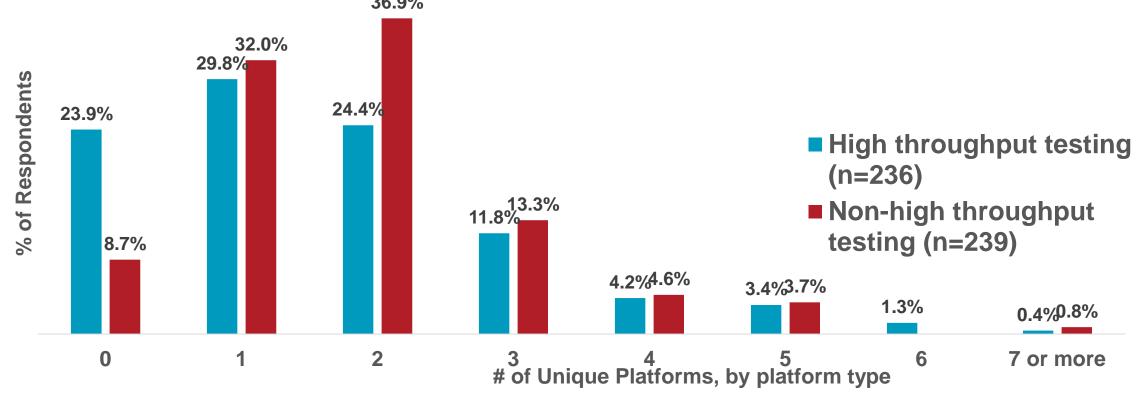
*Note: Excludes one observation of 80 High Throughput PCR platforms and one observation of 100 High Throughput PCR platforms

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5

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) 36.9%



*Note: Excludes one observation of 80 High Throughput PCR platforms and one observation of 100 High Throughput PCR platforms

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5

Laboratory directors reported problems acquiring reagents, pipette tips for COVID-19 testing; other supplies still difficult to acquire for some laboratories

Testing item	February	June	April
	2021	2020	2020
Reagents for platforms/test kits	45%	64%	69%
Pipette tips	30%	-	-
SARS-COV-2 instruments	19%	43%	42%
Flocked nasopharyngeal swab	18%	60%	66%
Viral transport media/universal transport media	17%	55%	62%
Personal protective equipment (PPE)	16%	30%	42%
Assay positive control material	15%	25%	24%
Extraction control material	14%	34%	30%
Extraction platform	13%	42%	40%

Many laboratory directors report difficulties in acquiring adequate staffing for COVID-19 testing

	CLIA Laboratory Directors
Staffing Item	(n= 129)
Specimen collection personnel (nurses, physicians, phlebotomists, etc.)	35.7%
COVID-19 testing personnel	43.4%
Accessioners	23.3%
Other staffing difficulties	17.1%
No staffing difficulties	38.8%
n	129

5

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.
 - Laboratories will compete for the same resources.
 - 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.





- <u>CAP Laboratory COVID-19 Impact Study May 2020</u>
- <u>CAP Laboratory COVID-19 Impact Study June 2020</u>

6

MENTIMETER ACTIVITY

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What questions do you still have regarding supply chain issues?

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Center for Surveillance, Epidemiology, and Laboratory Services

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) TTY: 1-888-232-6348 www.cdc.gov

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