

Clinical Laboratory COVID-19 Response Call

Monday, June 22nd, 2020 at 3:00 PM EDT

- **Welcome**
 - Nancy Anderson, Division of Laboratory Systems, CDC
- **Opening Remarks**
 - Jay Butler, MD, Deputy Director for Infectious Diseases, CDC
- **FDA Update**
 - Tim Stenzel and Sara Brenner, U.S. Food and Drug Administration (FDA)
- **Laboratory Workforce: Short Term Impact vs. Long Term Trends**
 - Jim Flanigan, American Society of Clinical Laboratory Science (ASCLS)
- **DLS Laboratory Training Resources**
 - Senia Wilkins, Division of Laboratory Systems, CDC

New Schedule for Clinical Laboratory COVID-19 Response Calls

- After today's call, we will host these calls every other week, and the calls will be extended from 45 minutes to one hour.
- The next call is scheduled for **Monday, July 6** from 3:00 PM to 4:00 PM EDT.



CDC Information for Laboratories

- **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/>
- **IVD Industry Connectivity Consortium**
<https://ivdconnectivity.org/livd/>
- **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>

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 and submit it
- Please do not submit a question using the chat button

- For media questions, please contact CDC Media Relations at media@cdc.gov

- If you are a patient, please direct any questions to your healthcare provider



Opening Remarks

Jay Butler, MD

Deputy Director for Infectious Diseases, CDC



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

FDA Update

Tim Stenzel and Sara Brenner
U.S. Food and Drug Administration (FDA)



U.S. Department of
Health and Human Services
Centers for Disease
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Food and Drug Administration (FDA)

- **COVID-19 Emergency Use Authorization (EUA) Information for Medical Devices**
<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>
- **COVID-19 In Vitro Diagnostic EUAs**
<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>
- **COVID-19 Frequently Asked Questions**
<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions>
- **COVID-19 Updates**
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>
- **FDA Townhall Meetings**
<https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-immediately-effect-guidance-coronavirus-covid-19-diagnostic-tests-06032020>

Food and Drug Administration (FDA)

COVID-19 Diagnostic Development: CDRH-EUA-Templates@fda.hhs.gov

Spot Shortages of Testing Supplies: 24-Hour Support Available

1. Call 1-888-INFO-FDA (1-888-463-6332)
2. Then press star (*)

Laboratory Workforce

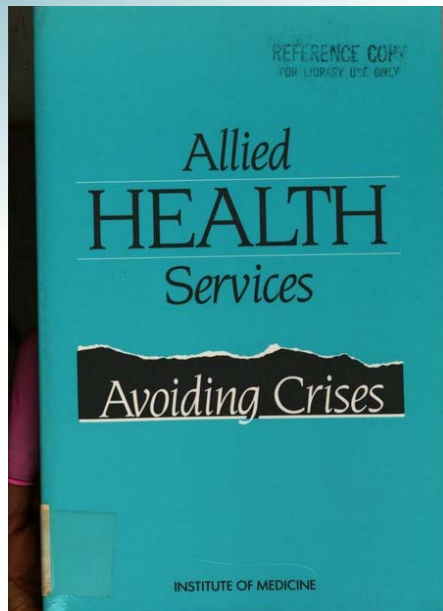
Short Term Impact vs. Long Term Trends

Jim Flanigan

American Society of Clinical Laboratory Science (ASCLS)



More than 20 Years



IOM 1989



Laboratory Personnel Summits - 6/16/2000 and 1/22/2001

ASCLS, AACC, ASCP-AMS, ASCP-BOR, ASM, AAB, ACLA, AMT, AMP, ASCT, AGT, APHL, ASAHP, CLMA, NAACLS, NCA, NSH, SOCRA, as well as CDC and FDA attended one or both meetings.

COVID-19 Short Term Impact

HealthPartners	UnityPoint Health – Des Moines Pathology Laboratory	Marcus Daly Memorial Hospital Hamilton Montana
8 hospital, 1 esoteric central lab, 75 POLs	Central Iowa Region: 5 laboratories – 4 hospital+1 Outreach/Reference	24 Best Critical Access Hospital 1 main and 4 PPMP laboratories
Clinic labs: ↓45%, Central lab: ↓70%, Crit Access Hosp: ↓40%	Pre-Covid Vol: 65k COVID Drop: 30- 60%	Volume down 19% from average of 12,443/mo to 10,158 in Apr + May
900 FTE: Furloughs (majority), Voluntary PTO, LOA, reduced hours, temp pool. Maintained benefits.	278 FTE: 30% staffing reductions through furloughs, personal leaves	23 FTE + 6 PRN
Volumes Returning to Normal or in Some Cases Increasing		
Permanent consolidation of resources	Pre-COVID – molecular was M-F, 1 shift /1 pro. Current - molecular 24/7 with 4 pros. 10 trained with 4 new to molecular	Lost 1 FT MLT and 1 PRN not replaced due to volumes and hiring freeze. Review on 7/1 may need wage cuts, furloughs continued hiring freeze and attrition.



