



COLLEGE of AMERICAN  
PATHOLOGISTS

# The Laboratory's Critical Role in the COVID-19 Novel Pandemic

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Jonathan L Myles MD, FCAP  
Member, Board of Governors  
Chair, Council on Government and Professional Affairs  
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# Opening Comments

- The role of the laboratory has never been greater than it is today.
- High-quality, adaptable laboratories are foundational to strong health care.
- Accreditation is foundational to building a high-quality, adaptable laboratory.
- COVID-19 is an excellent case study.





# Today's Presenter: Jonathan L. Myles, MD, FCAP

- Pathologist at Cleveland Clinic (Ohio, USA)
  - Subspecialty pathologist in genitourinary (GU), cardiovascular, and medical kidney pathology
  - Current roles include Quality Institute Officer for the Robert J. Tomsich Pathology and Laboratory Medicine Institute at Cleveland Clinic
  - Practices both anatomic and clinical pathology
- Involvement with the College of American Pathologists (CAP)
  - Member of Board of Governors
    - Chair of the Council on Government and Professional Affairs
    - Chair of the Investment Committee
    - Board Member of PathPAC
    - Member of Compensation and Finance Committee
  - Inspector in peer-based laboratory accreditation program



# Agenda

- The CAP Response as a Trusted Resource
- COVID-19 Effects on the Laboratory and Workforce
- Maintaining Testing Compliance and Excellence During Times of Crisis

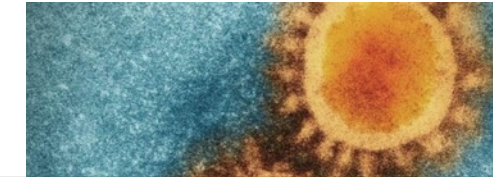
# **The CAP Responds During the COVID-19 Pandemic as a Trusted Resource**

**To ensure the quality of laboratory testing and diagnosis and the quality of care that patients receive**

# Supporting the Pathology and Laboratory Community

Two COVID-19 sections,  
accessible from [cap.org](https://cap.org):

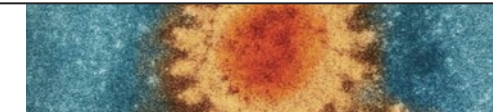
1. Updates on newly posted content
2. COVID-19 Information, including:
  - Extensive Q&As
  - CAP's statement on COVID-19 vaccine development
  - Hybrid and virtual laboratory inspection processes



## COVID-19 Updates

Access recent updates on COVID-19

[See the Updates](#)



## COVID-19 Information

CAP meets with White House officials to address testing supply shortages

[Read More](#)



# Responding to Laboratory Community Needs

CAP proficiency testing (PT) to validate COVID-19 testing

- Three SARS-CoV-2 PT programs
  - Molecular
  - Serology
  - Antigen
- Two Quality Cross Check programs
  - Molecular
  - Serology



