



PAMA Impact Survey

Survey Insights

March 6, 2023

An AMP report, created with support from



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Project Context and Process

Respondent Demographics

Survey Output

Demographic Subanalysis

AMP sought support in understanding the impact of PAMA on laboratory testing through a quantitative survey deployed to its membership

Project Context

- In 2014, Congress passed the Protecting Access to Medicare Act (PAMA), which led to significant changes to the mechanism by which Medicare assigns payment rates to laboratory tests
- Under PAMA, payment rates for tests on the Clinical Laboratory Fee Schedule (CLFS) are based on the weighted average of private payer rates
- Unfortunately, because of data collection rule-making by CMS, the specific values of different tests were not accurately represented because they were drawn from only a subset of performing labs
- AMP is now seeking to better understand the impacts that PAMA has had on clinical laboratories, hospital systems, and physicians, regardless of diagnostics vendor, and the downstream effects on patient access

Project Objectives

Develop quantitative survey that collects data on laboratory demographics, testing reimbursement and cost, and perspectives on the impact of PAMA

Deploy survey to AMP membership to collect quantitative results on impact of PAMA

Assess and analyze the quantitative results of the survey to better understand PAMA impact on laboratory testing and patient accessibility

Synthesize findings that AMP may use to develop policy reform approaches and advocacy materials to share with key policy stakeholders

ClearView worked with AMP to develop a multi-step approach to a quantitative survey and analysis to answer the key questions and accomplish AMP's objectives

1 Kickoff and Project Concept Alignment

- Conduct kickoff working session with AMP PAMA Taskforce, AMP Economic Affairs Committee, and AMP Professional Relations Committee
- Align on project objectives and research approach
- Discuss content, length, and format of survey instrument, along with key research questions
- Identify relative roles and responsibilities of ClearView, AMP PAMA Taskforce, and AMP staff
- Outline scheduling of update meetings and research readouts

2 Quantitative Survey Design and Execution

- Refine initial draft of quantitative survey provided by AMP
- Include key sections into survey: laboratory demographics, reimbursement and cost data for a selection of tests, perspectives on PAMA impact on patient access and industry
- Share survey draft with AMP for review, followed by revision based on such feedback
- Pilot survey with several AMP members to collect feedback on accuracy and clarity
- Deploy survey among AMP membership, with screener to select appropriate stakeholders

3 Survey Summary and Implications Analysis

- Synthesize findings of research into comprehensive PowerPoint presentation with key findings and data
- Provide analysis comparing survey results to changes proposed to PAMA to enable AMP to better advocate for its stakeholders
- Review output with AMP PAMA Taskforce
- Share final analysis with broader team so that it may be included in advocacy materials that would be shared with key policy stakeholders

Today's focus

The prior survey version was 15 – 20 minutes long, consisting of three required and one optional section, as well as an instruction guide

Prior Quantitative Survey Design

Sections	Section Objective	Example Question	Instruction Guide
Section 1: Laboratory Demographics	<ul style="list-style-type: none"> Identify laboratory characteristics, including type, region, and size Characterize patient population 	Approx. how many patients has your molecular laboratory served in the past month?	<ul style="list-style-type: none"> Provide overview of survey context and objectives (i.e., history of PAMA) Outline survey sections to ensure that the respondents understand scope Preview the data needed for Section 4, including details on how to obtain it (e.g., billing department), and emphasize that Section 4 is optional
Section 2: Molecular Testing Menu	<ul style="list-style-type: none"> Determine size and makeup of molecular testing menu 	Select tests from the list below that your molecular laboratory conducted in Q1 2022.	
Section 3: Impact of PAMA	<ul style="list-style-type: none"> Capture perspectives of PAMA impact and the consequent pressures the laboratory faces 	To what extent does reimbursement rate play a role in your decision to offer a test?	
Section 4: Quantitative Assay Data <i>(optional)</i>	<ul style="list-style-type: none"> Quantify volume, cost, and reimbursement of molecular assays included in testing menu 	What is the median private payer reimbursement for this test?	

The updated survey has been condensed to be 10 – 15 minutes in length, with two sections that prioritize lab demographics and impact of PAMA

Updated Quantitative Survey Design

Sections	Section Objective	Example Questions
Section 1: Laboratory Demographics	<ul style="list-style-type: none">• Identify laboratory characteristics, including type, region, and size• Determine size and makeup of molecular testing menu	<p>Approx. how many patients has your molecular laboratory served in the past month?</p> <p>What type of molecular testing is included in your test menu?</p>
Section 2: Impact of PAMA	<ul style="list-style-type: none">• Capture perspectives of PAMA impact and the consequent pressures the laboratory faces• Understand the role of reimbursement in laboratory decision-making	<p>How would you describe your lab's experience reporting data on a scale of 1 to 5?</p> <p>To what extent does reimbursement rate play a role in your decision to offer a test?</p>

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Project Context and Process

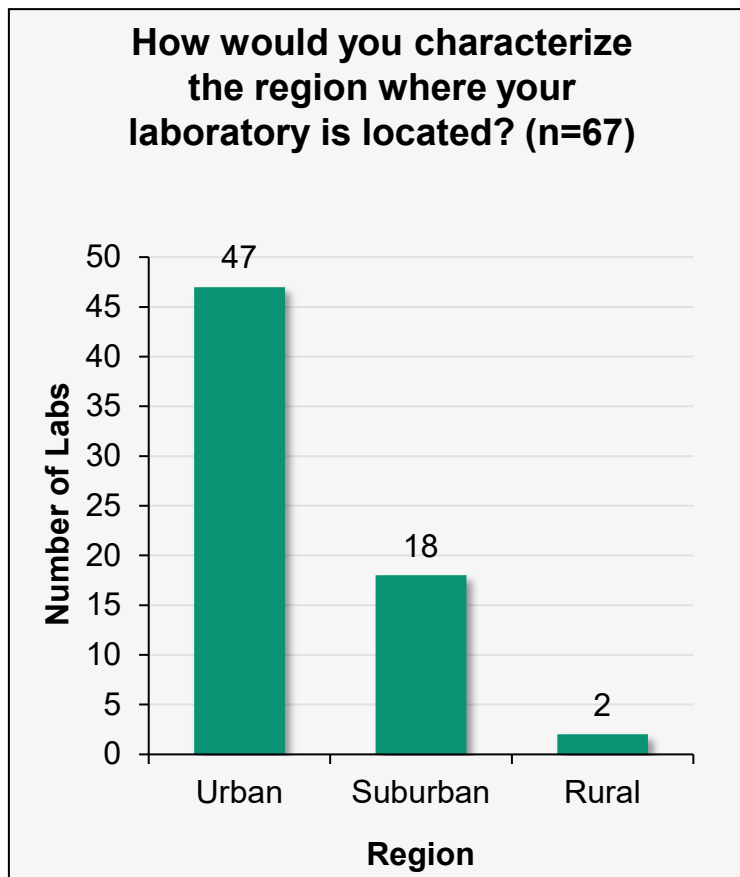
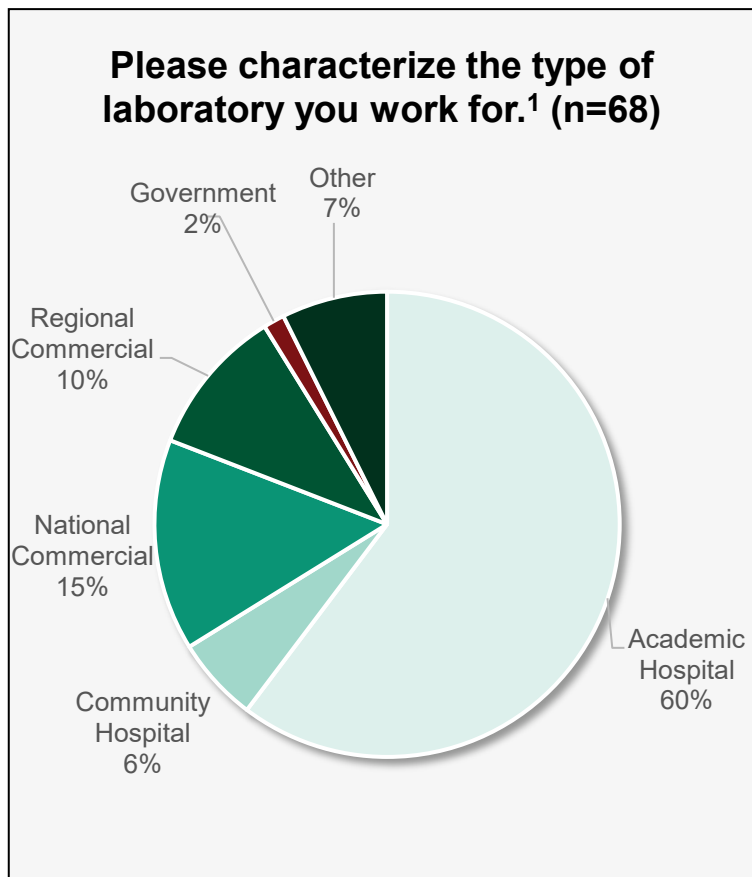
Respondent Demographics

Survey Output

Demographic Subanalysis

The survey has been completed by 68 respondents from a variety of institutions across the U.S., the majority from urban academic hospitals

Laboratory Demographic Breakdown



In which state/territory is your laboratory? (n=56)

