CAP Town Hall: COVID-19 Impacts on Accredited Laboratories

Overview of results for State Pathology Society Presidents
GoToWebinar Interface
Welcome

• Opening Remarks
  o CAP President Patrick Godbey, MD, FCAP

• Survey Results
  o Policy Roundtable Chair Thomas Wheeler, MD, FCAP

• Questions and Answers
  o President-elect Emily Volk, MD, FCAP
  o Council on Government and Professional Affairs Chair Jonathan Myles, MD, FCAP
  o Council on Scientific Affairs Chair Raouf Nakhleh, MD, FCAP
  o Council on Accreditation Chair Richard Scanlan, MD, FCAP
COVID-19 Impact Study

• The CAP’s survey for directors of CAP-accredited laboratories provides us with important data on the challenges of the COVID-19 pandemic.
• We will use this survey data to lobby for the resources your laboratories need.
• The CAP is fighting, and will keep fighting, for you during this challenging time!

Patrick Godbey, MD, FCAP
CAP President
Key CAP Advocacy and Policy Activities

- Advocate for Financial Assistance for Pathologists During the Pandemic
- Secure Regulatory Flexibility for Pathologists and Laboratories
- Influence Congress as it Acts on Providing Coverage, Payment, and Assistance to Physicians and Hospitals
- Collaborate with State Pathology Societies
State Emergency Actions

- Almost all states have received Section 1135 federal waivers allowing program flexibility in the administration of Medicare, Medicaid, and CHIP.
- Emergency declarations allow for interstate physicians and other professionals to practice.
- FDA has empowered states to determine whether a laboratory-developed test for COVID-19 administered at a high-complexity lab would meet emergency use authorization (EUA) criteria.
  - States may authorize testing without prior FDA approval for the duration of the emergency.
  - At present only CT, MD, MS, NV, NJ, NY, and WA are FDA approved for this purpose.
Survey Objective, Methodology & Response Rate

• **Objective**
  o To determine how the COVID-19 pandemic is impacting CAP accredited laboratories in the United States so CAP can better inform leaders, elected officials, and government regulators of the challenges laboratories are facing.
  o To identify what laboratories need as they strive to deliver quality testing for the patient populations they serve.

• **Methodology**
  o Target Audience: CAP Accredited Laboratories in the US
  o Respondent Profile: Laboratory Directors in the US

• **Response Rate**
  o 11.5% response rate (434 unique responses)
COVID-19 Testing by Respondent Laboratory Directors
COVID-19 Testing by CAP-Accredited Laboratories

• 59% of responding CAP-accredited laboratories currently provide on-site COVID-19 testing, and another 9% of laboratories expect to provide testing with the next 2-4 weeks

• Since March 1, the number of responding laboratories offering COVID-19 testing has increased substantially

• Most laboratory directors that report that they have substantial excess capacity for providing COVID-19 testing

• Respondents expect their COVID-19 testing to increase by about 40% over the next two weeks
59% of Responding Laboratories Provide COVID-19 Testing—and 9% More are Working to Get Online Soon

Q Which of the following best describes your laboratory’s COVID-19 testing status? (n = 434)

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Percent of Responding Laboratories Offering COVID-19 Testing, by Week

- 1st COVID-19 Case Reported in the US. (Jan 20th)
- FDA Issues Policy and EUA for COVID-19 Testing (Feb 29th)

% of Laboratories Testing vs. # of weeks since survey began

0% to 0.7% range:
- 0.2% (15 Weeks)
- 0.5% (14 Weeks)
- 2.1% (13 Weeks)
- 3.8% (12 Weeks)
- 9.7% (11 Weeks)
- 14.4% (10 Weeks)
- 24.8% (9 Weeks)
- 36.1% (8 Weeks)
- 57.8% (7 Weeks)
- 59.0% (6 Weeks)

