Robust Response of the Clinical Laboratory to the COVID-19 Pandemic Despite Significant Challenges

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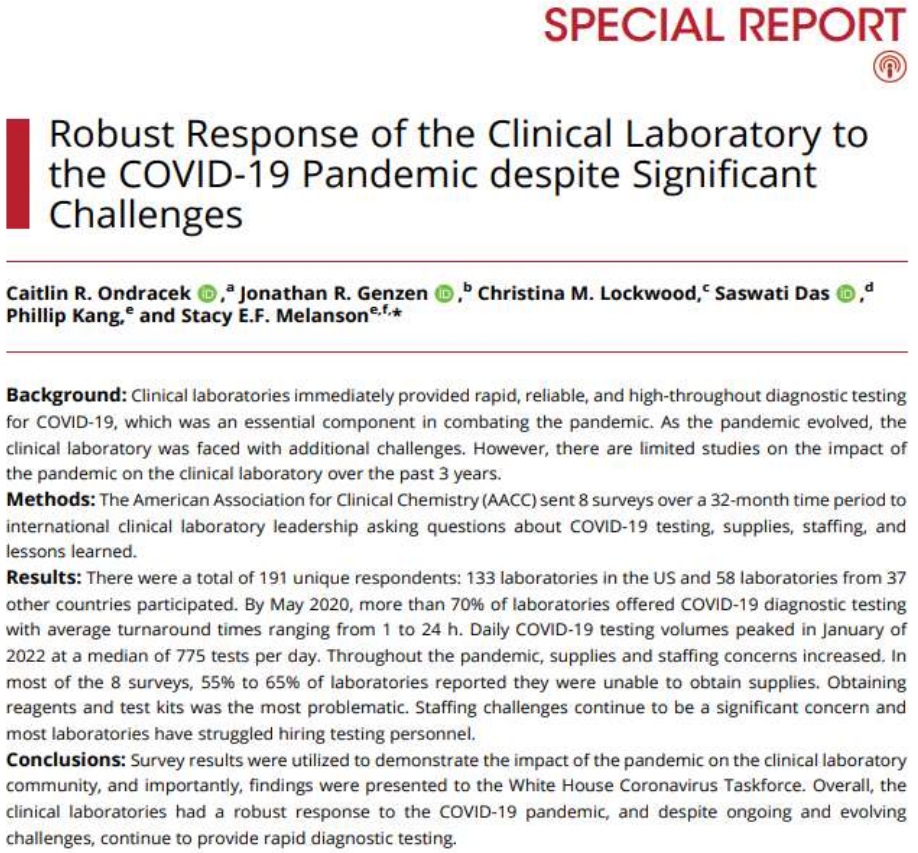
8th Edition CAHOCON 2024

6TH & 7TH APRIL 2024

Introduction

- Clinical laboratories played a crucial role in combating the pandemic by providing rapid and reliable diagnostic testing
- Limited studies exist on the pandemic's impact on clinical laboratories over the past 3 years
- **Objective**: Determine global impact, increase transparency, and advocate for clinical laboratories.



SPECIAL REPORT

Robust Response of the Clinical Laboratory to the COVID-19 Pandemic despite Significant Challenges

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Background: Clinical laboratories immediately provided rapid, reliable, and high-throughout diagnostic testing for COVID-19, which was an essential component in combating the pandemic. As the pandemic evolved, the clinical laboratory was faced with additional challenges. However, there are limited studies on the impact of the pandemic on the clinical laboratory over the past 3 years.

Methods: The American Association for Clinical Chemistry (AACC) sent 8 surveys over a 32-month time period to international clinical laboratory leadership asking questions about COVID-19 testing, supplies, staffing, and lessons learned.