Demographics Are Relentless

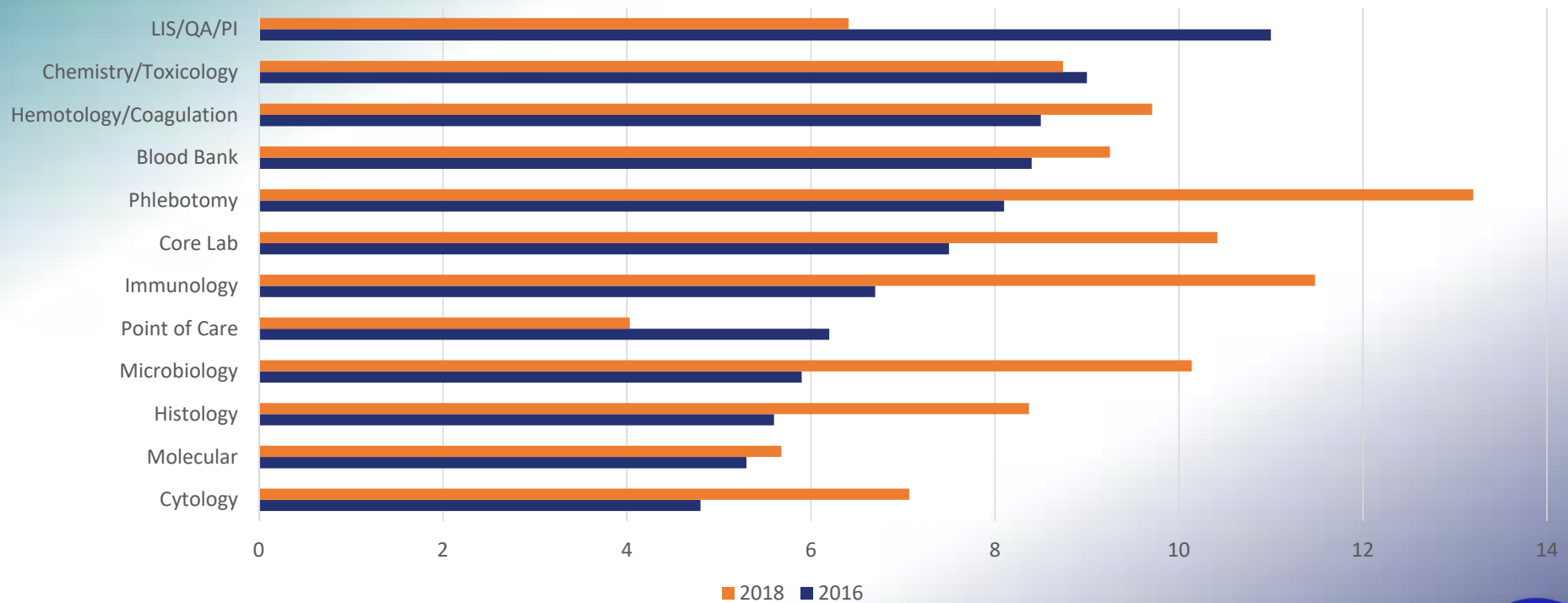
- Growth in demand from aging population and the number and complexity of diagnostic tests.

MEETS

- An aging and stressed out workforce not able to train enough new professionals to replace those lost to retirement or burnout.