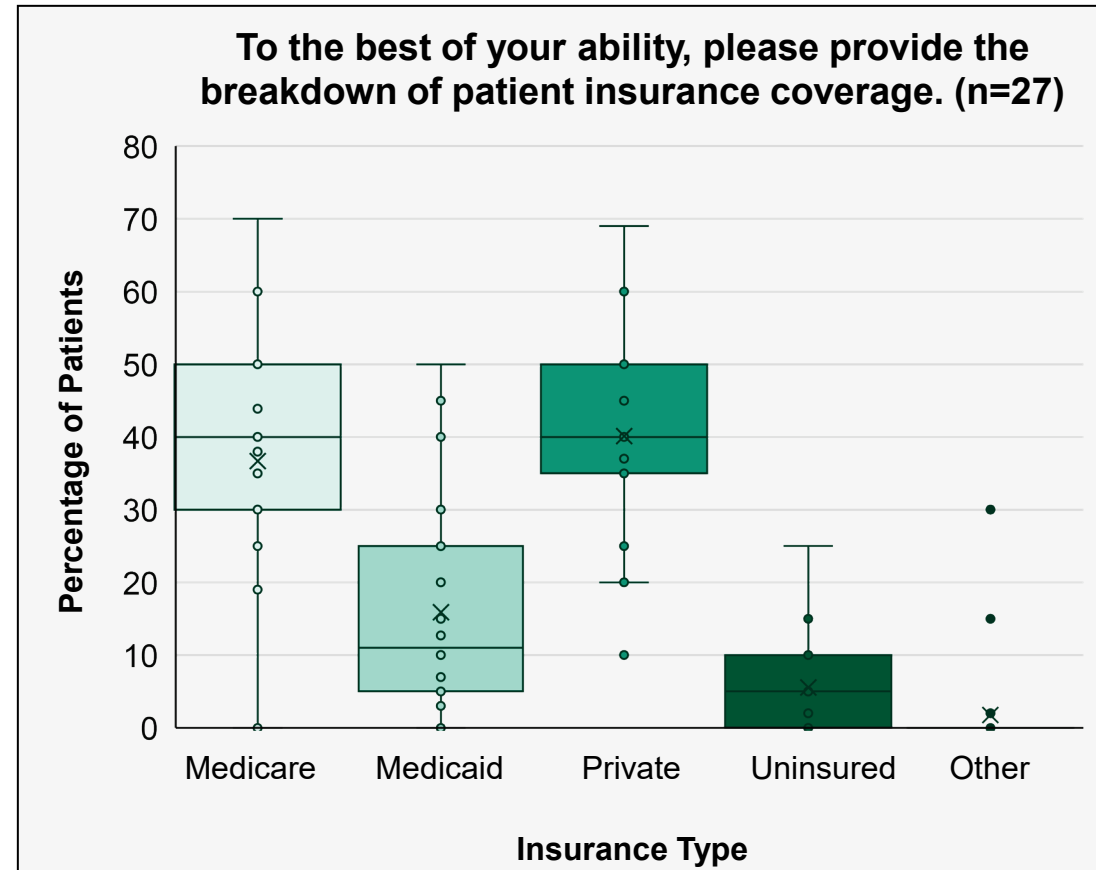
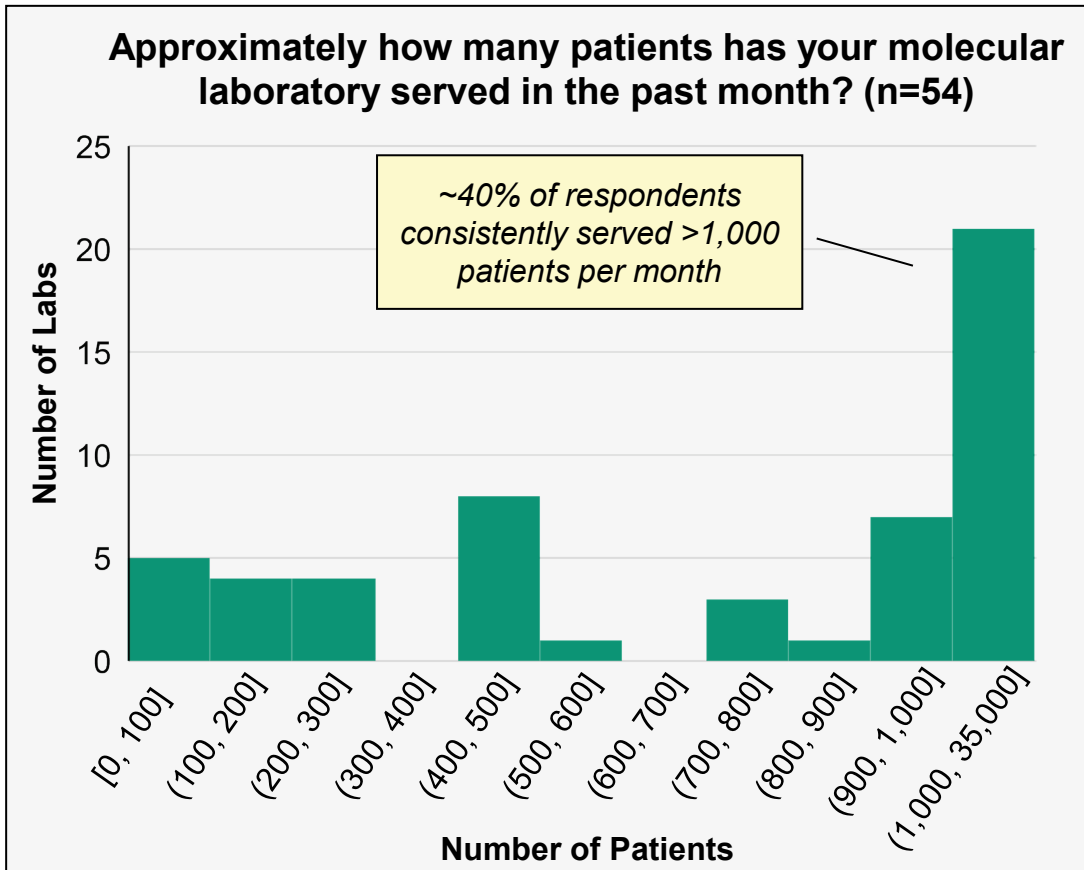
Lab State	Respondents
Alabama	1
Arizona	1
California	8
Connecticut	2
District of Columbia	2
Florida	3
Georgia	1
Illinois	2
Indiana	1
Kentucky	2
Maryland	3
Massachusetts	4
Michigan	1
Missouri	2
New Hampshire	1
New Jersey	2
New York	6
North Carolina	6
Ohio	1
Oklahoma	1
Pennsylvania	2
South Carolina	1
Tennessee	3
Texas	6
Utah	2
Washington	1
Wisconsin	2

¹ Other includes lab benefits manager, screening/diagnostic lab services, private sector lab, design development firm, and biotech company/CLIA lab.

The respondents' laboratories served up to 35,000 patients, with insurance coverage varying between Medicare, Medicaid, private, and uninsured

Patient Demographic Breakdown

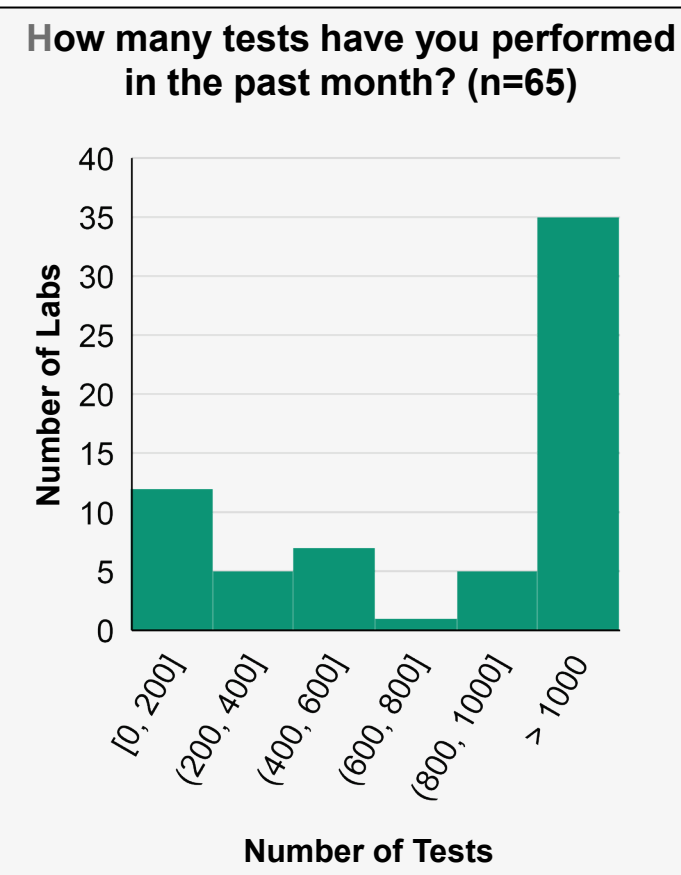
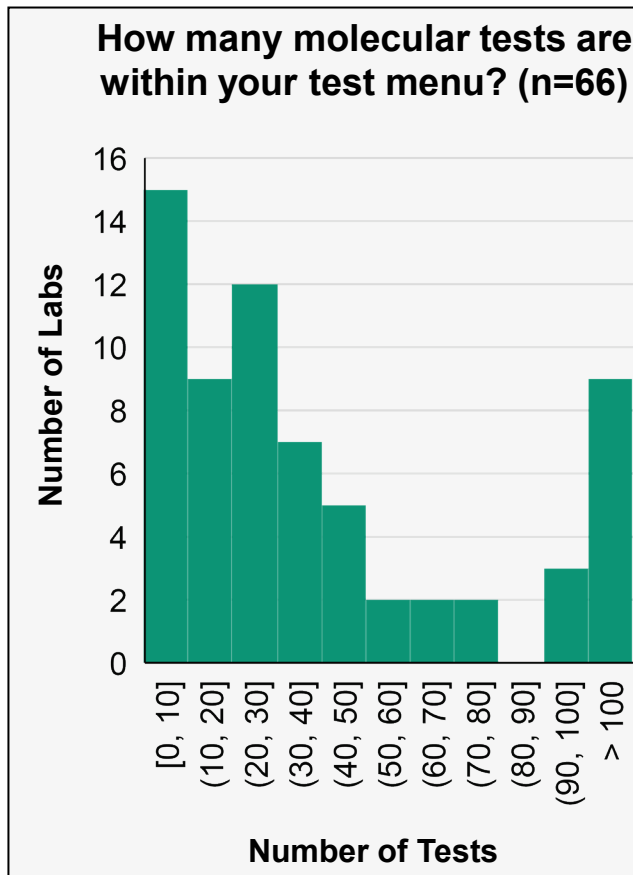
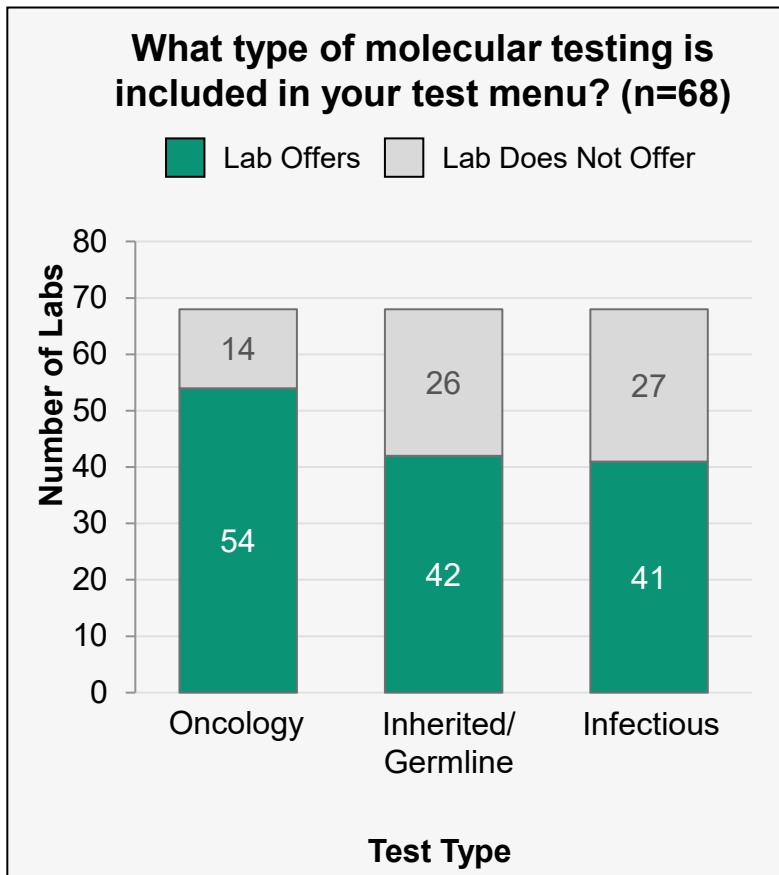
This question was not asked on the shortened survey



Respondents more often offered oncology testing than infectious and inherited assays, typically in test menus consisting of fewer than 50 assays

Note: Patient demographics do not appear to vary by lab type

Test Menu Breakdown



Labs most commonly offered BCR/ABL1 among oncology tests, FMR1/CFTR among inherited conditions, and SARS-CoV-2 among infectious diseases

Assays Included in Survey (n=68)¹

Oncology		
Test	CPT Code	% of labs offering
BCR/ABL1	81206	50%
BRAF	81210	46%
EGFR	81235	41%
JAK2	81270	41%
Oncology GSP ≥51 genes	81455	32%
Oncology GSP 5-50 genes (hematolymphoid neoplasm)	81450	29%
Oncology GSP 5-50 genes (solid organ neoplasm)	81445	26%
BRCA Panel (BRCA1, BRCA2)	81162	18%

Inherited Conditions/Germline Testing		
Test	CPT Code	% of labs offering
FMR1	81243	31%
CFTR	81220	31%
Chromosomal Microarray	81229	28%
SMN1	81329	25%
Exome sequence analysis	81415	24%
Severe inherited condition GSP	81443	21%
CYP2C19	81225	19%
Hearing loss GSP	81430	9%
HLA Class I and II Typing	81370	4%
HLA Class I Typing	81374	3%

Infectious Diseases		
Test	CPT Code	% of labs offering
SARS-Cov-2	87635	37%
CT	87491	35%
SARS-CoV-2, Influenza A, Influenza B	87636	32%
STI panel	87801	31%
HepC	87521	28%
Influenza, multiple types	87502	26%
Respiratory infectious disease GSP, 12-25 targets	87633	26%

¹Assays selected on the basis of CMS claims data, laboratory testing websites, market reports, and prior ClearView research.

