CLIA Onsite Survey Experience

2025 Survey Summary Report

May 2026

Contents

Tables

Background

In response to member feedback regarding Clinical Laboratory Improvement Amendments (CLIA) onsite surveys, the Association of Public Health Laboratories' (APHL) Board of Directors authorized an effort to formally evaluate the scope and impact of these experiences. The first-ever member CLIA survey was administered in the Fall of 2023. APHL fielded a repeat member feedback survey from September 1 – November 25, 2025, to evaluate changes in member experience associated with CLIA onsite surveys.

The survey was distributed via the Laboratory Directors CollABorate online community, with supplemental outreach conducted through regional consortia. Target respondents included Laboratory Directors or their designated quality managers/quality assurance officers.

Explore the *2023 CLIA Onsite Survey Report*

In alignment with APHL's Data Use Policy, all responses remained anonymous, and results are presented as de-identified aggregate data. It should be noted that participation was optional, and not all respondents answered every question. The following analysis compares experiences with surveyors from the US Centers for Medicare and Medicaid Services (CMS) against those from other CLIA-accrediting agencies.

APHL recognizes that CMS no longer uses a regional structure. The regional groupings in the data collected instrument and in this report are for comparison purposes only.

Inspection Details

Respondents Demography

In total, the survey received 41 responses in 2025 (a 15-response decline, ~27% fewer compared to 2023). By region, responses were consistently highest in the Western & Central group (19), followed by the Northeastern & Midwestern (14) and Southern (8) regions, so most of the decline came from the two higher-responding regions. By surveyor/inspector type, most respondents reported CMS (28), with smaller counts for CAP (4) and Other (9).

Table 1. Respondents' Demographic Distribution by Year, Region and Agency

		2023	2025
By Region	Northeastern & Midwestern	20	14
	Southern	9	8
	Western & Central	27	19
By Surveyors	CMS	44	28
	CAP	2	4
	Other	10	9
Overall		56	41

Survey Frequency and Timing

In 2025, the most recent survey had occurred in the late spring through early fall, with activity increasing starting in April (6), peaking in June (7), and remaining relatively high through August (5) and September (5). Very few respondents indicated a last survey in the early months of the year (January 0; February 1; March 2), suggesting that most onsite activity captured by this survey took place mid-year. This timing pattern is largely driven by CMS-related surveys, while CAP/Other surveys appear less frequent overall and are distributed more evenly across the year, with modest concentrations in August–September.

Table 2. Comparison of Last Surveyed Month and Year Among Accrediting Agencies

Agency	Year	Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.	Total
CMS	2023	-	-	-	1	-	-	-	-	-	-	-	1	**2**
	2024	-	-	1	-	1	-	-	1	-	-	3	-	**6**
	2025	-	-	-	4	2	4	7	1	2	-	-	-	**20**
	Total	**0**	**0**	**1**	**5**	**3**	**4**	**7**	**2**	**2**	**0**	**3**	**1**	**28**
CAP / Other	2023	-	-	-	-	-	-	-	-	-	-	1	-	**1**
	2024	-	1	-	-	1	-	-	-	1	1	-	1	**5**
	2025	-	-	1	1	-	-	-	3	2	-	-	-	**7**
	Total	**0**	**1**	**1**	**1**	**1**	**0**	**0**	**3**	**3**	**1**	**1**	**1**	**13**
Overall Total		-	1	2	6	4	4	7	5	5	1	4	2	41

Surveying Entity: CMS vs. CAP/Other

Most respondents reported being surveyed/inspected directly by CMS, though the share decreased from 44 of 56 responses (79%) in 2023 to 28 of 41 (68%) in 2025, while CAP/Other increased from 12 (21%) in 2023 to 13 (32%) in 2025. In 2025, CMS responses were evenly split between the Northeastern & Midwestern (11) and Western & Central (11) regions, with fewer in the Southern region (6). CAP/Other responses in 2025 were concentrated in the Western & Central region (8), with smaller counts from the Northeastern & Midwestern (3) and Southern (2) regions, indicating that the uptick in CAP/Other reporting in 2025 is driven primarily by respondents in Western & Central.