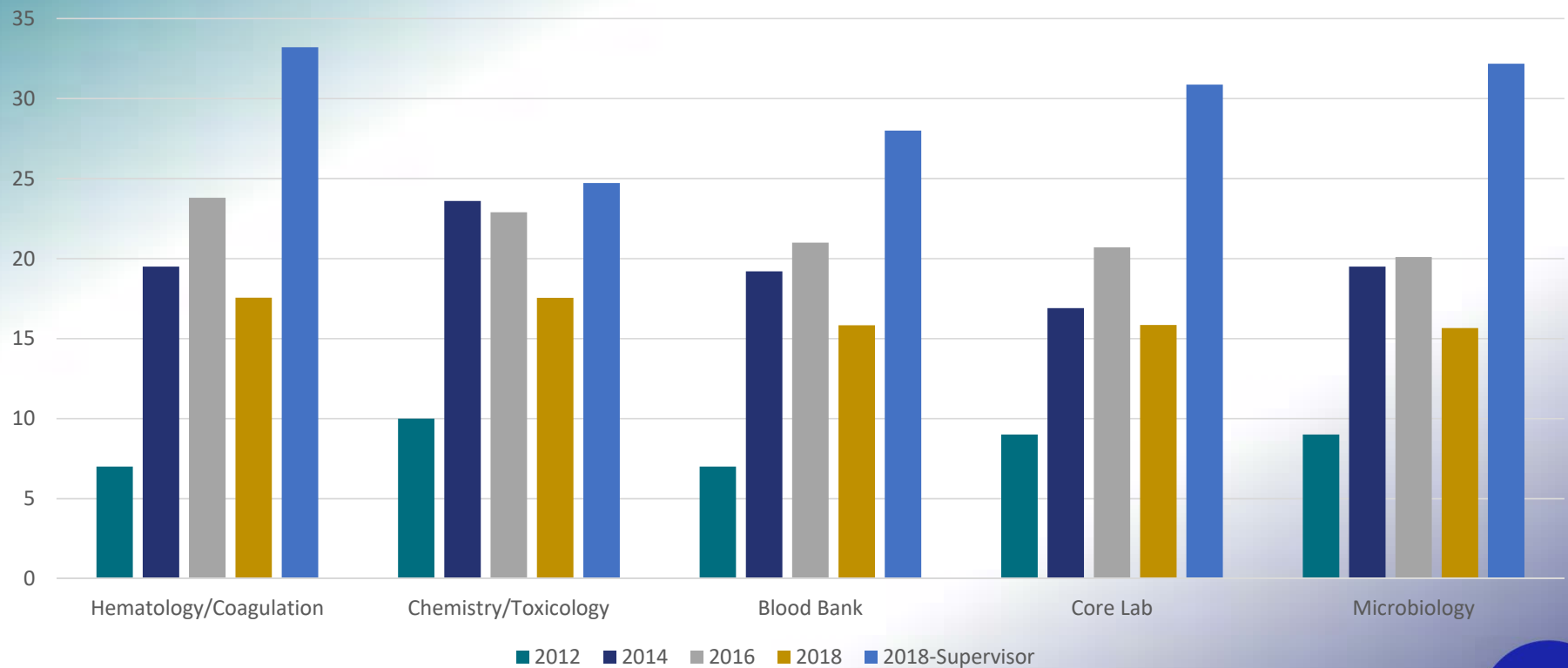
Vacancy Problem is Acute



From: The American Society for Clinical Pathology's 2016-2017 Vacancy Survey of Medical Laboratories in the United States. Am J Clin Pathol. Published online March 07, 2018. doi:10.1093/ajcp/aqy005
The American Society for Clinical Pathology's 2018 Vacancy Survey of Medical Laboratories in the United States American Journal of Clinical Pathology, aqz046, <https://doi.org/10.1093/ajcp/aqz046>



Wave of Retirements (% Next 5 Years)