# Study on the Effects on Laboratories and Workforce



# CAP-Accredited Laboratories are Very Involved in COVID-19 Testing

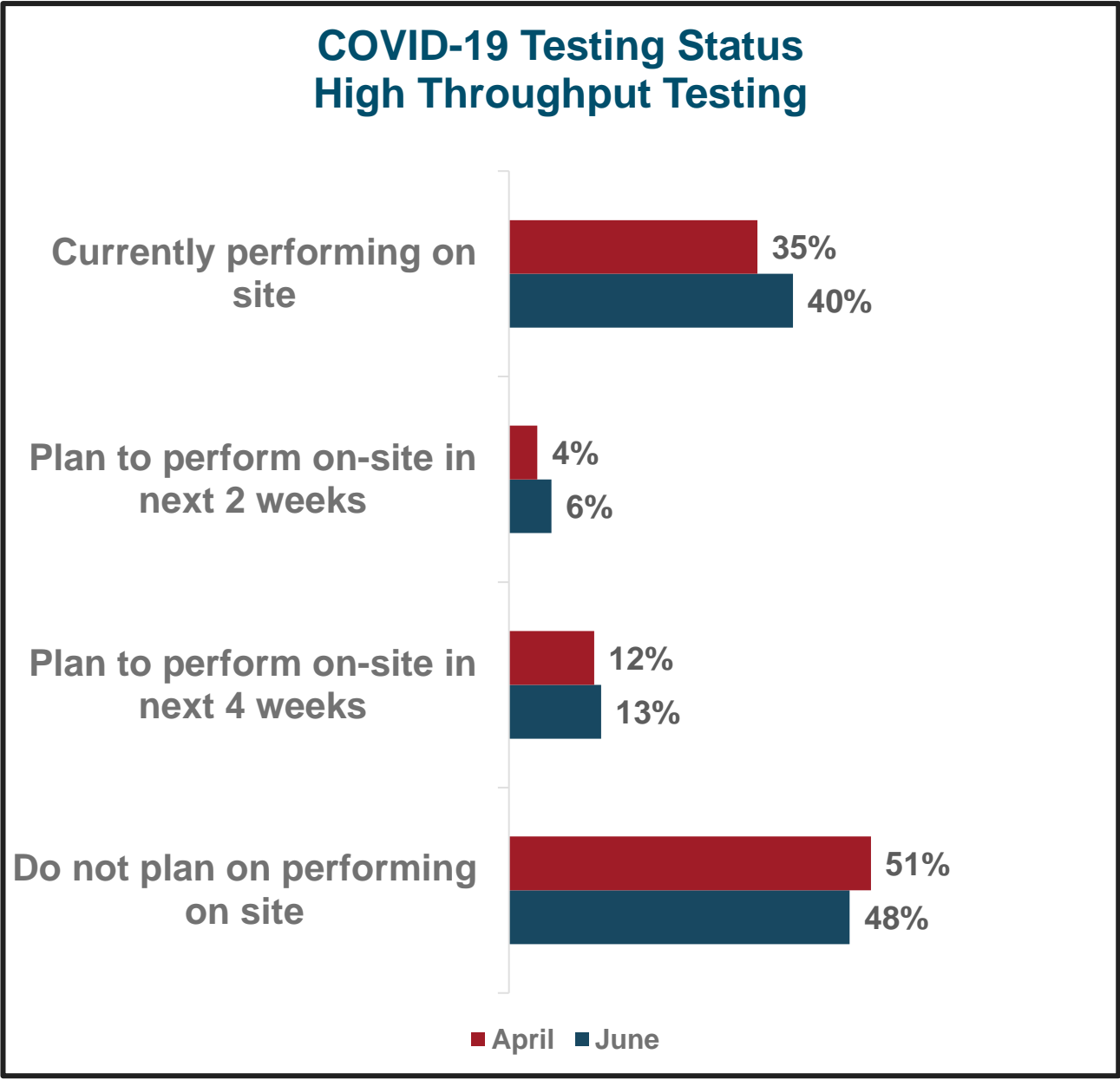
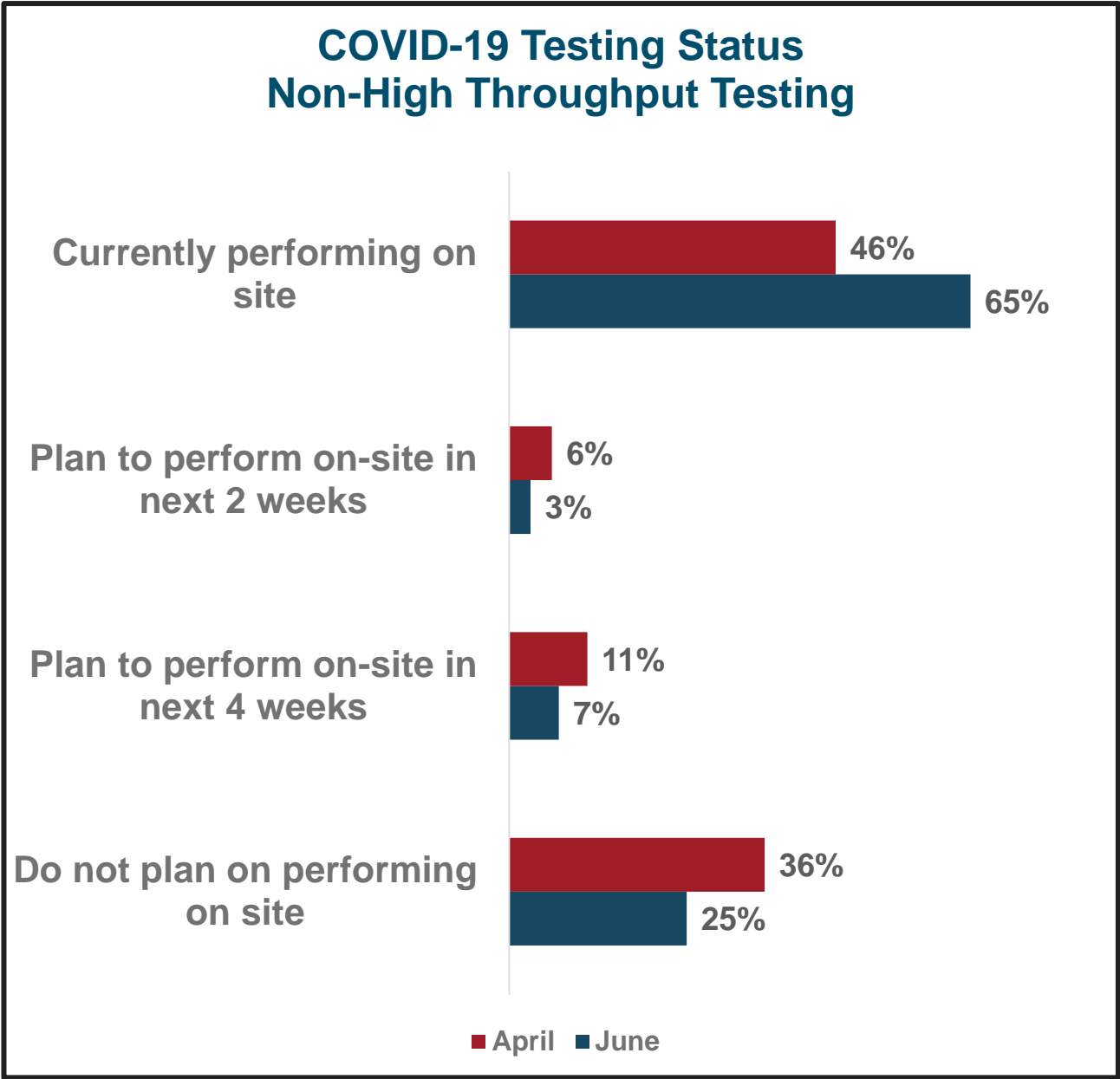
- Responding CAP-accredited laboratories providing on-site COVID-19 testing increased from 59% at end of April to 76% in early June.
- Most laboratories have more than one testing platform
  - >25% have more than two platforms.
- Most laboratory directors report:
  - Substantial excess capacity for providing COVID-19 testing.
  - Substantial instrument testing capacity.