GSP: genomic sequence panel

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Project Context and Process

Respondent Demographics

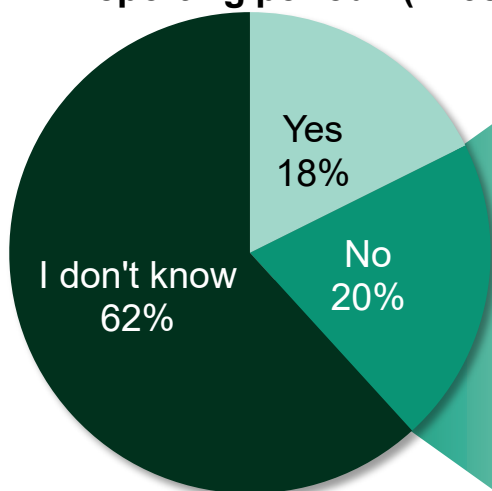
Survey Output

Demographic Subanalysis

18% of respondents indicated that they had reported PAMA data to CMS in 2017, but 62% were unaware of their laboratory's reporting status

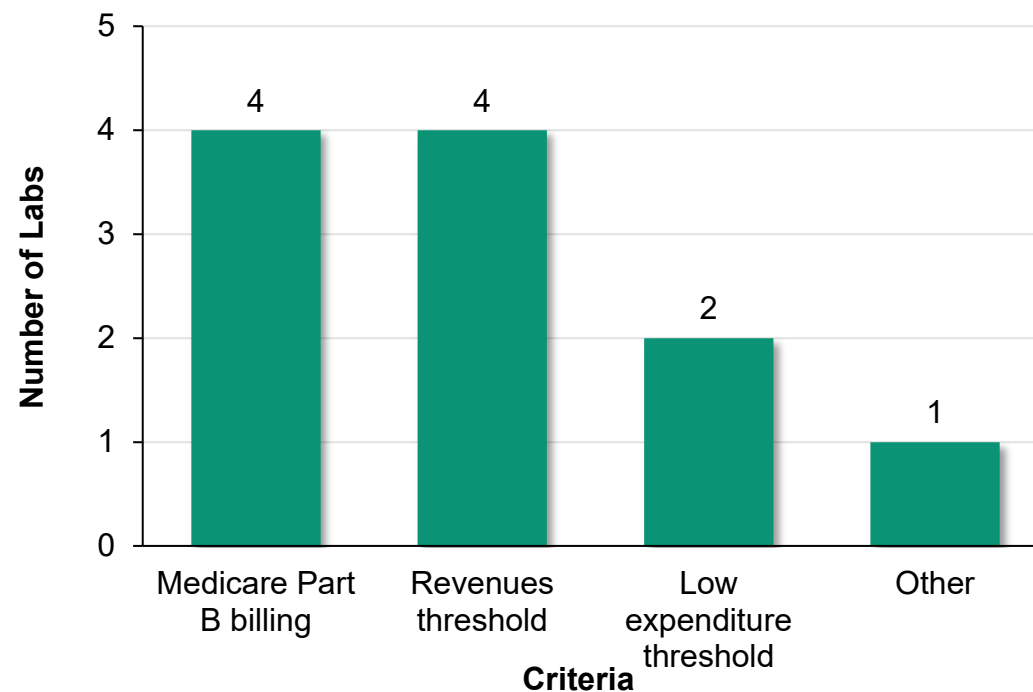
PAMA Reporting Breakdown

To the best of your knowledge, did your lab report reimbursement data to CMS during the initial PAMA reporting period? (n=68)



This question was not asked on the shortened survey

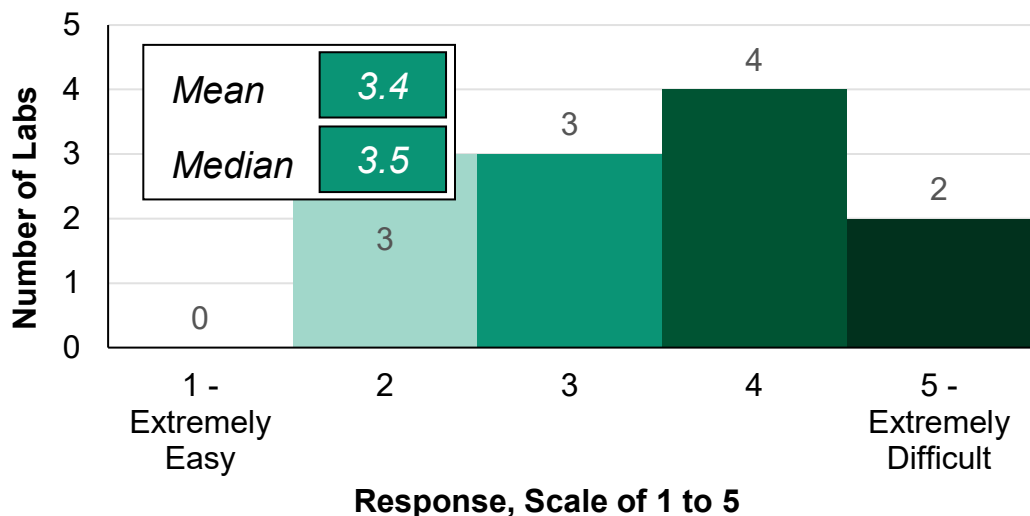
To the best of your knowledge, for which of the following reasons did you not fit the criteria required to report data? Select all that apply. (n=7)



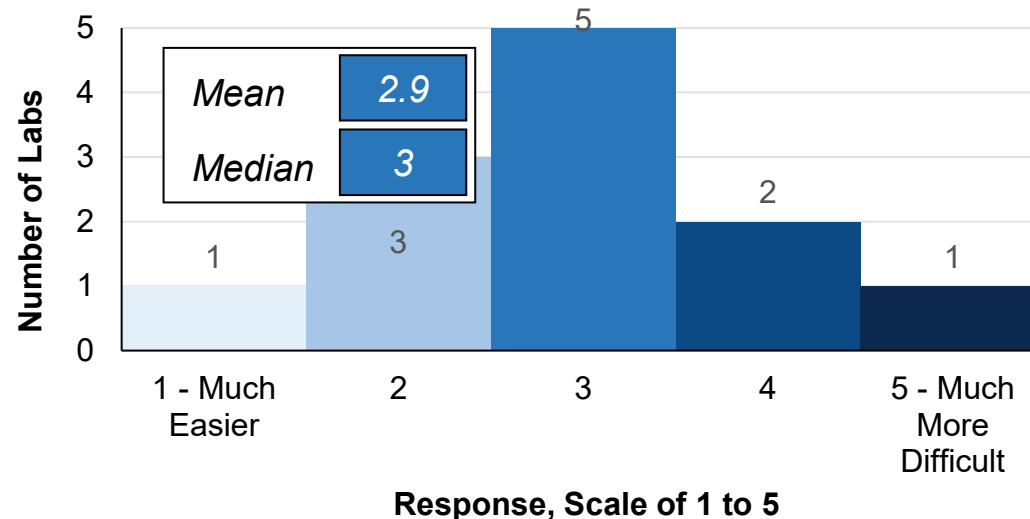
Respondents typically found the last round of reporting to be a burden on their lab's resources, anticipating a slightly easier experience next period

PAMA Reporting Experience

How would you best describe your laboratory's experience reporting data during the last reporting period, on a scale of 1 to 5? (n=12)



How do you anticipate the ease of reporting during the next reporting period to compare to the first reporting period, on a scale of 1 to 5? (n=12)



"The portal for reporting was difficult to navigate."
– Suburban National Commercial

"Data acquisition was difficult."
– Suburban Regional Commercial

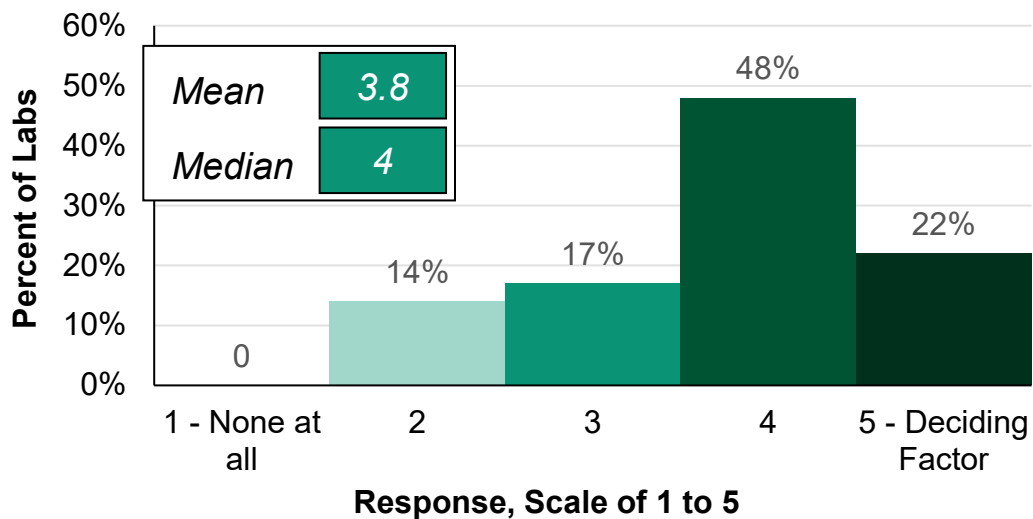
"With the initial round of cuts, my laboratory is constantly strapped for resources."
– Urban Regional Commercial

"I would hope that it is slightly less difficult (at least based on previous experience)."
– Urban Academic Hospital

Reimbursement plays a large role in a lab's decision to continue offering a test and a slightly greater role in the decision to offer a new test

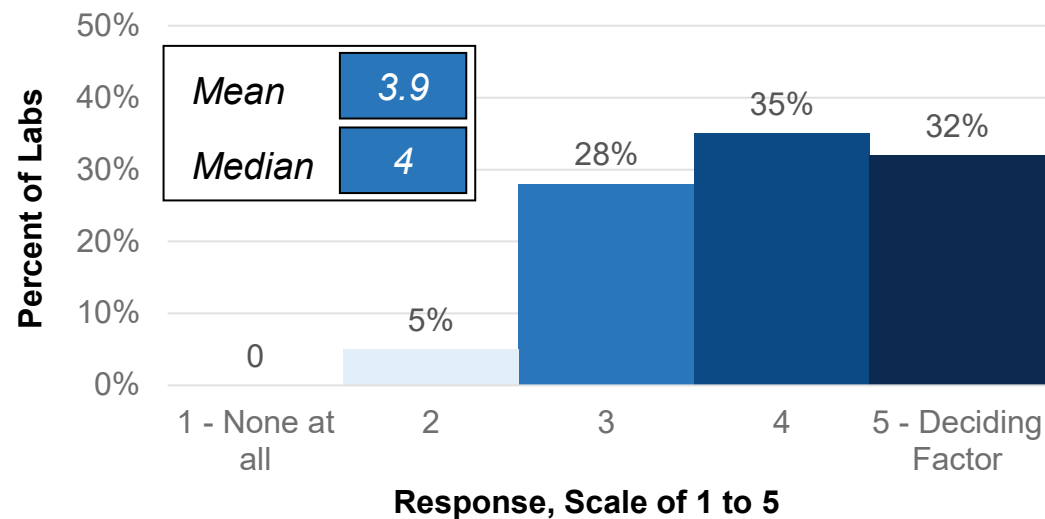
Role of Reimbursement

To what extent does reimbursement rate play a role in your decision to offer a test, on a scale of 1 to 5? (n=58)