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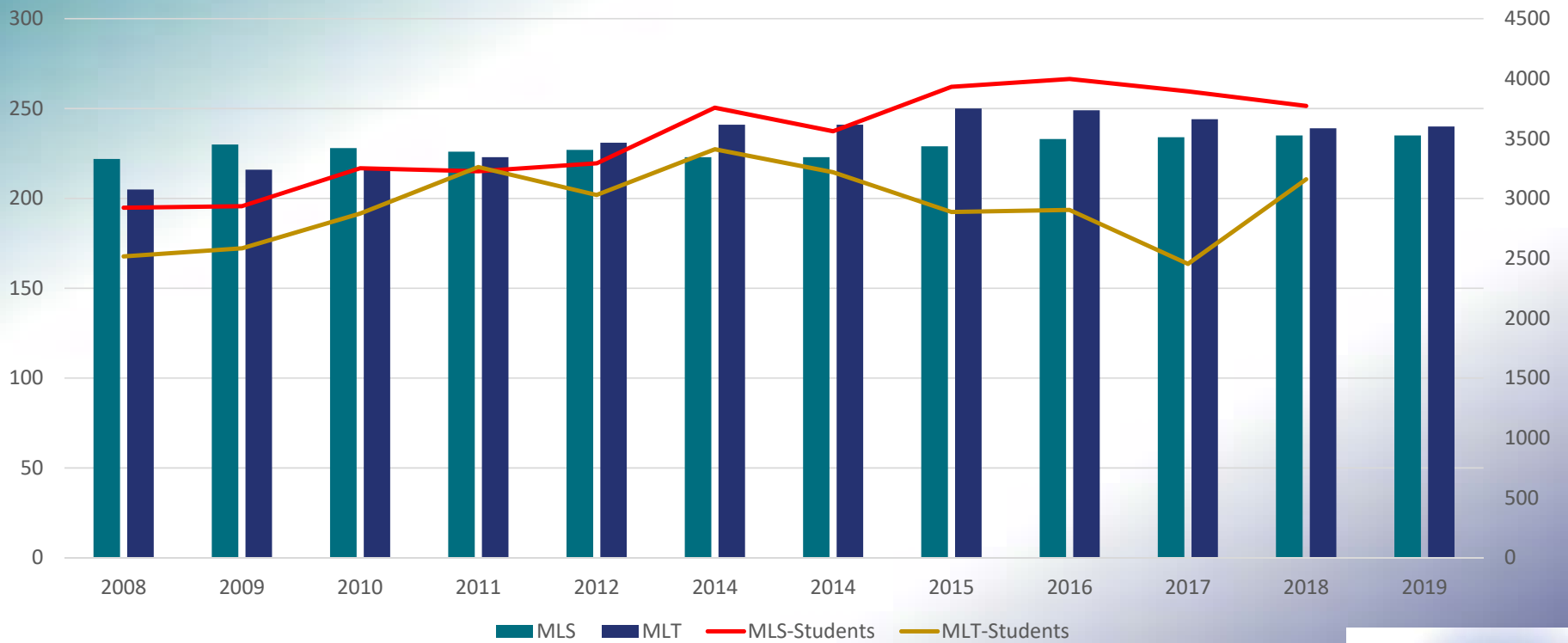
Stressed Out and Everywhere to Go

- 37.2% of respondents are somewhat or very dissatisfied with their jobs. **Significantly higher rates of younger professionals (25-44) are dissatisfied** with their jobs
- A majority of all respondents (53.4%) reported feeling “a lot of stress.” You will note that **one of the top three responsibilities is being involved in education**, which means preceptors are stressed out and potentially modeling negative emotions to our students.
- Most respondents reported feeling overwhelmed (varying degrees) by their workload (slightly overwhelmed, 37.6%; moderately overwhelmed, 29.5%; and very overwhelmed, 17.9%). **Only 14.7% reported not feeling overwhelmed.**
- Nearly **50% of respondents are currently experiencing burnout** and almost 90% have experienced at some point in their career.

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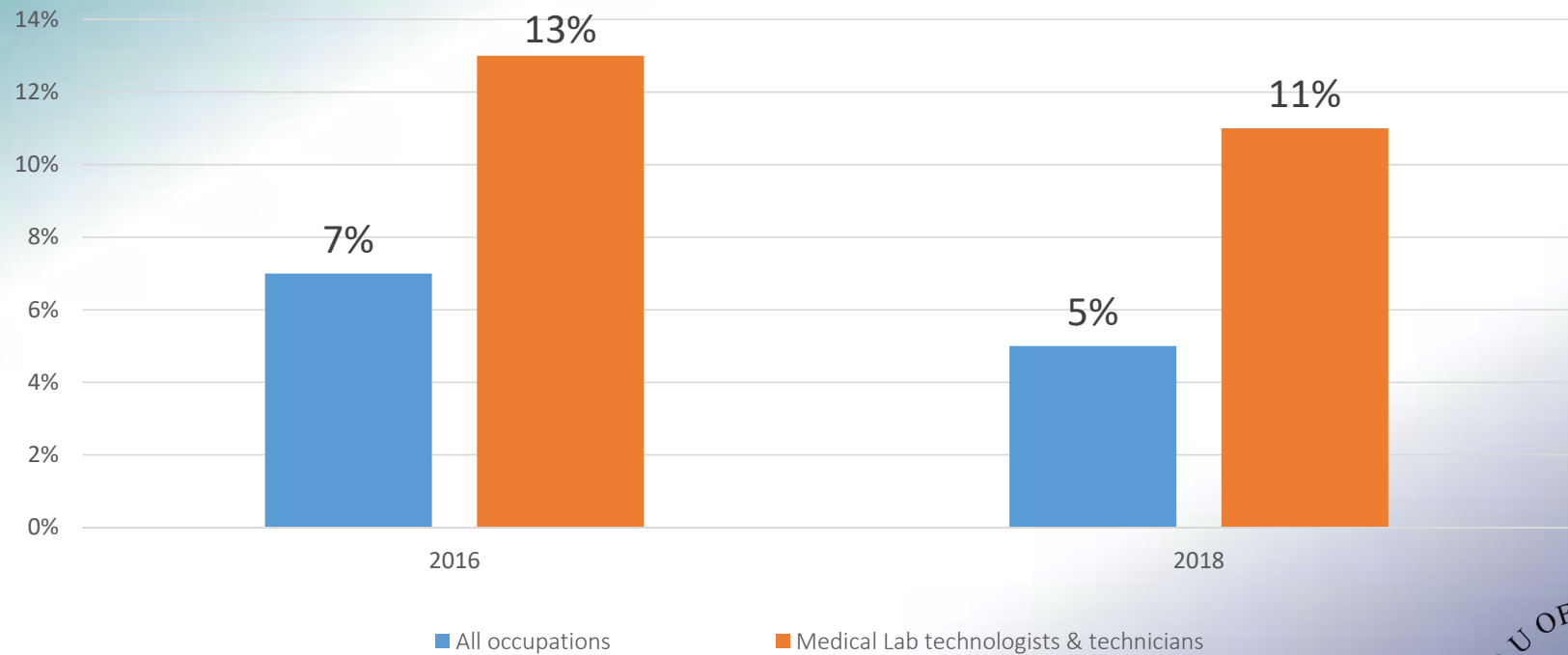
Programs and Graduates