# Impediments Reported by Laboratory Directors

- Substantial barriers to getting the equipment needed for testing:
  - Test kits
  - Swabs
  - Testing media
- Volume decreases compared to 2019
  - Conditions are improving



# CAP-Accredited Laboratory Testing, By Type

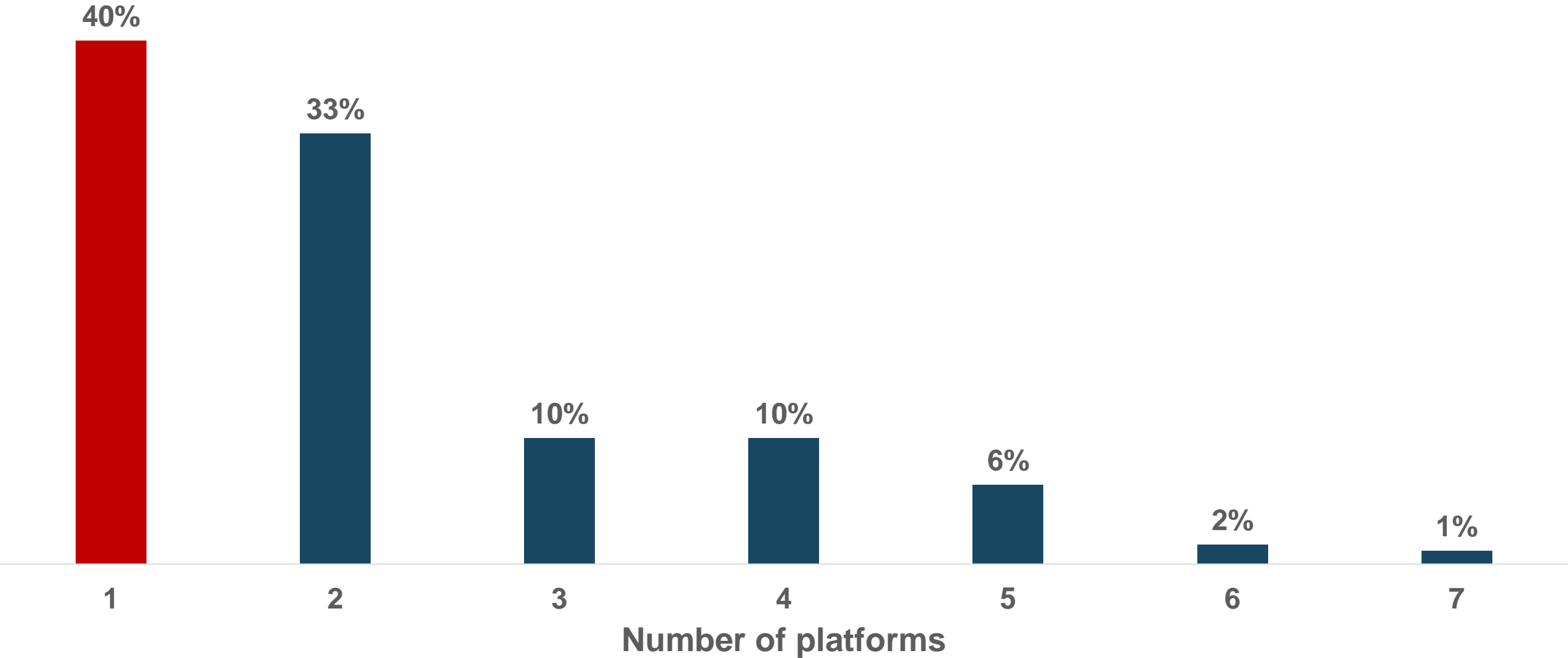


Q Which of the following best describes your laboratory's COVID-19 testing status?

April n = 434  
June n = 306

# 60% have More Than One Testing Platform

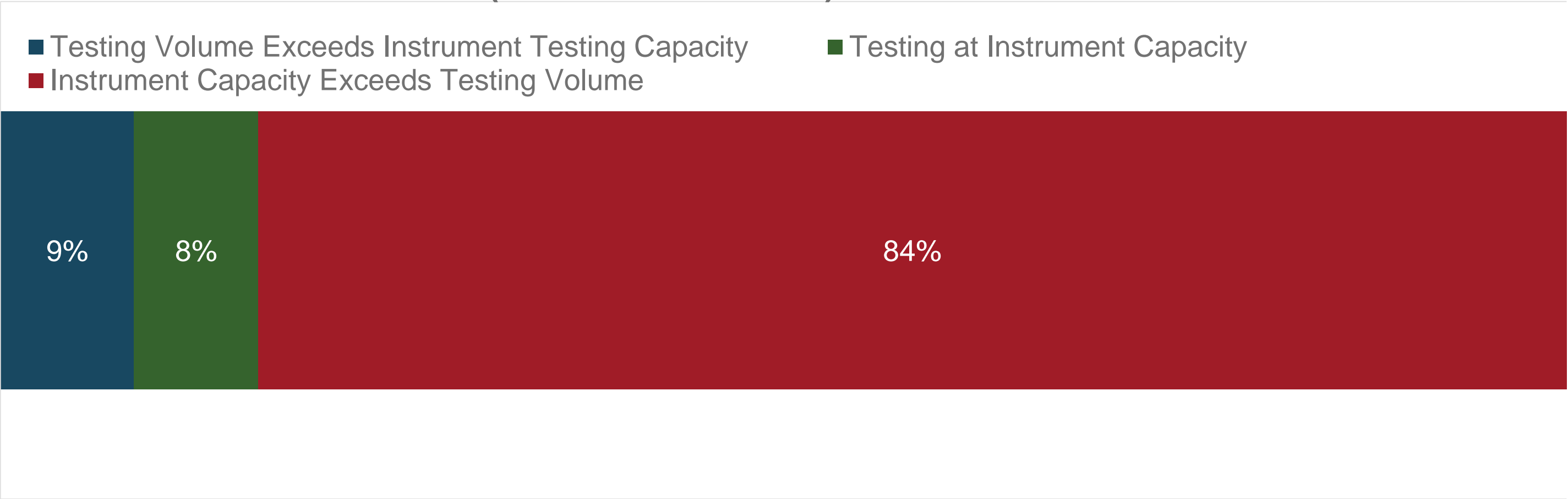
Total Number of Unique Platforms  
(Non-high and High Throughput Testing)