*"If we cannot get reimbursed at a rate that makes it profitable then we won't be doing it for very long."
– Suburban Academic Hospital*

To what extent does reimbursement rate impact your willingness to offer a new test, on a scale of 1 to 5? (n=57)

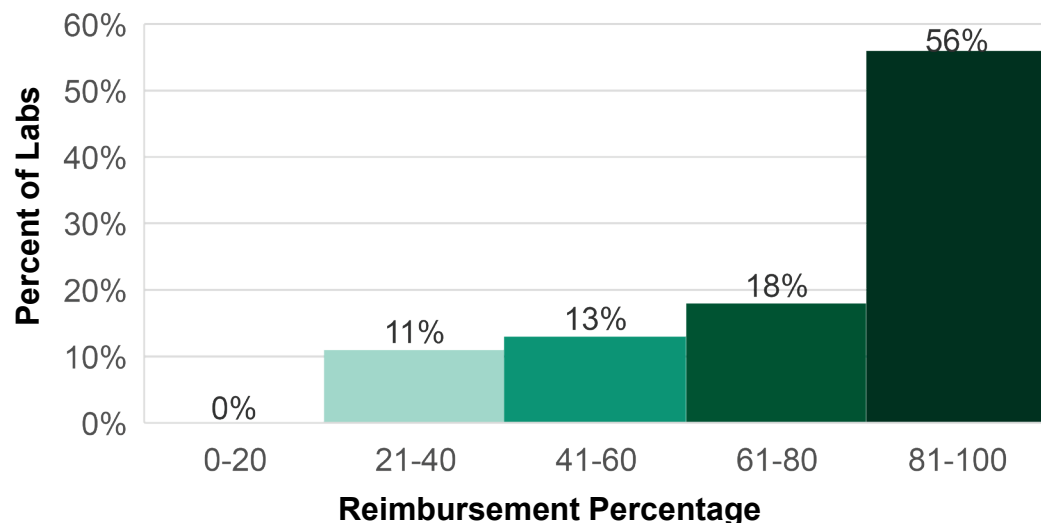


*"Reimbursement challenges impair the ability of many labs to offer new tests, which limits access to testing for many patients and creates inequity in access to comprehensive care."
– Urban Academic Hospital*

Approximately 60% of respondents indicated that they expect a test, whether existing or new, to be at least 81% reimbursed

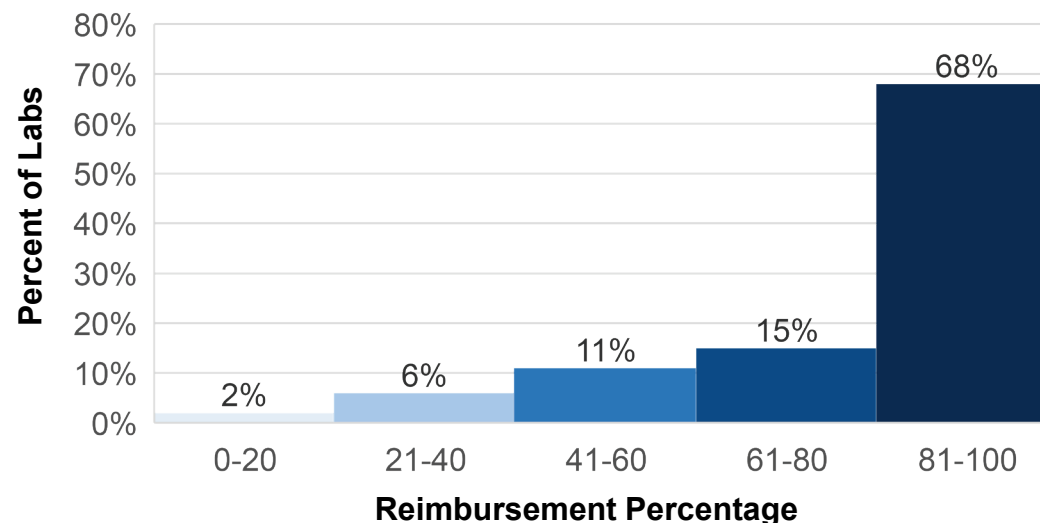
Reimbursement Threshold¹

What percentage of a test's cost must be reimbursed in order for you to continue offering that test?² (n=45)



*"If we cannot get reimbursement to cover our testing costs, then we would have to reevaluate if the test should be removed from our testing menu."
– Urban Academic Hospital*

What percentage of a new test's cost must be reimbursed in order for you to continue offering that test?³ (n=47)

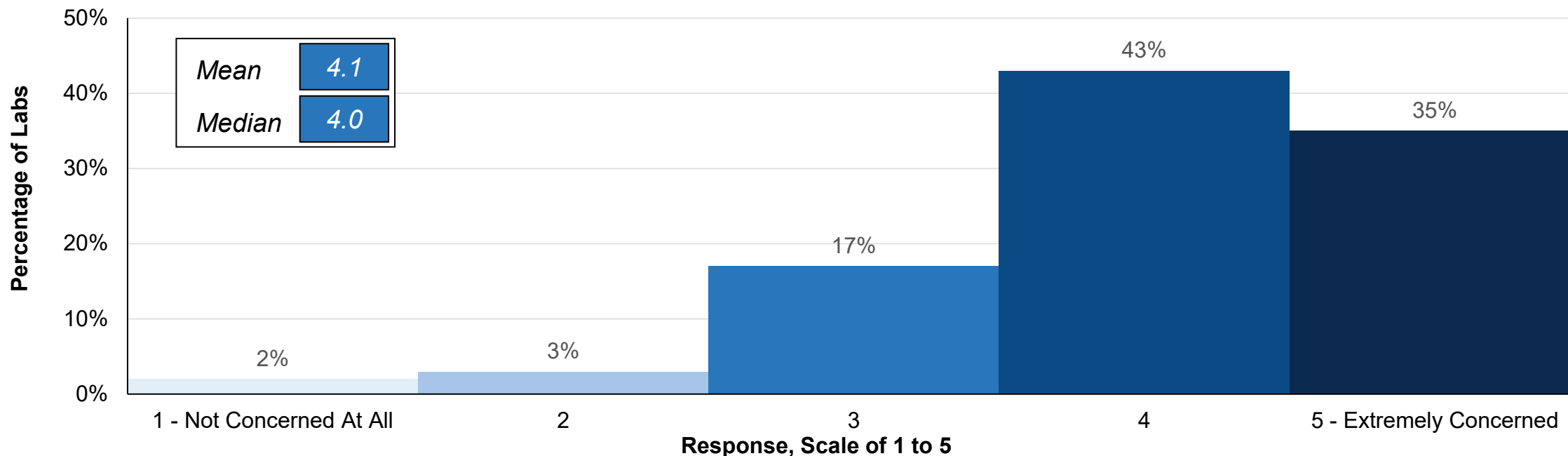


*"The lab does a very careful cost analysis when bringing in a new assay. If a good commercial assay is available but cost is greater than reimbursement, we may create a lab-developed test to break even."
– Urban Academic Hospital*

80% of respondents noted concern (i.e., ranking 4 or 5) for offering a new test crosswalked to a test with a declining reimbursement rate

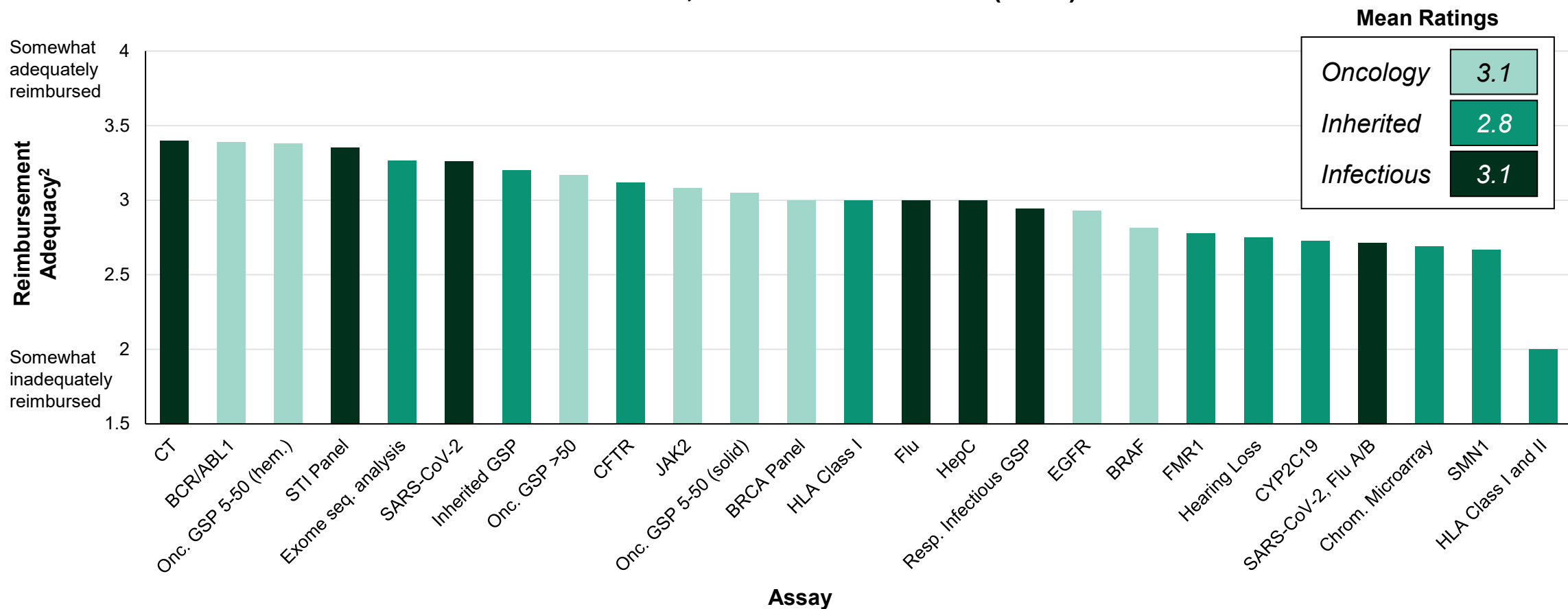
New Test Crosswalking

If a new test were crosswalked to a test whose reimbursement rate was declining, to what extent, if at all, would you be concerned about offering this new test in your lab, on a scale of 1 to 5? (n=60)



Rating on test reimbursement adequacy varied, though none of the tests were seen as exceedingly inadequate or completely adequate

To what extent do you believe this test is adequately reimbursed, on a scale of 1 to 5? (n=68)¹