Table 3. Regional Distribution of Accrediting Agencies Conducting Assessments

Region	CMS			CAP/ Other		
	2023	2025	Trend	2023	2025	Trend
Northeastern & Midwestern	17	11	- 35%	3	3	-
Southern	8	6	- 25%	1	2	+ 50%
Western & Central	19	11	- 42%	8	8	-
Total	**44**	**28**	**- 36%**	**12**	**13**	**+8%**

Test Volume

In 2025, reported annual test volume varied widely across responding laboratories, indicating a mix of small, mid, and very high-volume operations. Overall, the minimum reported volume was 5,625 tests, the average was 1,584,249, and the maximum reached 8,500,000.

Table 4. Comparative Analysis of Testing Volumes Across Accrediting Agencies and Regions

Agency	Region	Minimum	Average	Maximum
CMS	Northeastern & Midwestern	5,625	166,263	926,959
	Southern	102,636	2,764,514	8,248,981
	Western & Central	46,000	903,752	4,201,975
CAP or Other	Northeastern & Midwestern	6,567,555	6,567,555	6,567,555
	Southern	2,951,421	2,951,421	2,951,421
	Western & Central	5,500,000	7,000,000	8,500,000
Total		**5,625**	**1,584,249**	**8,500,000**

Laboratory Specialties/Subspecialties

In 2025, respondents most frequently reported Microbiology (41 selections; 34%) and Diagnostic Immunology (40; 33%), indicating these are the most common specialty areas represented among participating laboratories. Chemistry was also widely selected (29; 24%). Fewer respondents indicated Hematology (10; 8%), and very small shares selected Immunohematology (2; 2%), suggesting these specialties were less commonly listed in the reported testing scope. Because this was a "select all that apply" question, percentages reflect the distribution of selections rather than the percentage of respondents. Also, 18/41 respondents (44%) conduct Newborn screening tests internally.

Table 5. Comparison of Laboratory Specialties and Subspecialties Across Accrediting Agencies and Regions

Speciality	Region	CMS	CAP or Other	Total
Chemistry	Northeastern & Midwestern	8	2	**10**
	Southern	5	2	**7**
	Western & Central	9	3	**12**
	Total	**22**	**7**	**29**
Diagnostic Immunology	Northeastern & Midwestern	11	3	**14**
	Southern	6	2	**8**
	Western & Central	11	7	**18**
	Total	**28**	**12**	**40**

Speciality	Region	CMS	CAP or Other	Total
Hematology	Northeastern & Midwestern	-	1	1
	Southern	3	-	3
	Western & Central	4	2	6
	Total	7	3	10
Immunohematology	Northeastern & Midwestern	-	1	1
	Southern	-	-	-
	Western & Central	1	-	1
	Total	1	1	2
Microbiology	Northeastern & Midwestern	11	3	14
	Southern	6	2	8
	Western & Central	11	8	19
	Total	28	13	41

Number of Onsite Surveyor(s)/Inspectors

There was a general increase in the average number of personnel onsite for surveys between 2023 and 2025, with a notably sharper rise in the CAP/Other category compared to CMS. While the total average for CMS surveyors remained relatively stable, shifting slightly from 1.2 to 1.3, the CAP/Other inspections saw a significant jump from an average of 1.7 to 2.8 personnel.

Table 6. Average Surveyors and Inspectors onsite by Types of Accrediting Agencies

Region	CMS		CAP or Other	
	2023	2025	2023	2025
Northeastern and Midwestern	1.1	1.0	2.0	3.7
Western and Central	0.9	1.4	1.5	2.3
Southern	2.3	1.6	3.0	3.5
Total	1.2	1.3	1.7	2.8

Days Surveyor(s) Remained Onsite

Onsite duration was stable overall from 2023 to 2025, with the average remaining 2.2 days in both years; however, the overall range shifted slightly, with the maximum increasing from five to six days and the minimum increasing from 0.5 to one day.