Q On how many unique platforms does your laboratory perform COVID-19 molecular testing? Note If your laboratory has 3 instruments, 2 are the same manufacturer/model, 1 is different, the number you would enter is "2": 2 unique platforms.

# 84% Report Excess Instrument Capacity for Additional Testing

COVID-19  
ACTUAL TEST VOLUME VS INSTRUMENT TESTING CAPACITY  
(JUNE DATA ONLY) N=164





# Total Testing Volume seems to be Recovering, but still Below 2019 Levels

- 75% of respondents reported that YTD non-COVID CP testing volume decreased between 2019 and 2020
- 90% reported that YTD AP testing volume decreased between 2019 and 2020
  - But the changes were lower than those reported in the earlier laboratory director surveys

## Estimated change in year-to-date (YTD) testing volume, 2020 vs. 2019

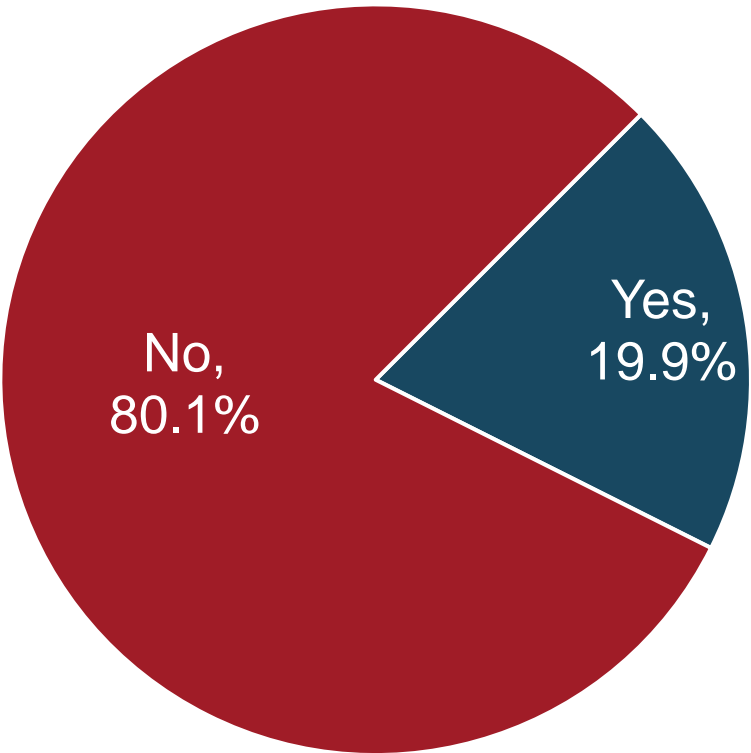
	Mean	Median	June Laboratory Director Survey*		April Laboratory Director Survey*	
			Mean	Median	Mean	Median
<b>Non-COVID CP Testing (n=431)</b>	<b>-15.9%</b>	<b>-19.0%</b>	-34%	-38%	-41%	-46%
<b>AP Testing (n=618)</b>	<b>-24.5%</b>	<b>-24.0%</b>	-48%	-50%	-64%	-69%

\*Note: The June and April Laboratory Director Surveys asked respondents to compare volume from the same month in 2019

Q10. Using your best estimate, how has the volume of non-COVID-19 clinical pathology and anatomic pathology testing changed between calendar year-to-date 2020 and the same period in 2019 for your laboratory? If there has been no change, please select "0"