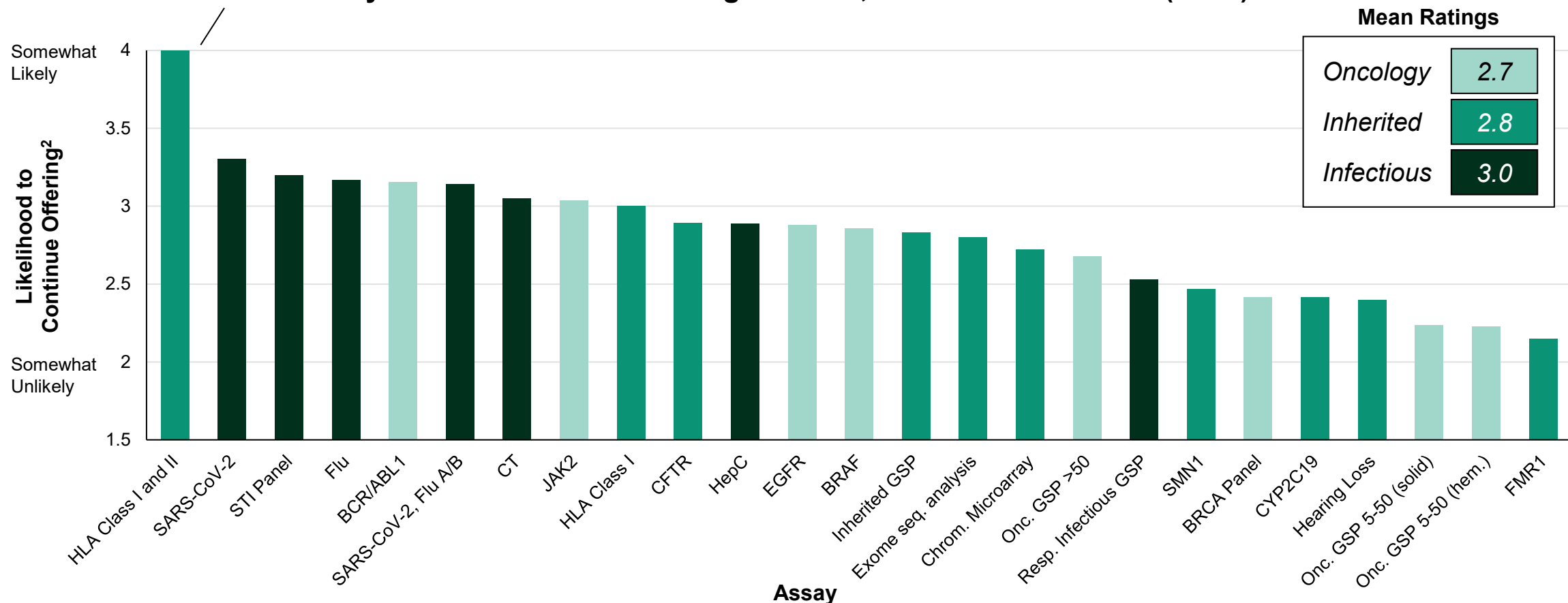
¹There was a total of 57 responses for the set of tests, while each test's specific N is equated to the number of respondents that offer this test, as indicated on slide 11. ² Values in table represent the mean.

Key: ■ Oncology ■ Inherited/Germline ■ Infectious

Respondents were more likely to continue offering infectious disease tests despite 10 – 15% reimbursement cut, while oncology/inherited testing varied

Low sample size (i.e., n=3) offering HLA Class I and II may affect high score

Assuming a 10-15% reimbursement cut on this test, how likely would you be to continue offering this test, on a scale of 1 to 5? (n=68)¹

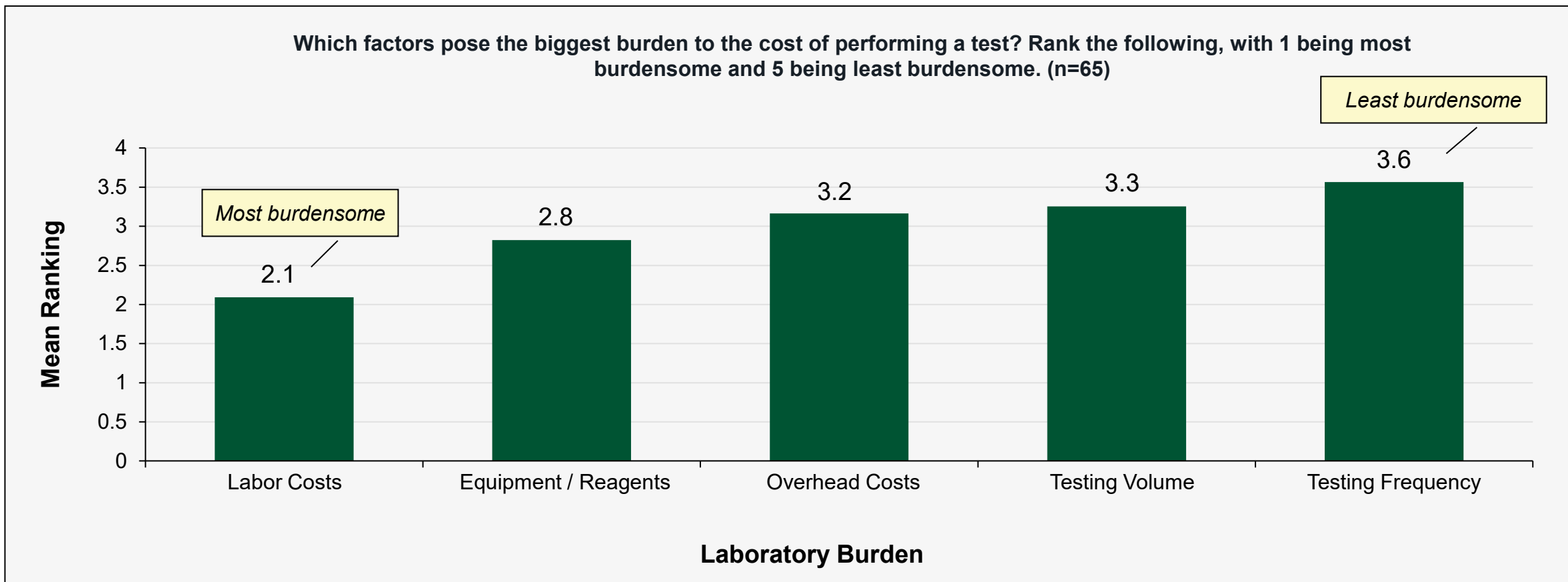


¹There was a total of 57 responses for the set of tests, while each test's specific N is equated to the number of respondents that offer this test, as indicated on slide 11. ² Values in table represent the mean.

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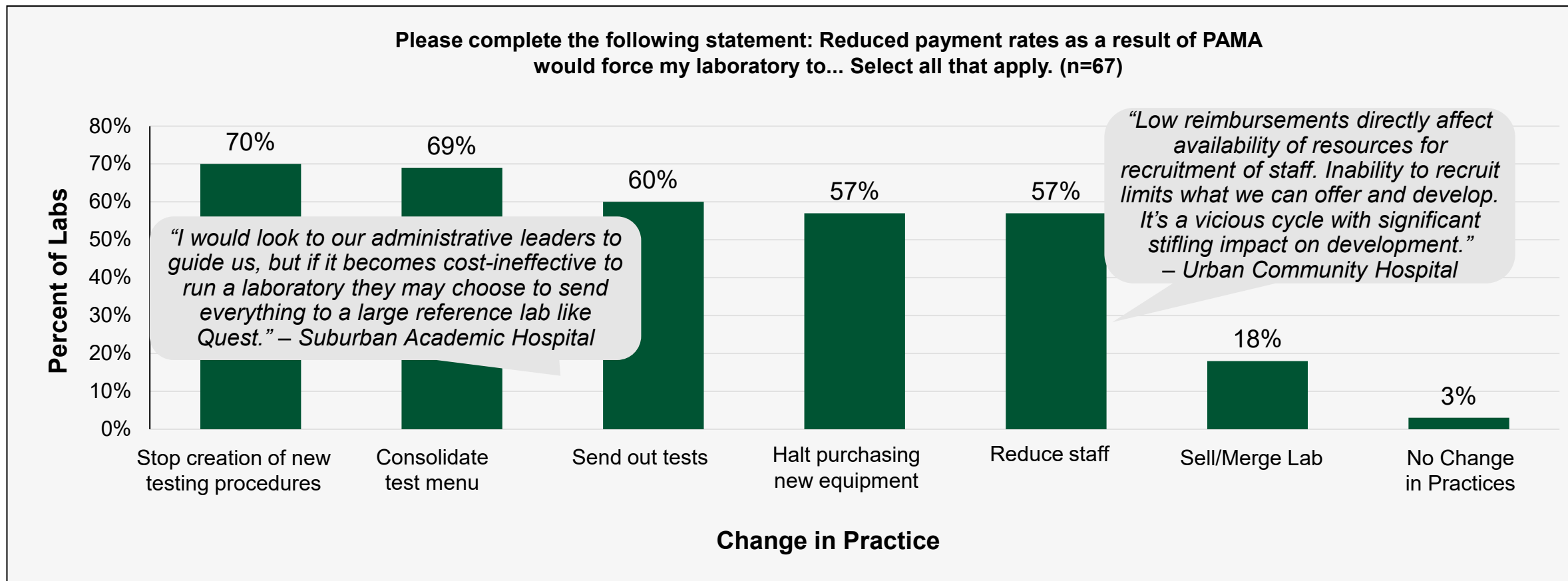
Labor costs and equipment pose the greatest burden to cost; thus, reimbursement cuts may lead to resource challenges

Burden to Laboratories



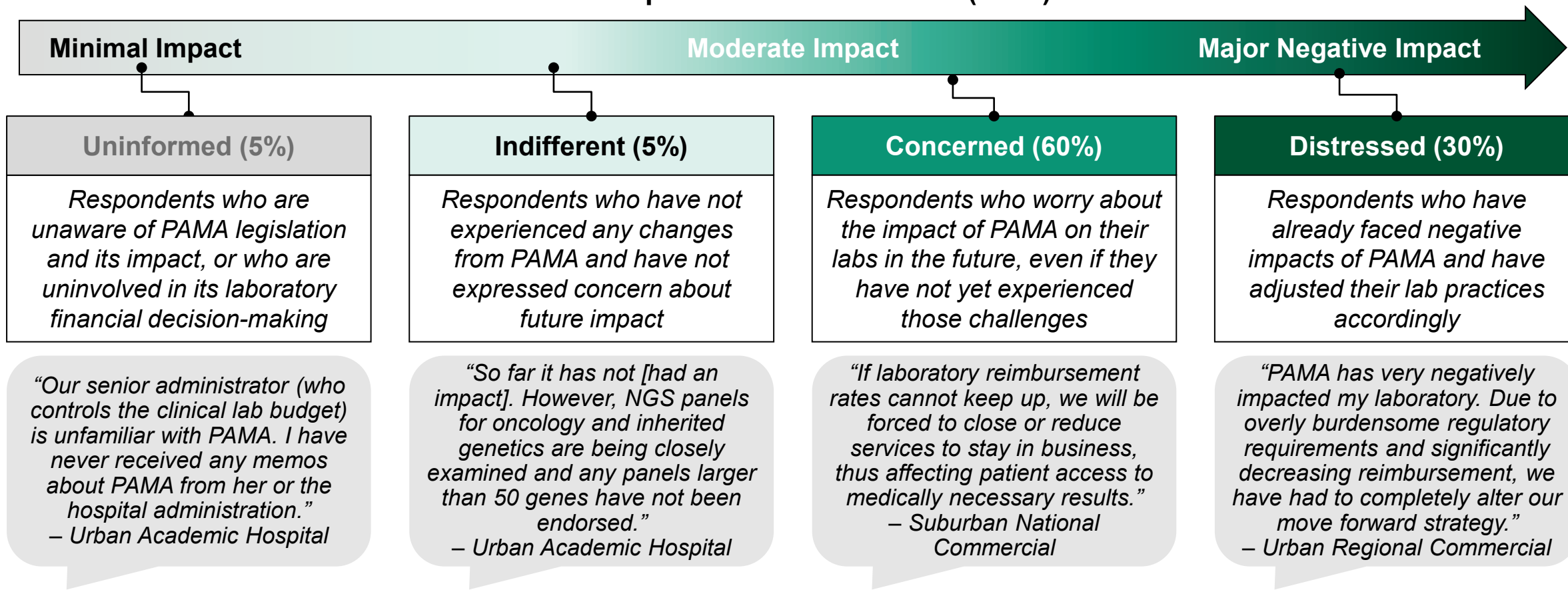
When polled, respondents noted reduced payment rates may cause their labs stop new testing, consolidate testing menu, and/or send out testing