# of weeks since survey began:
- 0 Weeks (4/23)
- 1 Week (4/16)
- 2 Weeks (4/9)
- 3 Weeks (4/13)
- 4 Weeks (3/26)
- 5 Weeks (3/19)
- 6 Weeks (3/12)
- 7 Weeks (3/5)
- 8 Weeks (2/27)
- 9 Weeks (2/20)
- 10 Weeks (2/13)
- 11 Week (2/6)
- 12 Weeks (1/30)
- 13 Weeks (1/23)
- 14 Weeks (1/16)
- 15 Weeks (1/9)
79% Of Responding Laboratories Report Having Excess Capacity For COVID-19

- Current median daily test volume: 50
- Current average daily test volume: 211
- Median daily excess capacity: 78
- Average daily excess capacity: 302
Median Excess Capacity for Providing COVID-19 Testing, by Number of Tests Currently Provided per Day

Q Using your best estimate…

a) What was the average daily COVID-19 test volume for the past 7 days?
b) What is your daily COVID-19 testing capacity? (ie, number of COVID-19 tests your laboratory is ABLE to test daily)
Respondents Expect Their Testing to Increase by About 40% in Two Weeks

Average Expected Increase in Testing Capacity in Next Two Weeks

- **OVERALL**: 40%
- **50 or less**: 40%
- **51 - 100**: 30%
- **101 - 300**: 50%
- **301 - 1000**: 60%
- **> 1000**: 30%

(Overall n = 216)
Impediments Reported By Responding Laboratory Directors
Impediments Reported by Laboratory Directors

• Laboratory directors are reporting substantial barriers to getting the equipment needed for testing, particularly test kits, swabs, and transport media.

• Laboratory workforces are facing substantial stresses, regardless of whether the laboratory is providing COVID-19 testing.

• Nearly all laboratories are reporting substantial losses in revenues and financial stress, but few have applied for federal assistance programs.
## Items Most Frequently Cited as Most Difficult to Acquire for Performing Testing

<table>
<thead>
<tr>
<th>Item</th>
<th>% citing as “difficult” or “very difficult”</th>
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</thead>
<tbody>
<tr>
<td>Test kits for your instrument platform</td>
<td>69%</td>
</tr>
<tr>
<td>Flocked nasopharyngeal swab to collect and transport patient samples</td>
<td>66%</td>
</tr>
<tr>
<td>Viral transport media/universal transport media (VTM/UTM)</td>
<td>62%</td>
</tr>
</tbody>
</table>
Stresses Affecting the Laboratory Workforce

• The COVID-19 pandemic is affecting pathologists and other laboratory professionals, regardless of whether the laboratory is providing COVID-19 testing.

• The top issues reported by laboratory directors among pathologists are reduced work hours (72%), reductions in pay (41%), increased burnout (21%), and increased work hours (20%).

• The top issues among non-pathologist laboratory professionals are reduced work hours (69%), reduced staff capacity (36%), temporary furloughs (34%), and increased burnout (31%).
Financial Stresses On Laboratories

- Respondents report a median drop of 69% in AP testing and 46% in CP testing, regardless of whether they are doing COVID-19 testing.
- Average and median laboratory revenue have decreased by about 50% among all respondents, regardless of whether they provide COVID-19 testing.
- This adds substantial financial stresses to the laboratory. For those laboratories performing COVID-19 testing, it adds workload stresses to some pathologists and professional staff.
- While there are federal assistance programs that could help laboratories, only slightly more than half of laboratory directors were aware of these and relatively few sought assistance or received benefits from these programs.
Summary, and Questions and Answers
Survey Recap

• Nearly 60% of respondents are currently providing COVID-19 testing.
• Many laboratories are reporting substantial excess capacity and are expecting to ramp up testing by about 40% in the next 2-4 weeks.
• Nevertheless, these laboratories are reporting difficulties in acquiring the supplies they need to test for COVID-19.
• There’s no question that pathologists and laboratory professionals are under substantial amounts of pressure.

Patrick Godbey, MD, FCAP
CAP President
CAP Officers

Patrick Godbey, MD, FCAP
CAP President

Emily Volk, MD, FCAP
CAP President-Elect
Council Chairs

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Affairs

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Questions and Answers

• Please type your questions in the ‘Question’ pane
Conclusion

• Thank you to all participants!
• For any questions we could not get to today, we will follow-up with you by email.
• For more information on COVID-19-related guidance and updates, please go to cap.org