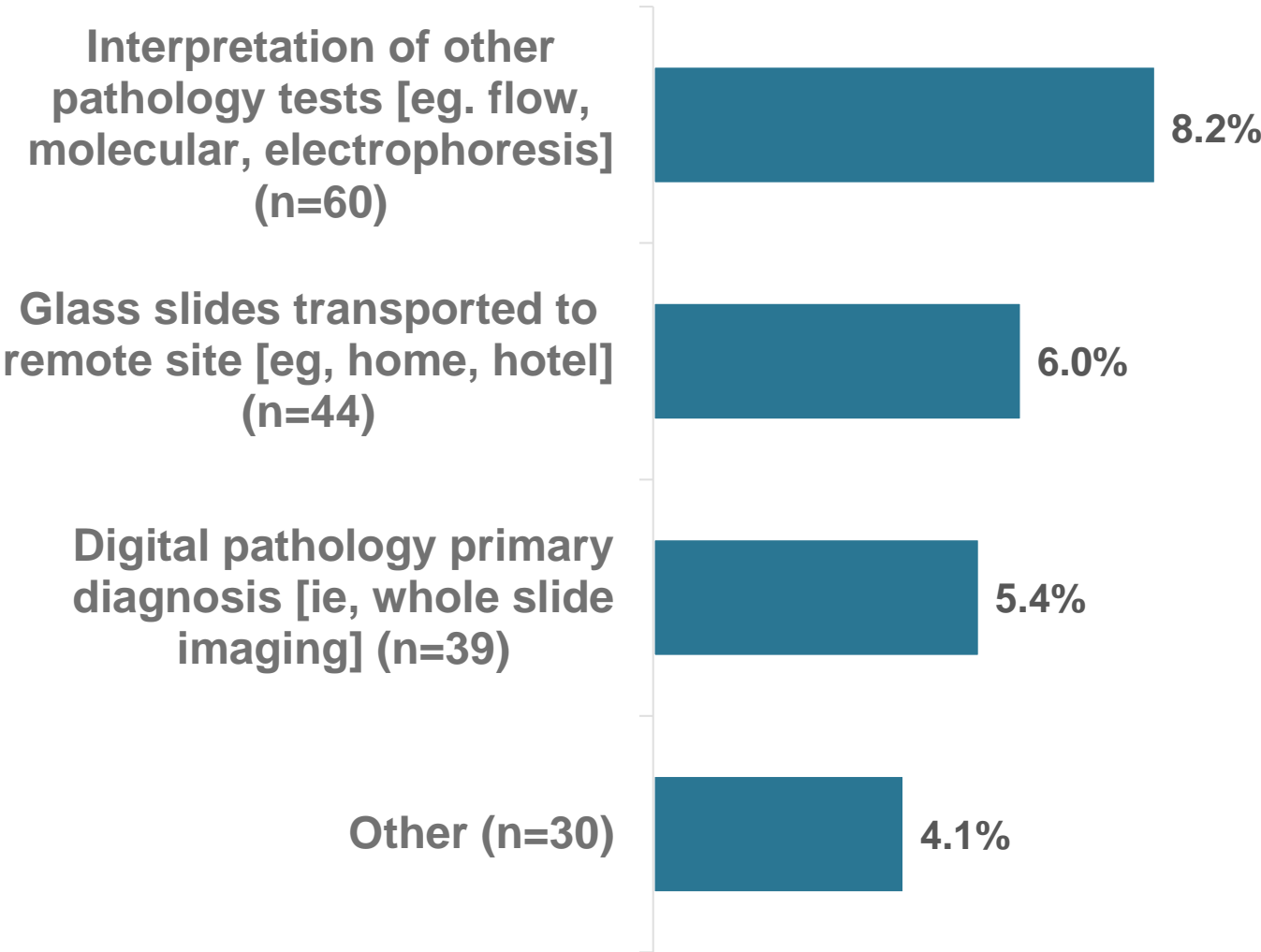
# Nearly 20% Performing Remote Sign-out since the Start of the Pandemic; Few Used Digital Pathology

Q22: Have you begun performing any form of remote sign-out since the start of the COVID Pandemic? (n=728)