Changes to Laboratory Practices



Respondents expressed greater concern about the downstream impact of PAMA on their laboratories and patients than the reporting itself

How has PAMA impacted your decision-making, test offerings, and/or patient access to care? (n=29)



Lab professionals surveyed expressed concern about the increased strain on their laboratories from continued PAMA reporting and reimbursement cuts

Key Insights

1

More than half of laboratories who reported to PAMA in 2017 indicated the experience to be burdensome and a strain on laboratory resources

2

About 95% of respondents indicated that **reimbursement cuts would force them to stop offering new tests and/or consolidate menu**, though fewer than 20% anticipated the need to sell or merge their laboratory

3

Respondents expressed **concern about the future impact of PAMA** and how the next round of reimbursement cuts may force them to adapt their laboratory practices and limit patient access to care

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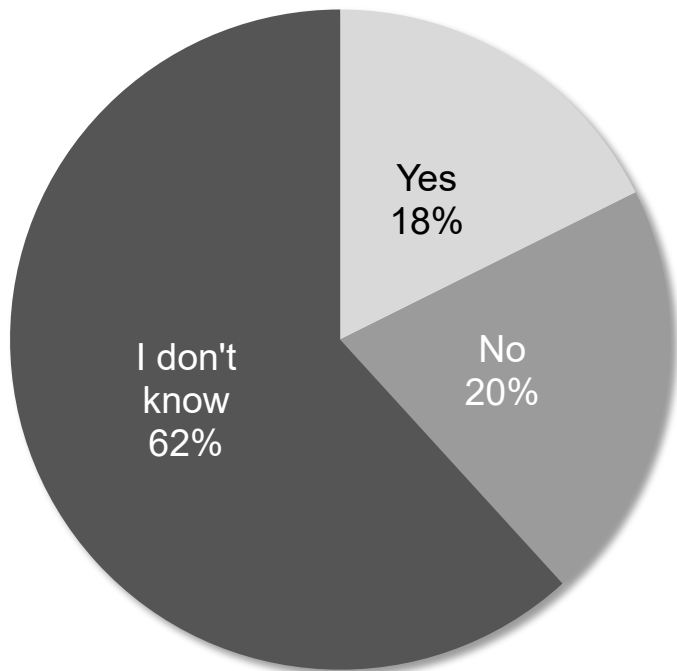
Survey Output

Demographic Subanalysis

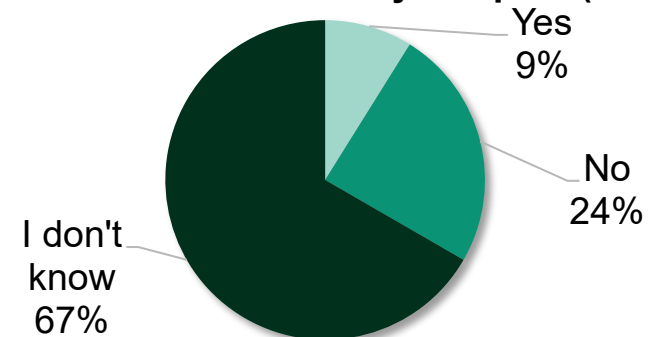
40% of respondents from commercial laboratories indicated that their lab reported during last PAMA period vs. 10% of hospital laboratories

PAMA Reporting Demographic Subanalysis

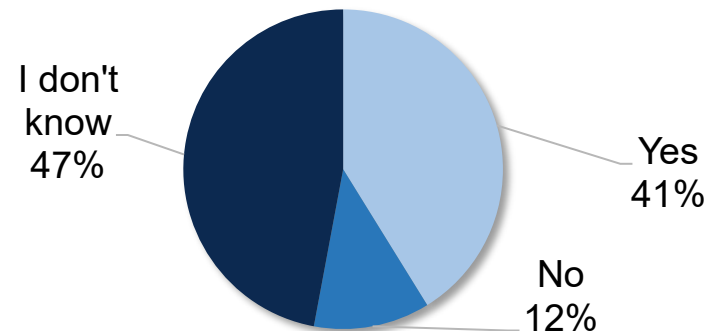
To the best of your knowledge, did your lab report reimbursement data to CMS during the initial PAMA reporting period? (n=68)



Academic and Community Hospital (n=45)



National and Regional Commercial (n=17)

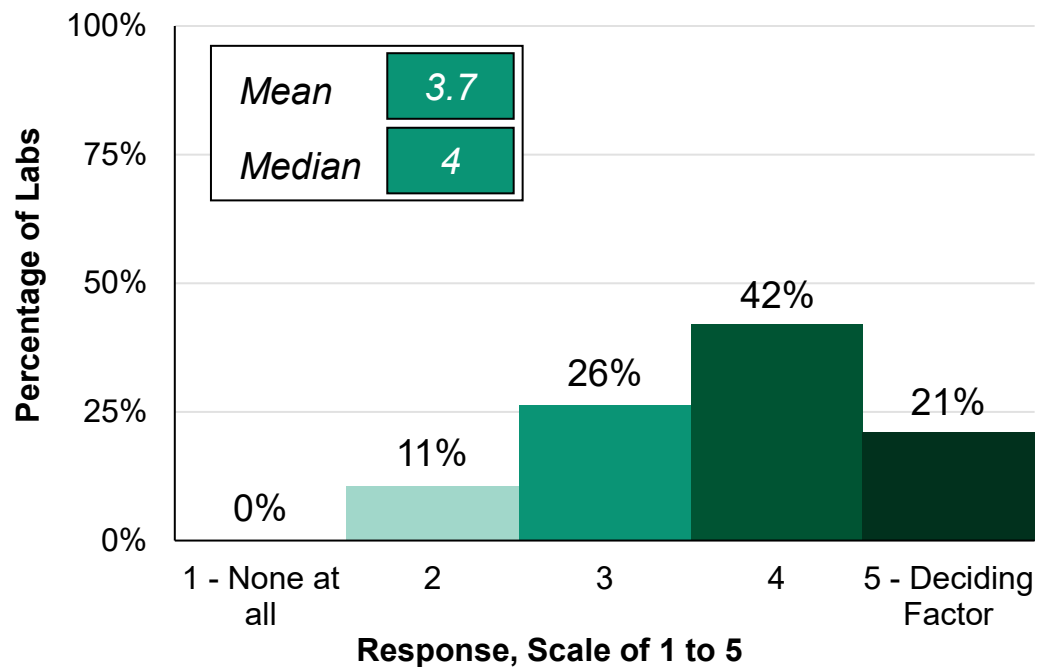


Commercial laboratory respondents indicated a greater role of reimbursement in continuing tests vs. hospital laboratory respondents

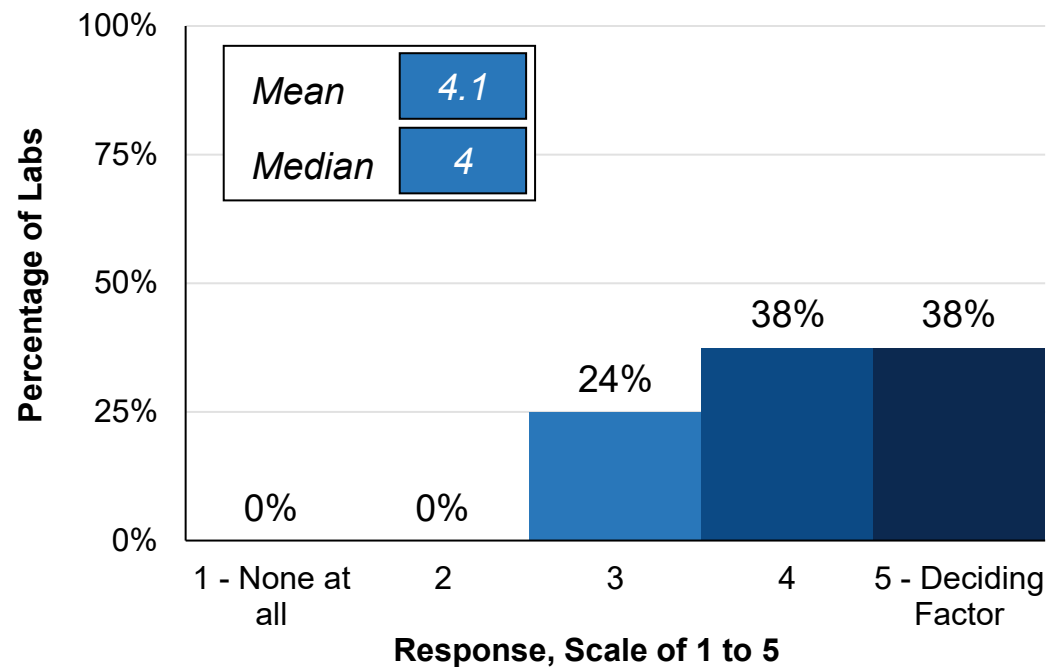
Existing Test Reimbursement

To what extent does reimbursement rate play a role in your decision to offer a test, on a scale of 1 to 5? (n=54)

Academic and Community Hospital (n=38)



National and Regional Commercial (n=16)

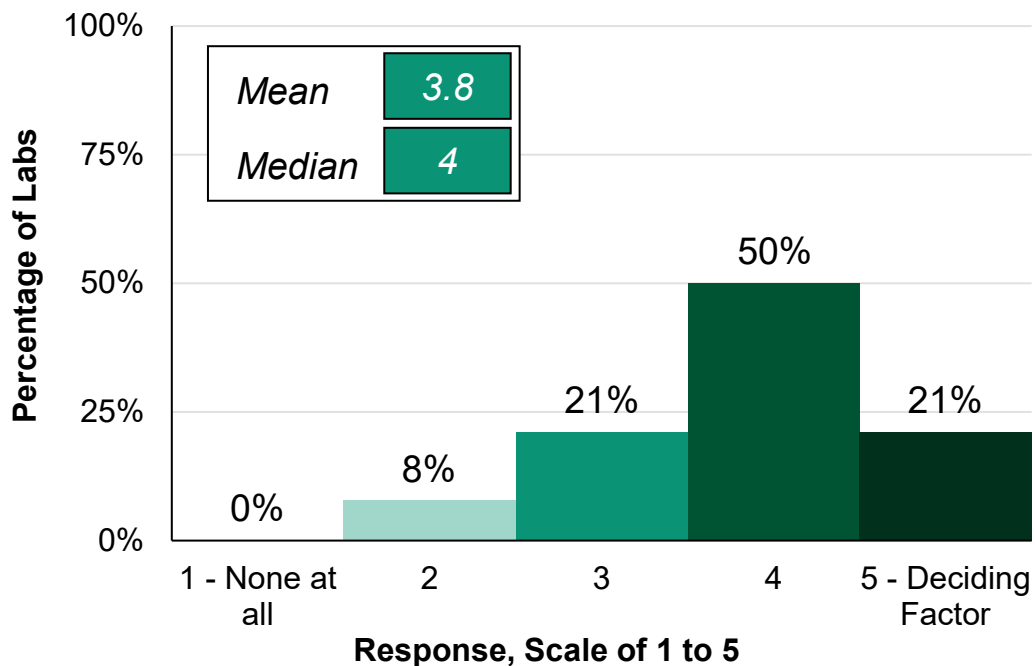


Respondents from commercial labs indicated a greater role of reimbursement in offering new tests vs. hospital laboratory respondents