In 2025, respondents overwhelmingly indicated that reviewing personnel qualifications, proficiency testing (PT) and competency records prior to the onsite survey would help reduce the total time devoted to survey activities. Of the responses shown, 31 indicated “Yes” compared with 5 “No,” reflecting broad support for a pre-review approach.

Table 7. Days a Surveyor(s) Remained Onsite, by Accrediting Agency

Agency	Average		Maximum		Minimum	
	2023	2025	2023	2025	2023	2025
CMS	2.5 days	2.7 days	5 days	6 days	1 day	1 day
CAP	1.3 days	1 day	1.5 days	1 day	1 day	1 day
Other	0.9 day	1.2 days	2 days	2.5 days	0.5 day	1 day
Total	**2.2 days**	**2.2 days**	**5 days**	**6 days**	**0.5 day**	**1 day**

Citations and Level of Deficiencies

Overall Average

Overall, in 2025, respondents reported low levels of high-severity findings, with an average of 0.2 Condition-level citations and no Immediate Jeopardy citations across the deficiency areas shown. Most findings were reported at the Standard level (overall average 2.2), indicating that citations were more commonly related to compliance gaps that require correction rather than conditions posing immediate risk (**Table 8**).

Across surveying entities, Quality Systems (Subpart K) emerged as the most frequently cited area and the primary driver of Standard-level findings. For laboratories surveyed by CMS, Quality Systems had the highest average Standard-level citations (5.4) and the highest Condition-level average (0.5) compared with other categories, while other areas showed relatively small Standard-level averages and near-zero Condition-level findings.

A similar pattern was observed for CAP, where Quality Systems again had the highest Standard-level average (8) and the highest Condition-level average (1). Findings reported under other surveyors were comparatively limited overall, though Quality Systems remained the leading category (Standard 1.2; Condition 0.2).

Table 8. Average Disparities in Citations and Deficiency Levels by Accrediting Agency

Citation Type	Standard Level			Condition Level			Immediate Jeopardy		
	CMS	CAP	Other	CMS	CAP	Other	CMS	CAP	Other
General Administration (Subpart F)	1.4	2.7	-	-	1	-	-	-	-
Proficiency testing (Subparts H or I)	1.2	1	-	-	-	-	-	-	-
Facility Administration (Subpart J)	0.4	-	-	-	-	-	-	-	-
Quality Systems (Subpart K)	5.4	8	1.2	0.5	1	0.2	-	-	-
Personnel (Subpart M)	1.7	-	0.4	0.3	-	-	-	-	-
Other (please describe)	1.3	2	-	-	-	-	-	-	-
Overall Average	**2.8**	**2.8**	**0.3**	**.02**	**0.6**	**0**	**-**	**-**	**-**

CMS Citation Patterns and Accrediting Agency Comparison

The 2025 survey results reveal a significant disparity in how public health laboratories are cited across regions and oversight agencies.

- **Regional Trends:** The Western and Central region accounts for the highest volume of regulatory activity, with 90 total citations across 18 laboratories. However, the Southern region shows the highest frequency of issues per individual facility, averaging 5.13 citations per laboratory (**Table 9**).
- **Focus on Quality Systems:** By far, the most cited area for all agencies is Quality Systems (Subpart K), which represents over 70% of all CMS citations and over 60% of CAP/Other citations (**Tables 10 & 11**).
- **Personnel and Testing Gaps:** CMS identifies significantly more deficiencies in Personnel (Subpart M) and Proficiency Testing (Subparts H or I) than other accreditors (**Tables 10 & 11**).