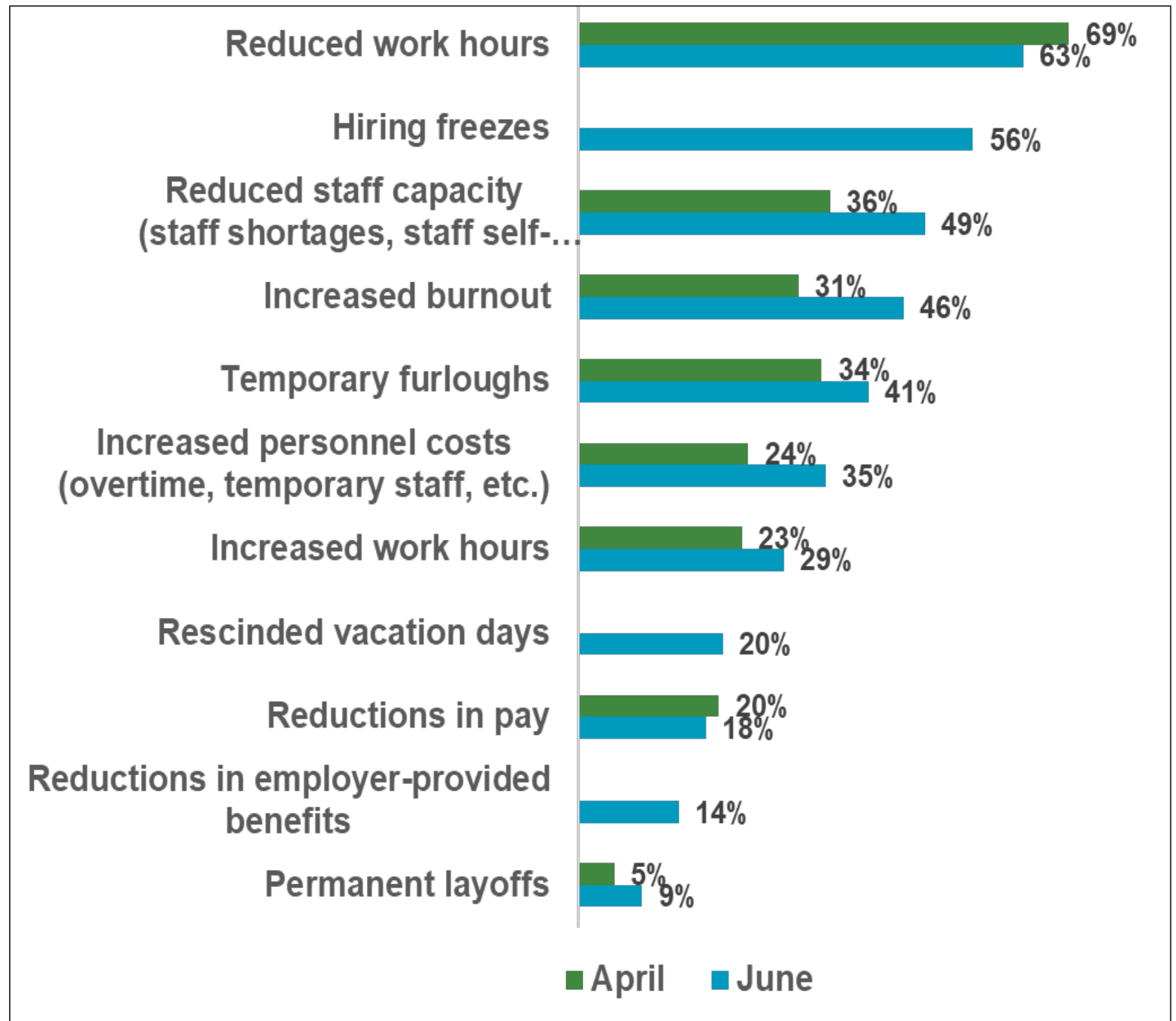


■ Yes ■ No

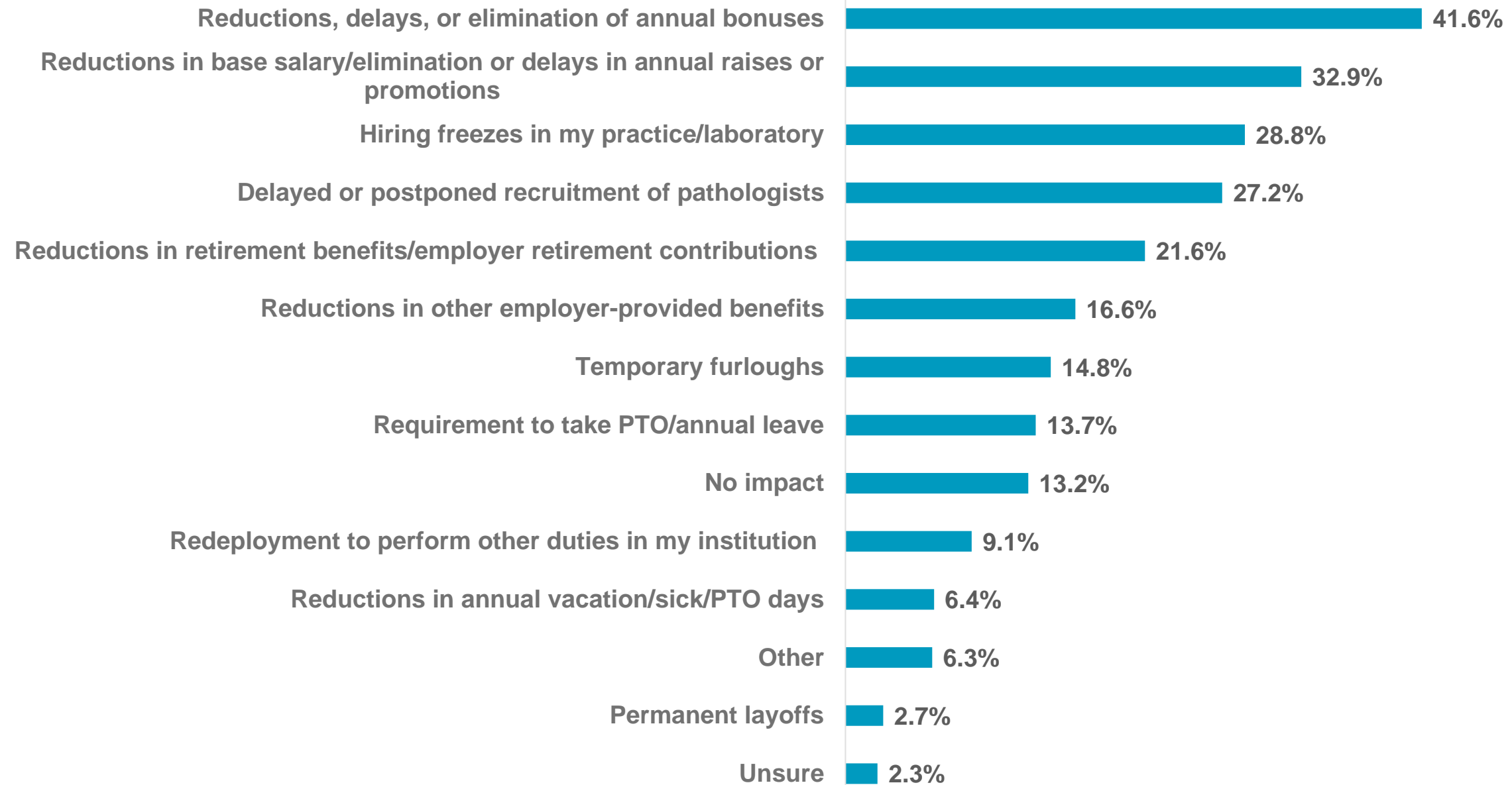
Q23: Which of the following have you used for remote sign-out? (select all that apply)  
Responses shown as a % of all respondents to Q22