Source: NAACLS Annual Reports



Bureau of Labor Statistics Projected Increase in Workforce Needs 2016 vs 2018



2018-2028 Projection: 3,500 new jobs per year



Supply and Demand

Assumption: Workforce 335k (BLS) – 358k (BOC)

Outflow

- Retirements (20% in 5 years)
- -13,400 - 14,300/year

Demand (BLS)

- +3,500/year

Total Need

- 16,900 – 17,800/year

Inflow/Year

- New Certificates +14,800
- MLT to MLS -2,100

Net MLS/MLT

- +12,700/Year

Total Annual Shortfall

- 4,200 – 5,100/year



Resources

CCCLW

www.ccclw.org

Laboratory Science Careers

www.laboratorysciencecareers.com

ASCLS Position Paper

www.ascls.org/position-papers/321-laboratory-workforce



Jim Flanigan

jimf@ascls.org

@JimFlaniganCAE



DLS Laboratory Training Resources

Yesenia (Senia) Wilkins

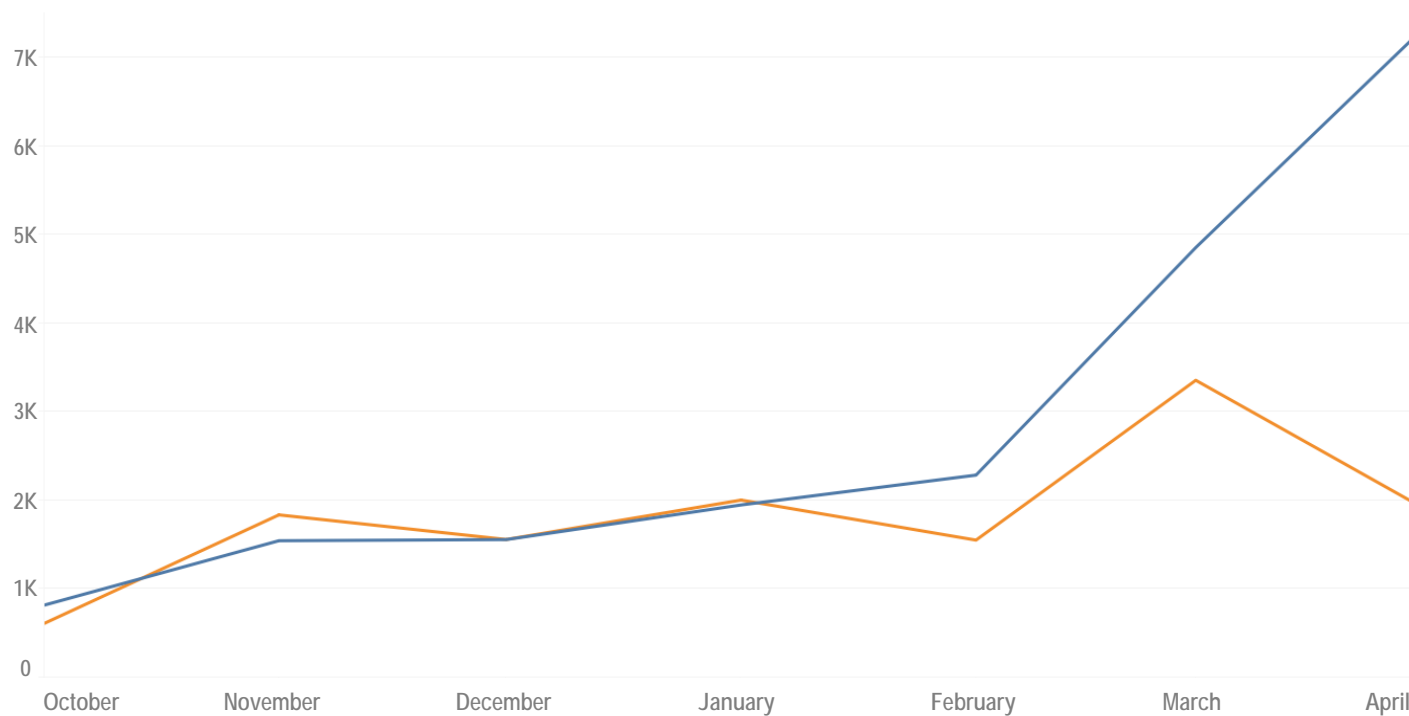
Chief, Training and Workforce Development
Division of Laboratory Systems, CDC