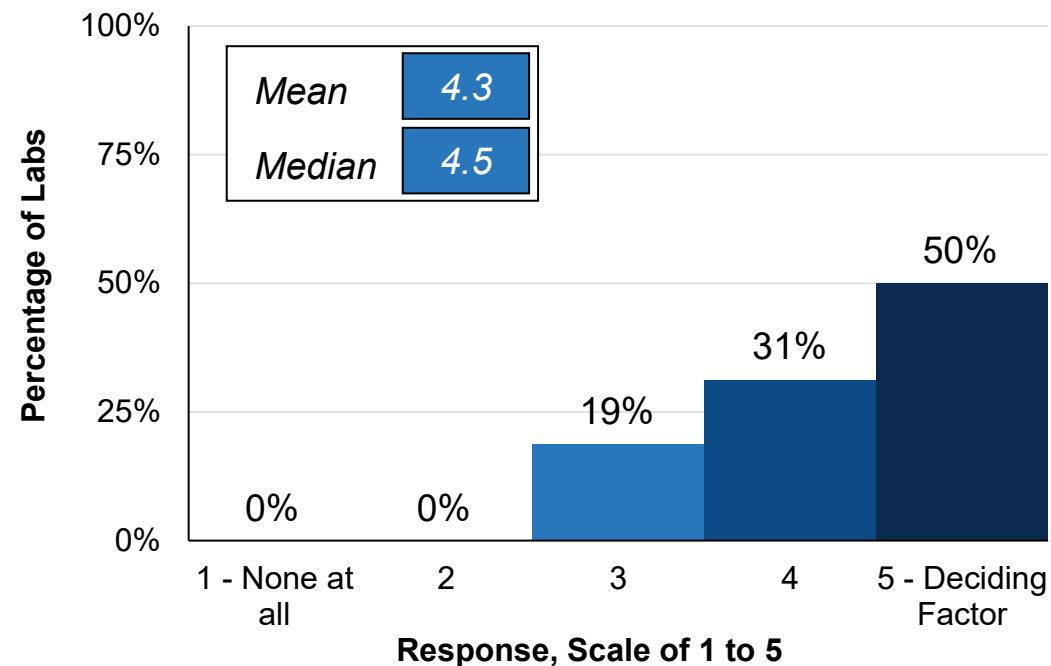
New Test Reimbursement

To what extent does reimbursement rate impact your willingness to offer a new test, on a scale of 1 to 5? (n=54)

Academic and Community Hospital (n=38)



National and Regional Commercial (n=16)

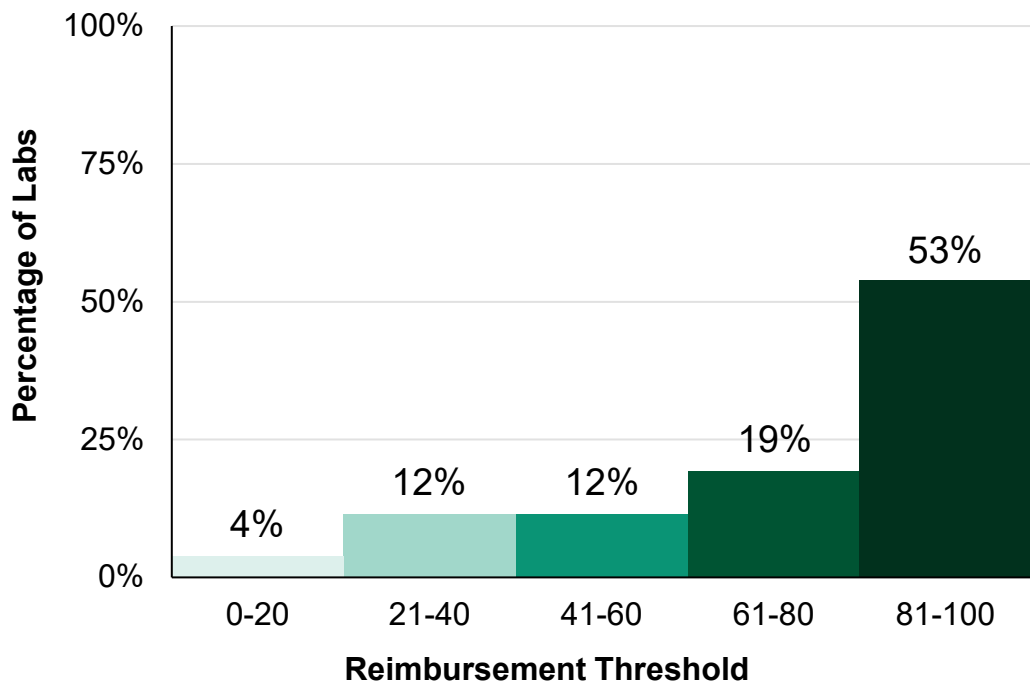


Majority of both hospital and commercial lab respondents require over 80% reimbursement, though 16% of hospital respondents would accept $\leq 40\%$

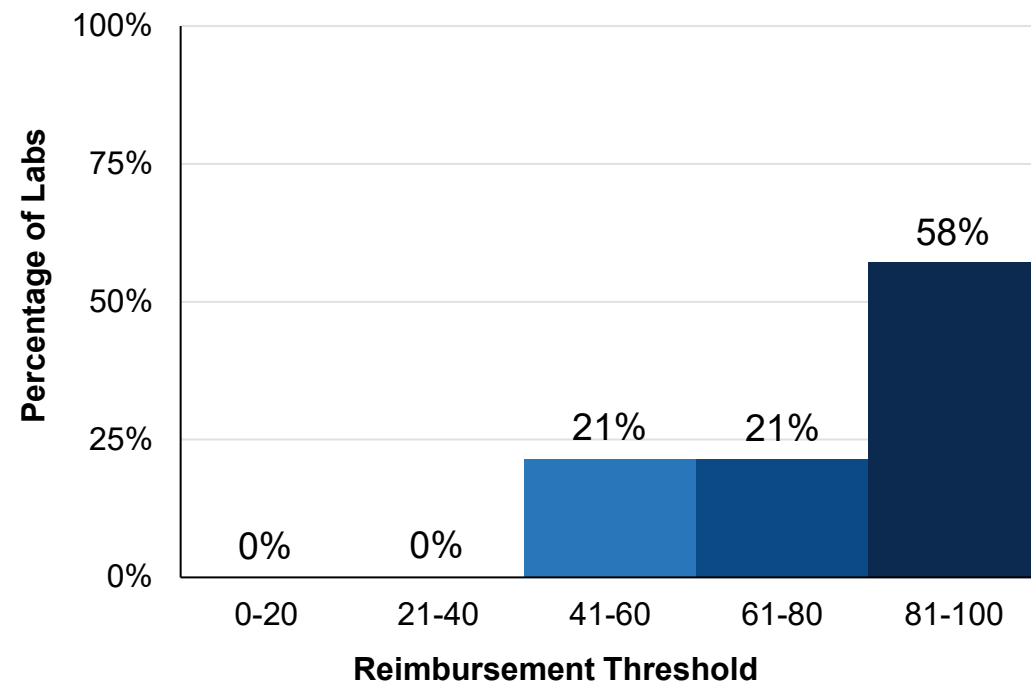
Existing Test Reimbursement Threshold

What percentage of a test's cost must be reimbursed in order for you to continue offering that test?¹ (n=40)

Academic and Community Hospital (n=26)



National and Regional Commercial (n=14)



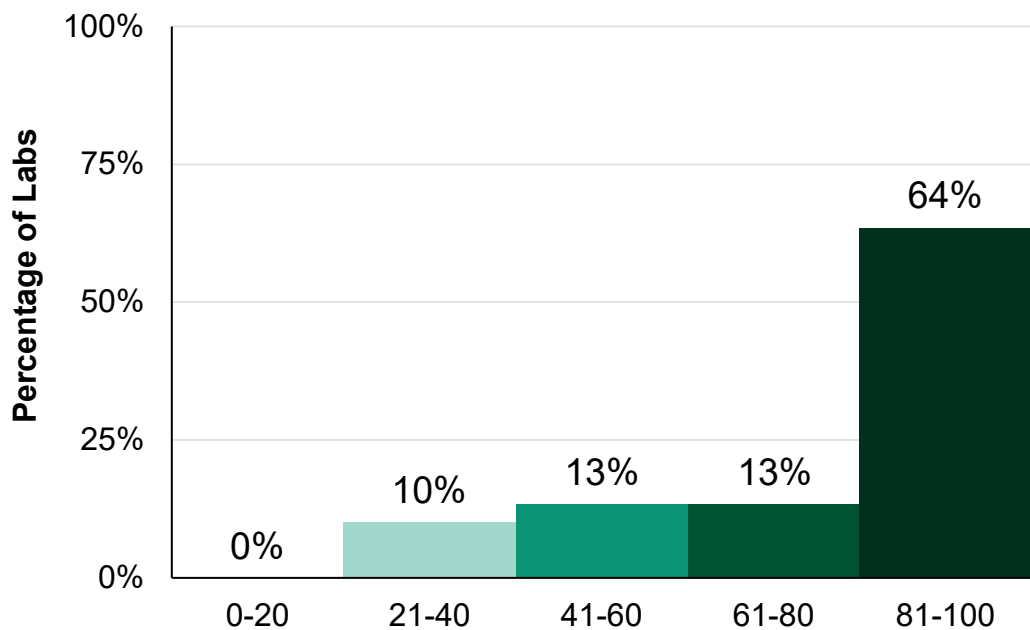
¹In earlier survey version, these questions were posed as free response, whereas newer version formatted as multiple-choice of buckets in 20% intervals; exact responses from earlier survey version have been distributed into corresponding buckets.

Reimbursement threshold is higher for new tests among all stakeholders, though 10% of hospital labs continue to accept $\leq 40\%$ reimbursement

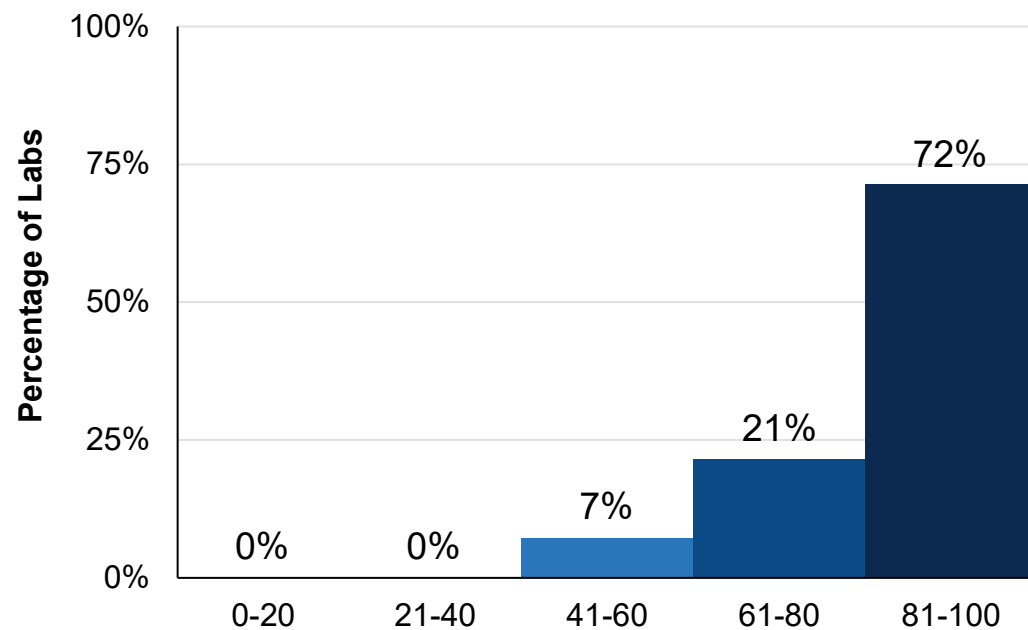
New Test Reimbursement Threshold

What percentage of a new test's cost must be reimbursed in order for you to continue offering that test?¹ (n=44)

Academic and Community Hospital (n=30)



National and Regional Commercial (n=14)