# Substantial Stressors on the Laboratory Workforce caused by Pandemic



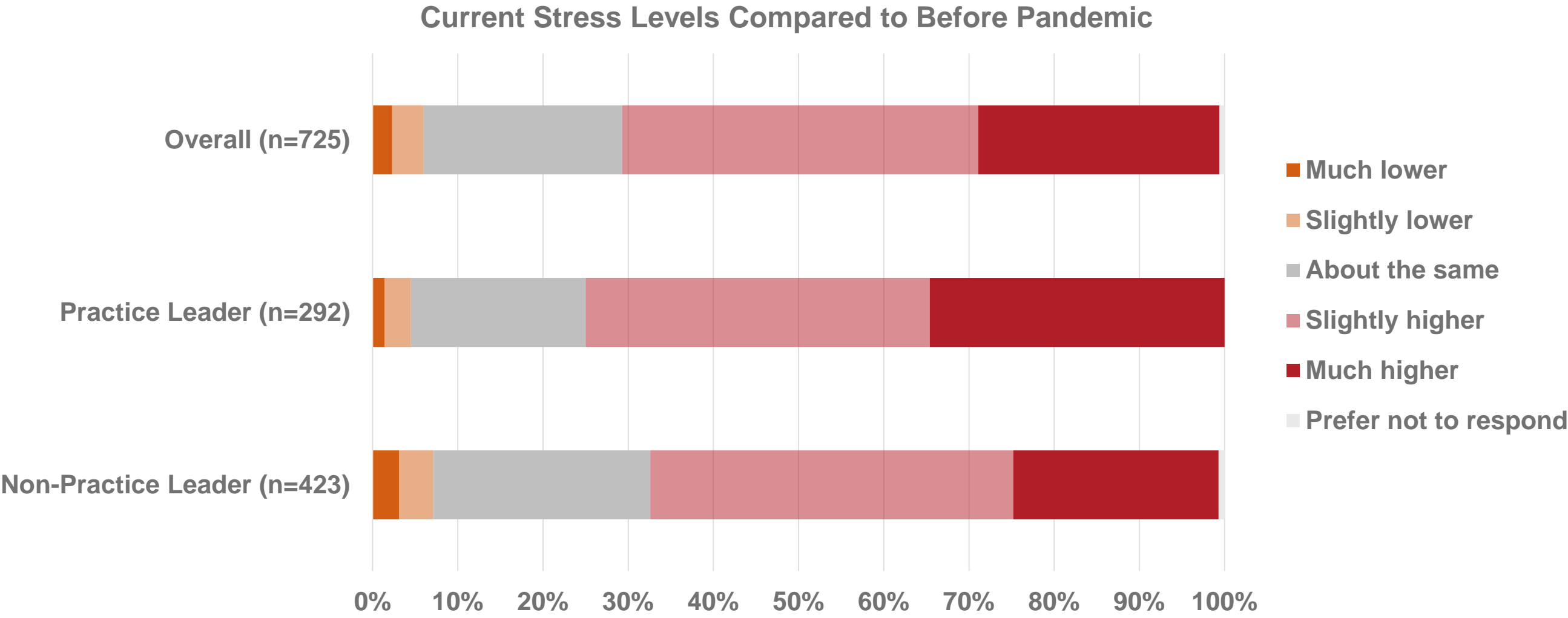
# Nearly 85% Report an Adverse Economic Impact from the Pandemic



n=735

Q9 - How has the COVID pandemic impacted pathologists in your pathology group/practice? (select all that apply)

# Stress: About 70% Report Higher Stress Levels after COVID-19



Q26: How would you rate your current level of work-related stress relative to what it was prior to the COVID pandemic? Symptoms of stress can include having less energy, increased anxiety, overactive emotions, or increased hyperactivity.

\*Note that Leader + Non-Leader  $\neq$  Overall. Some responses included in the Overall count could not be categorized by Leader/Non-Leader status.