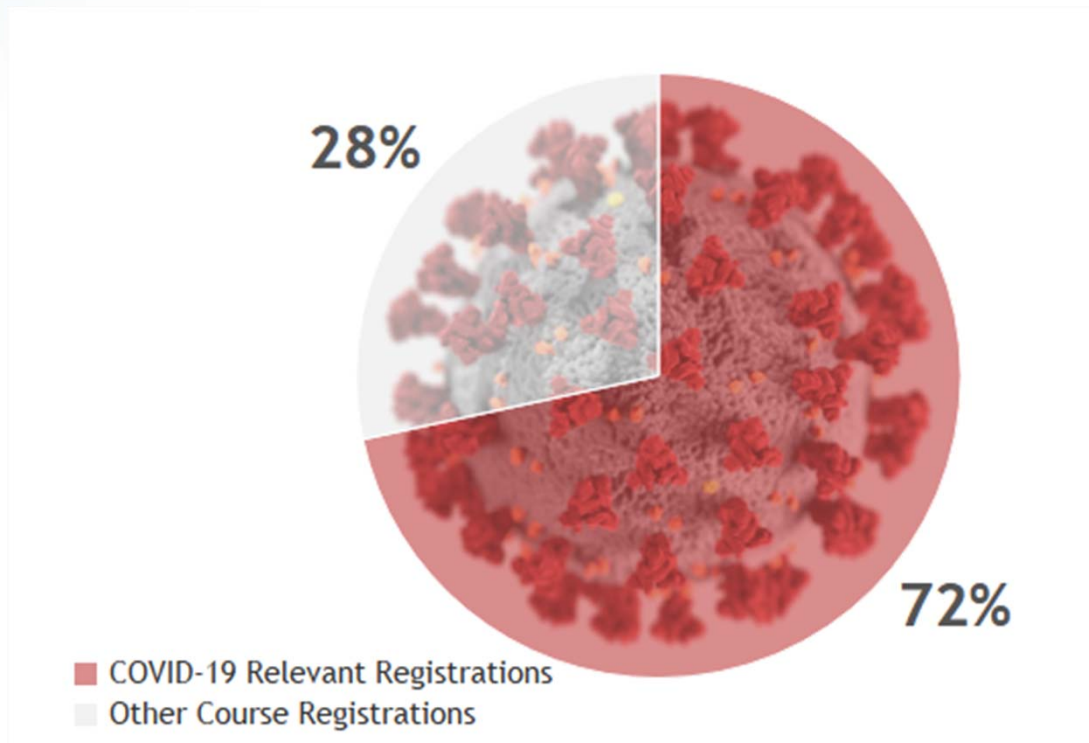
U.S. Department of
Health and Human Services
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Course registration trends, before vs. during COVID-19

There was a significant increase in registrations from **October 2019 - April 2020** when compared to the same time period from the **previous year**.



Registration for COVID-19 relevant courses vs. other courses, January 2020 – May 2020