Reimbursement Threshold

Reimbursement Threshold

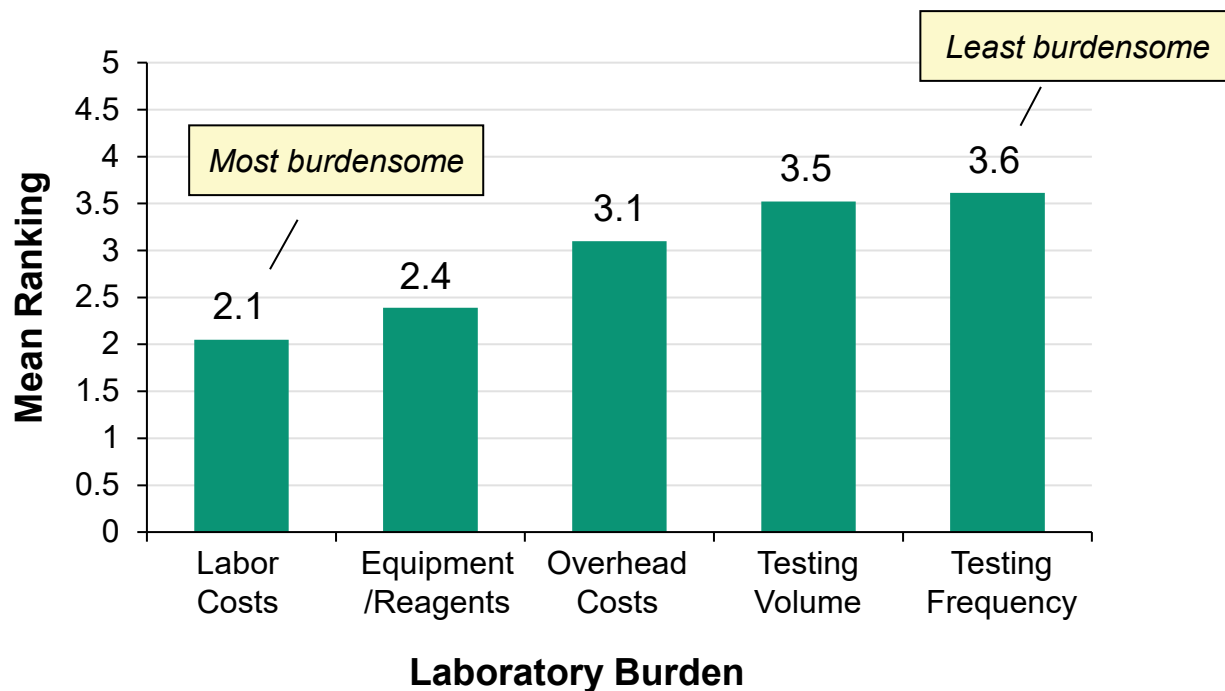
¹In earlier survey version, these questions were posed as free response, whereas newer version formatted as multiple-choice of buckets in 20% intervals; exact responses from earlier survey version have been distributed into corresponding buckets.

Hospital and commercial labs rank burdens similarly, though hospital respondents noted higher burden from sourcing equipment and reagents

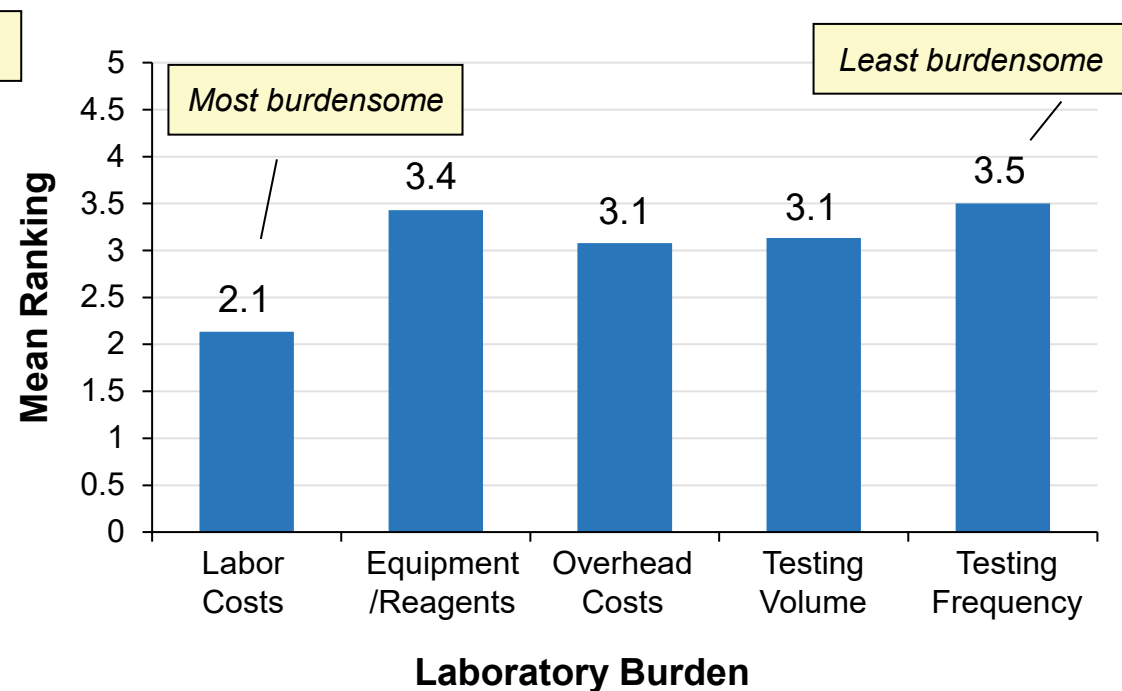
Laboratory Burdens

Which factors pose the biggest burden to the cost of performing a test? Rank the following, with 1 being most burdensome and 5 being least burdensome. (n=59)

Academic and Community Hospital (n=44)



National and Regional Commercial (n=15)

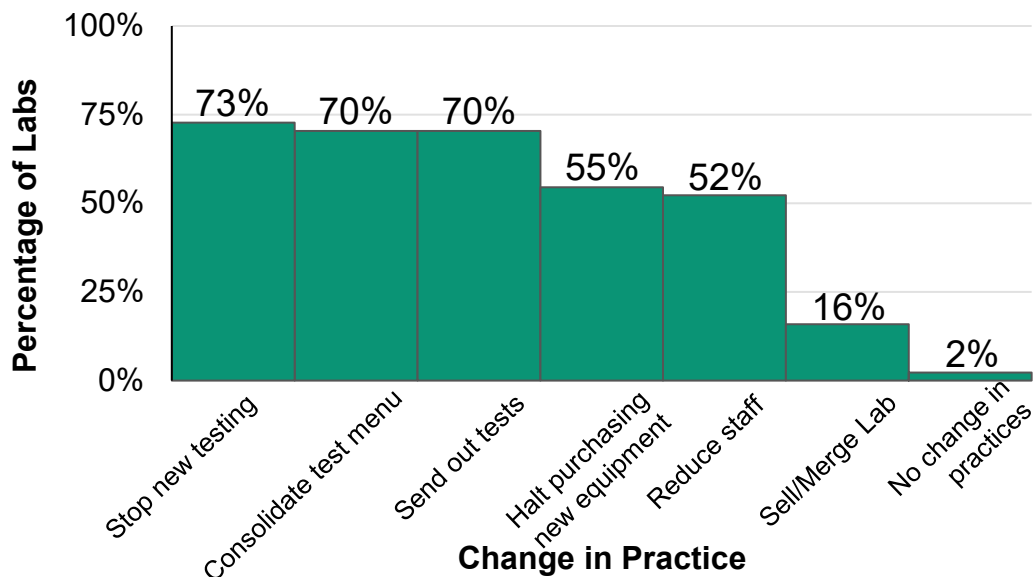


Both demographics would largely stop new testing, but 53% of commercial respondents would consider selling or merging lab vs. 16% of hospital labs

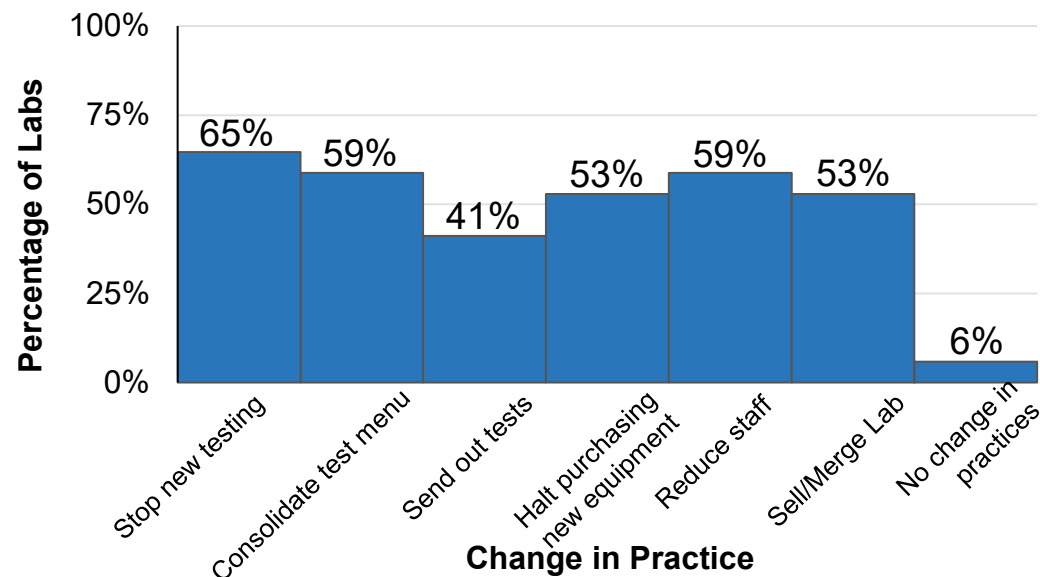
Laboratory Compensation Practices

Please complete the following statement: Reduced payment rates as a result of PAMA would force my laboratory to...
Select all that apply. (n=61)

Academic and Community Hospital (n=44)



National and Regional Commercial (n=17)



Given these reported shifts in practice, reduced payments may result in academic labs outsourcing tests at a greater rate, while industrial labs may seek to sell or merge to increase efficiency



Subanalysis of respondent demographic identified key similarities and differences across groups

Key Subanalysis Insights

- 1** More commercial laboratory respondents indicated **laboratory reported reimbursement data** to CMS during the initial PAMA reporting period compared to hospital laboratories, they also were more likely to indicate challenges in reporting
- 2** Commercial respondents indicated a greater **role of reimbursement** in decision to offer tests, both existing and new, vs. hospital respondents, though majority of both groups required >80% reimbursement
- 3** When considering which factors pose a **burden to labs**, hospitals respondents ranked the cost of equipment and reagents as a higher burden than commercial respondents
- 4** **Reduced payment rates** would drive both demographics to primarily stop new testing; of note, 53% of commercial respondents would consider selling or merging lab vs. 16% of hospital labs

Reimbursement cuts from PAMA will continue to have a negative impact on the laboratory practices and patient access.

Key Implications

1

Decreasing Reimbursement Will Stifle Innovation

- A majority of respondents indicated that reimbursement cuts as a result of PAMA **would force them to stop offering new tests and/or consolidate menu**
- Almost all of the survey respondents expressed concern about offering a new test that was crosswalked to a test whose reimbursement rate was declining, **disincentivizing laboratories from bringing novel or improved tests to market**

2

Decreasing Reimbursement May Limit Patient Access To Testing

- Decreasing reimbursement rates will push academic and medical hospitals to send out molecular tests, while commercial respondents will consider merging or selling their lab, **leading to a decrease in laboratories performing testing over time**
- An increase in hospital laboratories sending out testing will likely increase the turn-around time for testing performed at those institutions, which will delay results for patients

3

Labor Costs to Laboratory are Extremely Burdensome And Expected To Worsen

- **Labor costs were identified as the greatest cost burden across laboratory types**
- The current laboratory staffing crisis continues to be coupled with rising labor costs and COVID-related burnout across the healthcare sector

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