Results: There were a total of 191 unique respondents: 133 laboratories in the US and 58 laboratories from 37 other countries participated. By May 2020, more than 70% of laboratories offered COVID-19 diagnostic testing with average turnaround times ranging from 1 to 24 h. Daily COVID-19 testing volumes peaked in January of 2022 at a median of 775 tests per day. Throughout the pandemic, supplies and staffing concerns increased. In most of the 8 surveys, 55% to 65% of laboratories reported they were unable to obtain supplies. Obtaining reagents and test kits was the most problematic. Staffing challenges continue to be a significant concern and most laboratories have struggled hiring testing personnel.

Conclusions: Survey results were utilized to demonstrate the impact of the pandemic on the clinical laboratory community, and importantly, findings were presented to the White House Coronavirus Taskforce. Overall, the clinical laboratories had a robust response to the COVID-19 pandemic, and despite ongoing and evolving challenges, continue to provide rapid diagnostic testing.

Methodology

- AACC/ADLM designed surveys to be sent to lab professionals with relevant titles and laboratories listed in the AACC/ADLM COVID-19 Testing Directory
- Survey Timeline: May 2020 to December 2022
- Participants: Initially 221 laboratory leaders, reduced to 165 from July 2020 onwards
- Survey Evolution: Started with 15 questions, expanded to 31 questions by December 2022

Survey Content and Participation

- Additional questions added periodically to assess evolving challenges during the pandemic.
- Participation: Participants not required to answer all questions.
- Data Linkage: Participants provided email addresses for survey linkage over time.
- Demographics: Initial survey collected basic demographic information including institution type and geographic location.
- Institution Types: Participants selected from a variety of institution types via a drop-down menu.
- Categorization: Selections grouped into government/public health laboratories, reference laboratories, research laboratories, independent clinical/medical laboratories, and hospital laboratories.
- Follow-Up: Participants contacted via email if demographic information couldn't be obtained initially.

Data Analysis

- **Data Collection**: Survey data downloaded from SurveyMonkey
- **Analysis Tool**: Microsoft Excel utilized for data analysis
- **Inclusion Criteria**: Only participants responding to more than the first 2 questions in each survey were included.
- **Outlier Exclusion**: Outliers removed using a cutoff of Q3 + (1.5 * IQR), where Q3 is quartile 3 and IQR is the interquartile range.
- Denominators for percentage calculations were those that responded to the specific question in the survey.

Results

- **Survey Response & Demographics**
- 191 unique respondents with varying response rates (26.1% to 59.4%).
- Average response to 2.5 ± 1.6 surveys and 15.2 ± 3.7 questions.
- Participants from 133 laboratories across 40 US states and 37 countries.