Total Registrations

32,763

COVID-19 Relevant Registrations

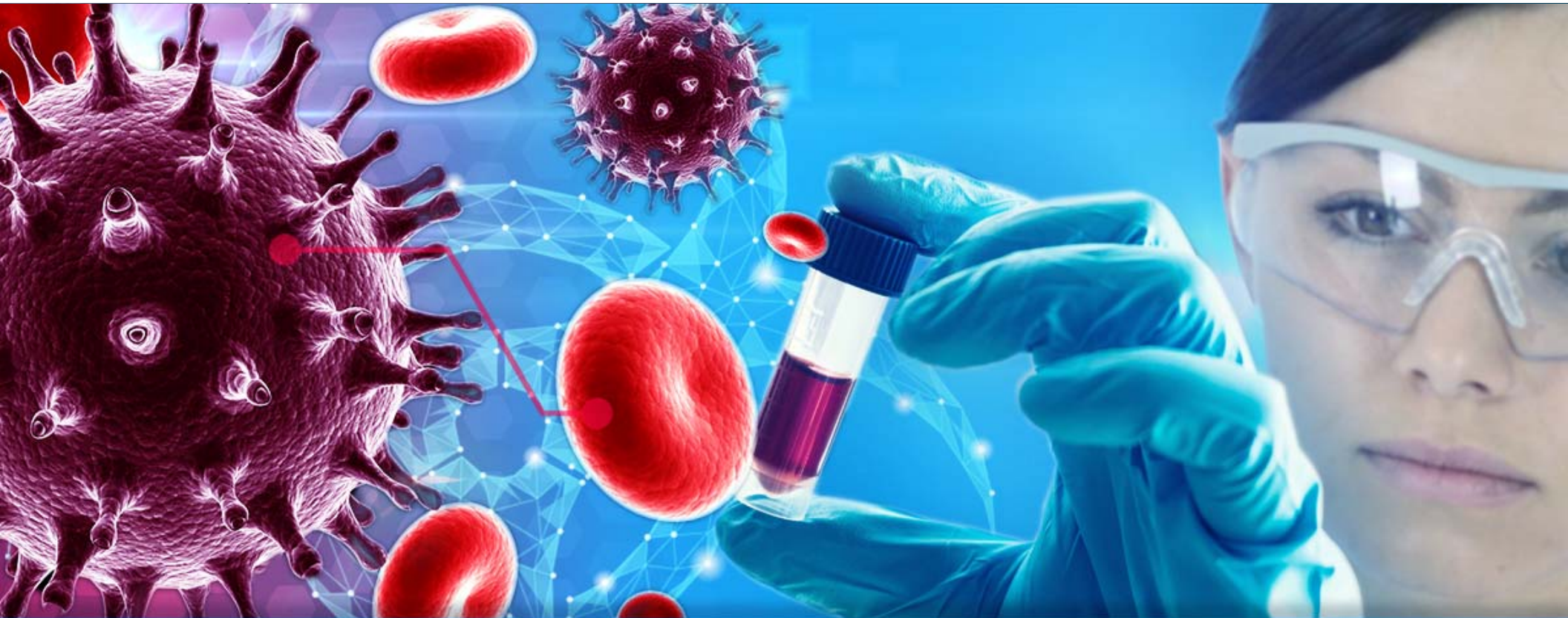
23,469

Total Courses

37

COVID-19 Relevant Courses

13



Fundamentals of Personal Protective Equipment





Packing and Shipping Division 6.2 Materials: What the Laboratory Professional Should Know





100100

Fundamentals of Working Safely in a Biological Safety Cabinet



CDC just made it easier to find the right lab training course for you!



An illustration of a female scientist in a white lab coat pointing towards a computer screen. The screen displays the CDC Laboratory Trainings search interface. The interface includes a search bar with the text "Search CDC Laboratory Trainings" and a search button. Below the search bar, there are filters for "Topics" and "Level". The "Topics" filter is expanded, showing a list of categories: Diagnostic Testing (5), Preparedness (11), Core Science (12), Safety (3), Informatics (3), and Packing and Shipping (1). The "Level" filter is also visible, showing Intermediate (7) and Advanced (0). The main content area shows a list of courses, including "Basic Molecular Biology Module 2: Laboratory Practice" and "Basic Molecular Biology Module 1: Basic Molecular Biology". Each course entry includes a thumbnail image, a title, a brief description, and a "Basic" level indicator. The scientist is smiling and has her hand on her hip, looking at the screen.

New search tool, active filters, and improved course page layouts

www.cdc.gov/labtraining

Receive e-mail updates on new courses

CDC TRAIN

 Manage Groups

Join By Group Search

National/CDC
↓ Laboratory Training



 Join Another Group

Join the Laboratory Training Group at www.train.org/cdctrain

Coming Soon!