# **Maintaining Testing Compliance and Excellence during Times of Crisis**

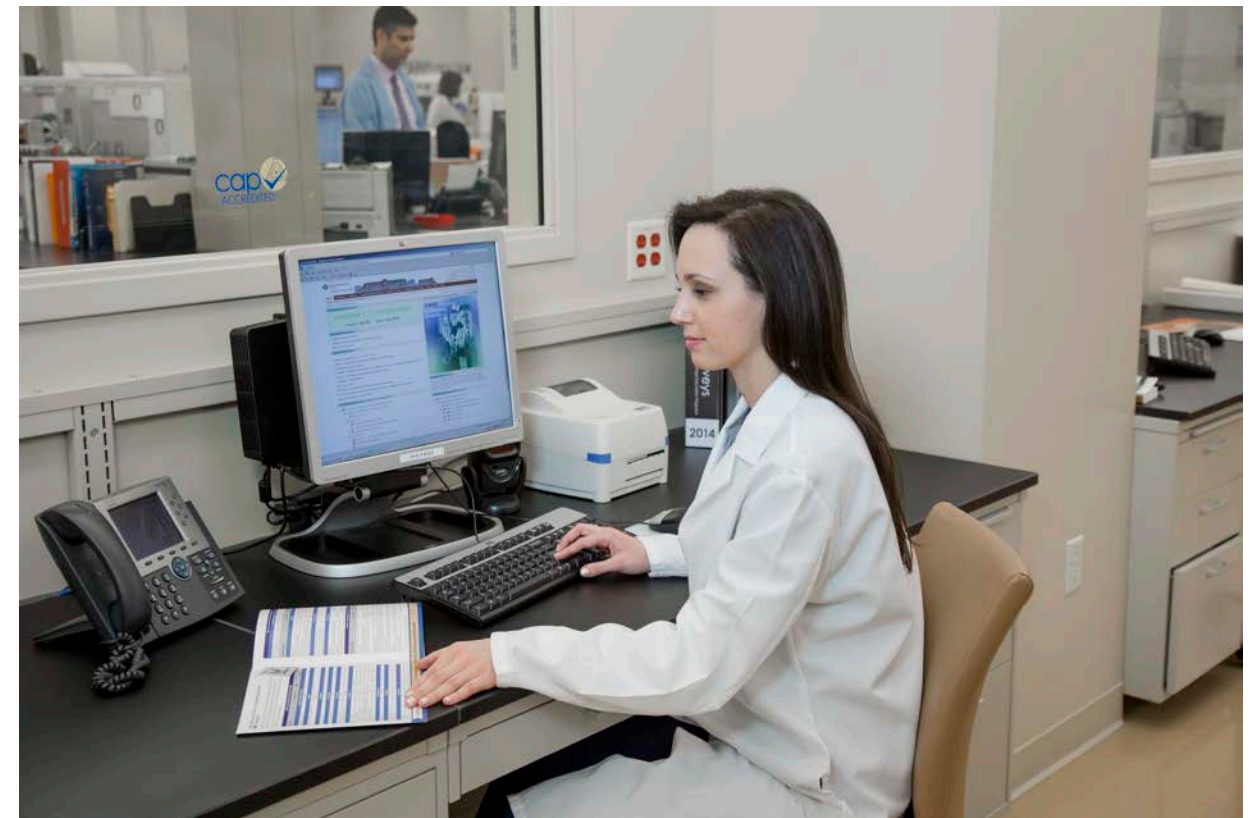
# Things to Consider

- Don't Forget – you have to run the rest of the laboratory too
- COVID Testing
  - Operations
  - Test Systems
- Staffing
- Performance Tracking
- Safety
- Pre-Analytic



# Additional Considerations

- Supply Chain
- Contracts
- Information Systems
- Strategic Planning
- Disaster Planning  
(if all else fails)



# Director-Specific Tasks and Ideas to Address

- Develop laboratory-specific incident management team
  - No need to do this alone
  - Define areas of responsibility and fully delegate
- Identify risks and assets and develop visibility into response
  - What are the biggest risks?
  - How are you monitoring them?
  - Is it getting better or worse?
- Review key indicators with the team every day
  - Develop fully transparent and clear communication channels.

# Celebrate Your Team!





# Educational COVID-19 Resources

## cap.org Website

- Newly posted COVID-related information
- Extensive Question & Answer section
  - Best Practices for Using Biological Safety Cabinets While Testing for COVID-19
  - Which COVID-19 diagnostic tests are available?
- Topic Center with material organized by specialty

## Webinars

- Latest technical and process insight from members around the world
- Topics included:
  - Post COVID-COVID – Will We Be Better Prepared for Round Two?
  - Validating Laboratory Testing During a Novel Pandemic

## Podcasts

- Members from world-renown institutions sharing their knowledge
- Podcasts included
  - “Using Proficiency Testing to Ensure Accurate SARS-CoV-2 Testing” by Dr. Pritt, Mayo Clinic
  - “Convalescent Plasma: Identifying the Laboratory’s Role in this Potential COVID-19 Treatment” by Dr. Ramsey, Northwestern Memorial Hospital

# CAP Accreditation Rigor – Benefits in a Pandemic

- Provides consistent procedural guidance with rigorous competency assessment requirements
- Checklist requirements updated to address COVID-19
  - Most significant changes to
    - Quality management
    - Infection prevention and control
    - Transfusion medicine
  - Enhancements to the bloodborne pathogen section
- Running PT/EQA provides benchmarking opportunities
  - Large peer groups
  - Educational opportunities for the laboratorians

# Summary

- The CAP serves as an **International Resource** to Pathologists and Laboratories
- Laboratories have responded to the COVID-19 pandemic by providing essential testing by maintaining accreditation and an intact workforce
- Communication and Education are vital to our role as Stewards of the Laboratory

**Thank you for joining our webinar.**  
**Please contact us with any questions.**



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# APPENDIX



# Supporting Accreditation during the Pandemic

# Current Status of Inspections During Pandemic

- CAP instituted a hold on all inspections in mid-March 2020
- COVID-related travel restrictions prevent US inspectors from entering many countries
- CAP began piloting virtual inspections in July
- Safe and effective mechanism to conduct inspections
  - US-based inspectors complete the inspection regardless of travel restrictions
  - Ensures laboratories are maintaining continuous compliance with accreditation requirements

# What is a Virtual Inspection?

- Very similar to on-site inspections
  - Move from in-person dialogue to video conferencing platforms
- All the components of an inspection will remain, but done remotely
  - Opening conference
  - Review of documents and records
  - Observation of technical processes and interviews in each department
  - Summation conference
- Currently accredited laboratories remain accredited