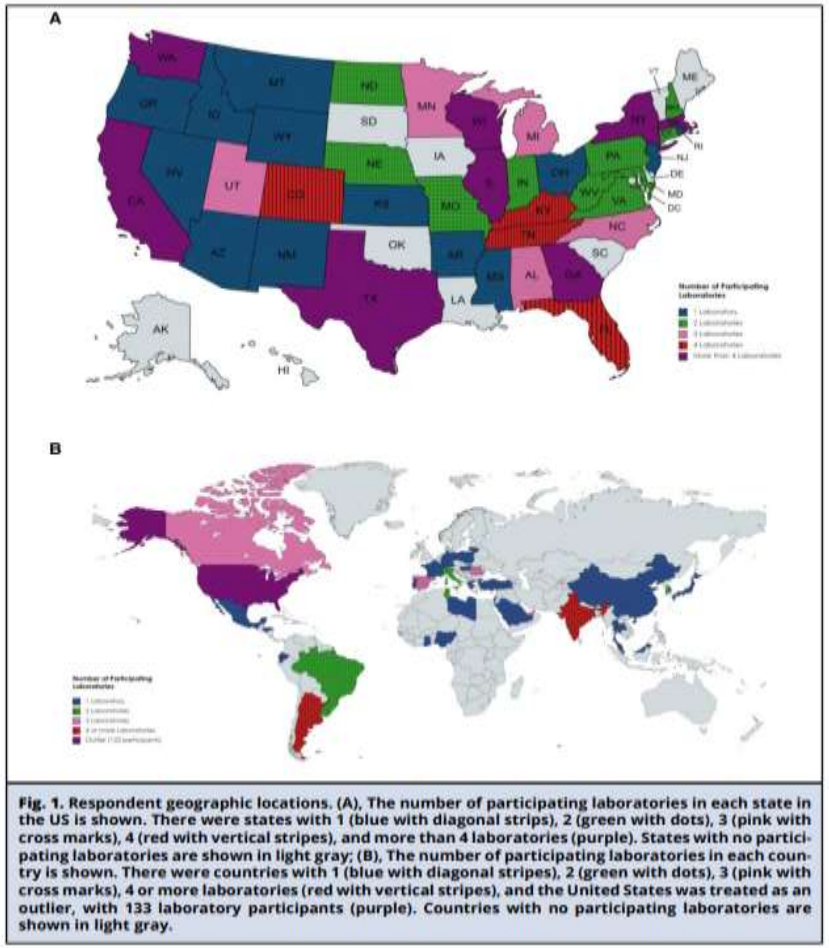

Fig. 1. Respondent geographic locations. (A), The number of participating laboratories in each state in the US is shown. There were states with 1 (blue with diagonal strips), 2 (green with dots), 3 (pink with cross marks), 4 (red with vertical stripes), and more than 4 laboratories (purple). States with no participating laboratories are shown in light gray; (B), The number of participating laboratories in each country is shown. There were countries with 1 (blue with diagonal stripes), 2 (green with dots), 3 (pink with cross marks), 4 or more laboratories (red with vertical stripes), and the United States was treated as an outlier, with 133 laboratory participants (purple). Countries with no participating laboratories are shown in light gray.

Results

- **COVID 19 Diagnostic Test**
- Over 70% of laboratories offered COVID-19 diagnostic testing in May 2020
- Increased steadily to 100% in January 2022 and slightly dropped to 98% in December 2022
- Median daily test volume rose from 100 per day in May 2020 to 775 per day in January 2022
- Most laboratories (82.3%) sent results to state agencies
- Use of FDA EUA test kits remained steady around 79.7%
- Turnaround time (TAT) ranged mostly from 1 to 24 hours

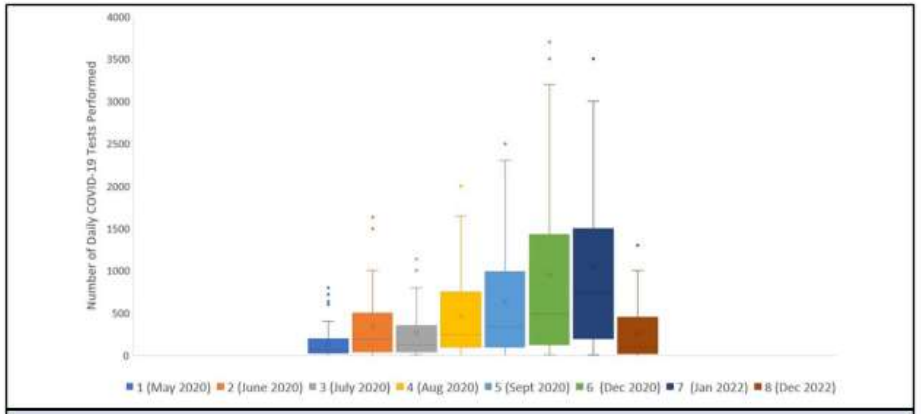

Fig. 2. Number of COVID-19 tests processed daily by laboratory. The median, 25th percentile, 75th percentile, minimum and maximum number of COVID-19 tests processed daily for each survey is shown. Surveys 1 through 8 are medium blue (1), orange (2), gray (3), yellow (4), light blue (5), green (6), dark blue (7), and brown (8), respectively.