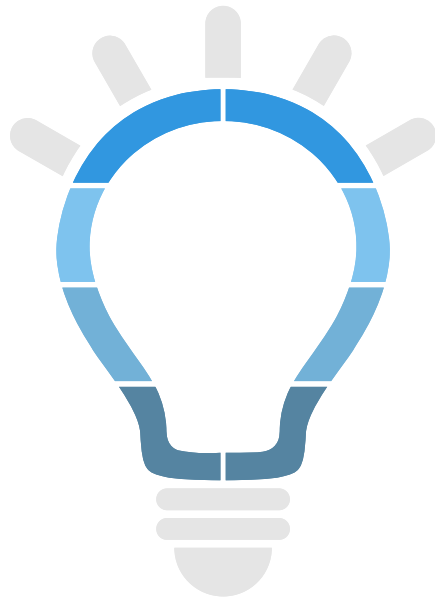
Available on
CDC TRAIN
and
 **STEAM®**



cdc.gov/labtraining



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CDC Social Media



<https://www.facebook.com/CDC>

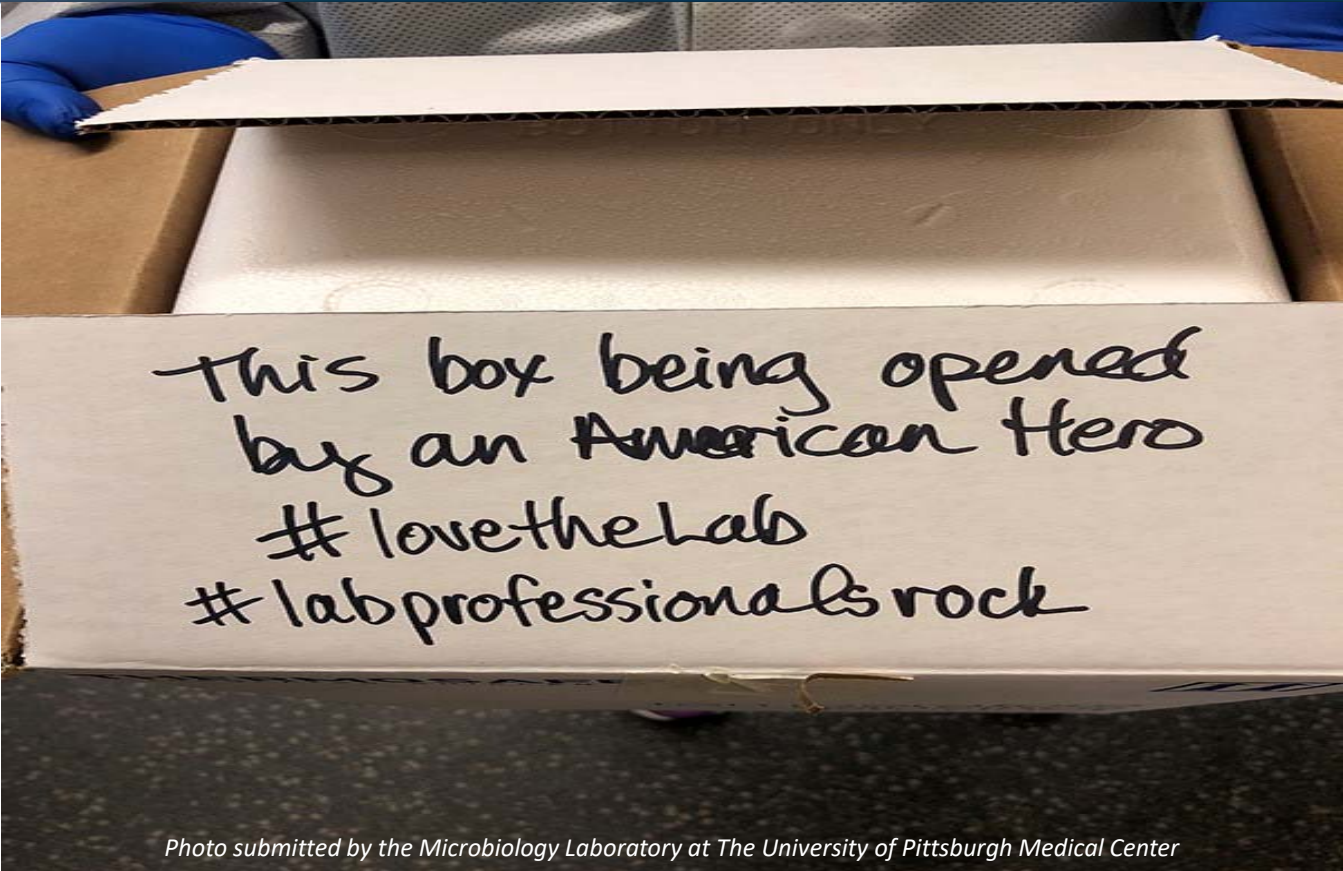


<https://twitter.com/cdcgov>



<https://www.linkedin.com/company/cdc>

Thank You For Your Time!



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

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