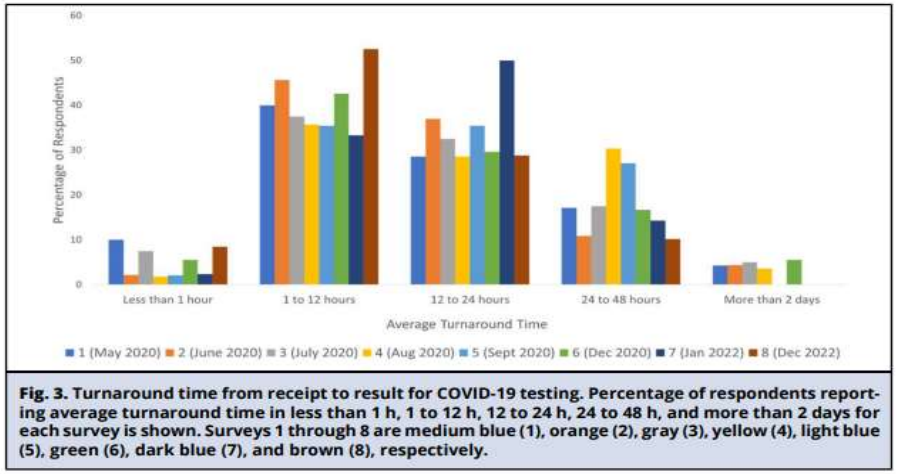

Fig. 3. Turnaround time from receipt to result for COVID-19 testing. Percentage of respondents reporting average turnaround time in less than 1 h, 1 to 12 h, 12 to 24 h, 24 to 48 h, and more than 2 days for each survey is shown. Surveys 1 through 8 are medium blue (1), orange (2), gray (3), yellow (4), light blue (5), green (6), dark blue (7), and brown (8), respectively.

Results

- **Serology Testing**
- Daily serology testing volumes remained low compared to molecular testing.
- Types of serology testing varied, including total antibody, IgG only, IgG and IgM, and IgG and IgA.
- Challenges with orthogonal testing and supply shortages were reported.

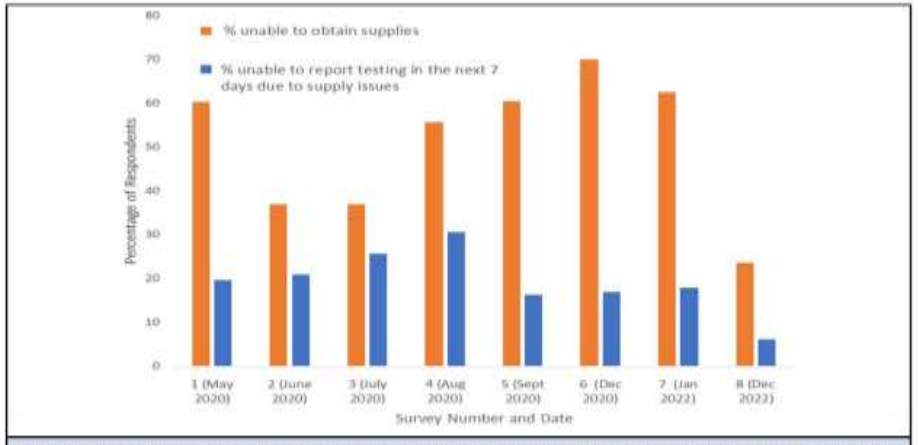

Fig. 4. COVID-19 testing supply challenges. The percentage of respondents answering "yes" to "unable to obtain supplies" (orange bars) and "unable to report testing in the next 7 days due to supply issues" (blue bars) for each survey is shown.

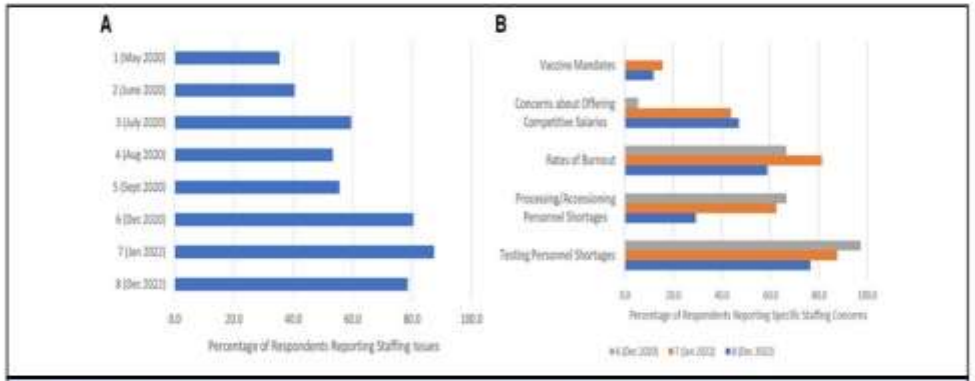

Fig. 6. Staffing issues and concerns. (A), The percentage of respondents reporting staffing issues (medium blue bars) in each survey is shown; (B), The percentage of respondents with vaccine mandate concerns, concerns about offering competitive salaries, high rates of burnout, processing/accessioning personnel shortages, and testing personnel shortages in the December 2020 (gray bars), January 2022 (orange bars), and December 2022 (blue bars) surveys.

Results: Supply & Staffing Shortages

- Laboratories faced challenges in obtaining supplies and experienced staffing shortages
- Staffing issues rose steadily from 35.4% in May 2020 to 87.5% in January 2022
- Burnout rates peaked at 81.3% in January 2022. Concerns about competitive salaries and vaccine mandates increased over time

Type of Supply	1 (May 2020)	2 (June 2020)	3 (July 2020)	4 (Aug 2020)	5 (Sept 2020)	6 (Dec 2020)	7 (Jan 2022)	8 (Dec 2022)
Reagents	55.0	46.2	55.6	73.0	59.4	55.3	73.1	62.5
Test kits	56.7	57.7	55.6	64.9	53.1	57.9	46.2	31.3
Transfer media	28.3	30.8	33.3	27.0	25.0	10.5	7.7	0.0
Swabs	55.0	42.3	50.0	32.4	34.4	15.8	11.5	12.5
Personal protective equipment	38.3	23.1	22.2	24.3	21.9	10.5	15.4	0.0
Pipette tips			16.7	24.3	31.3	18.4	30.8	12.5
Extraction plates			0.0	21.6	28.1	36.8	3.8	0.0

Fig. 5. Heatmap of type of issues for COVID-19 testing. Percentage of respondents with shortage of each type of supply by survey is shown. Percentages are shown in different colors: <15.0% (dark green), 15.1% to 30.0% (light green), 30.1% to 45.0% (yellow), 45.1% to 60.0% (orange), and >60% (red). Results for positive or negative controls, point-of-care testing supplies, automated liquid handlers consumables, and "other" are not shown, as all percentages were <15.0%.

Limitations

- **Subjective Responses**: Survey responses relied on the knowledge and experience of 191 laboratory directors, potentially introducing subjectivity.
- **Approximations**: Volume and Turnaround Time (TAT) data were approximations, affecting the precision of findings.
- **Geographic Distribution**: Responses covered a wide geographic distribution but may not be fully generalizable, especially outside the US.
- **Incomplete Responses**: Not all respondents answered all surveys, potentially impacting data comprehensiveness.

Conclusions

- **Future Testing Trends**: Shifts to home and antigen testing suggest evolving testing protocols
- **Challenges**: Difficulties in obtaining reagents and testing kits due to increased demand and supply chain issues
- **Lessons Learned:** Importance of rapid decision-making, high-throughput assays, and prioritizing staff well-being during pandemics.
- **Recommendations**: Emphasize partnerships with industry, standardized education, and sustaining a pipeline of laboratory scientists.
- **Enhancing Visibility**: Increase visibility of laboratory services to address staffing shortages and maintain supply chain continuity in future healthcare crises.