Table 9. CMS Citations by Region

Region	Number of PHLs	Total Citations	Citations per PHL
Northeastern & Midwestern	14	63	4.50
Southern	8	41	5.13
Western & Central	18	90	5

Table 10. Comparison of Citations by Type of Accrediting Agency

Citation Type	CMS	CAP or Other
General Administration (Subpart F)	11	10
Proficiency testing (Subparts H or I)	12	2
Facility Administration (Subpart J)	3	-
Quality Systems (Subpart K)	142	26
Personnel (Subpart M)	22	2
Other (please describe)	4	2
Total Citations	**194**	**42**
Number of Responses	**28**	**12**
Average Citation Per Agency Type	**6.92**	**3.50**

Table 11. Disparities in Citations and Deficiency Levels by Accrediting Agency and Region

Citation Type	Region	CMS	CAP or Other	Total
General Administration (Subpart F)	Northeastern & Midwestern	3	-	3
	Southern	0	1	1
	Western & Central	8	9	17
	Total	11	10	21
Proficiency testing (Subparts H or I)	Northeastern & Midwestern	7	-	7
	Southern	1	1	2
	Western & Central	4	1	5
	Total	12	2	14
Facility Administration (Subpart J)	Northeastern & Midwestern	1	-	1
	Southern	-	-	-
	Western & Central	2	-	2
	Total	3	-	3
Quality Systems (Subpart K)	Northeastern & Midwestern	41	3	44
	Southern	38	4	42
	Western & Central	63	19	82
	Total	142	26	168
Personnel (Subpart M)	Northeastern & Midwestern	11	-	11
	Southern	2	-	2
	Western & Central	9	2	11
	Total	22	2	24
Other	Northeastern & Midwestern	-	2	2
	Southern	-	-	-
	Western & Central	4	-	4
	Total	4	2	6
Overall Total		194	42	236

Post-survey Reporting and Administrative Burden

Managing Data and Information Requests Following an Onsite Survey

In 2025, a significant minority of respondents (16 of 41 laboratories, 39%) reported needing to respond to additional data or information requests after the onsite survey and before the final report, suggesting that activities continued beyond the onsite visit through follow-up questions and documentation requests. This pattern differed by surveying entity: among laboratories reporting CMS as the surveying body, 12 of 28 (43%) reported follow-up requests, compared with 4 of 13 (31%) among CAP/Other.

Within CMS responses, follow-up needs were fairly consistent across regions (**Table 12**), indicating that post-survey requests were not isolated to a single region but were experienced across the respondent base.

Table 12. Need to Respond to Data or Information Requests Following the Onsite Survey to Address Additional Surveyor Questions

Agency	Region	No	Yes
CMS	Northeastern & Midwestern	6	5
	Southern	3	3
	Western & Central	7	4
	Total	**16**	**12**
CAP or Other	Northeastern & Midwestern	1	2
	Southern	2	-
	Western & Central	6	2
	Total	**9**	**4**
Overall Total		**25**	**16**

Time Burden of Post-survey Follow-up

Among respondents, the average time spent responding to post-survey data or information requests decreased substantially from 2023 to 2025, with the overall average dropping from 13.55 hours (2023) to 3.22 hours (2025). This decline is driven primarily by CMS-related follow-up: the CMS average fell from 14.80 hours in 2023 to 3.53 hours in 2025. Regional CMS averages in 2025 clustered at relatively low levels (Northeastern & Midwestern 4; Southern 2.11; Western & Central 4), compared with much higher and more variable regional averages in 2023 (notably Western & Central 34.67). For CAP/Other, the reported follow-up time remained low in both years, increasing modestly from 10 hour (2023) to 20 hours (2025). Overall, these results suggest that while follow-up requests remained common for a subset of respondents, the average time required to address them was markedly lower in 2025, particularly for CMS surveys.

Table 13. Average Hours Spent on Post-survey Data Request by Year, Accrediting Agency and Region (Year-over-year)

Agency	Region	2023	2025
CMS	Northeastern & Midwestern	1.50	4
	Southern	12.67	2.11
	Western & Central	34.67	4
	CMS Overall	**14.80**	**3.53**
CAP or Other	Northeastern & Midwestern	-	30
	Southern	-	-
	Western & Central	10	0
	CAP or Other Overall	**10**	**20**
Overall Average		**13.55**	**3.22**

Days for Receiving Final Inspection Reports

Overall, respondents reported a shorter average turnaround time for receiving the final report in 2025 (11.80 days) compared with 2023 (13.87 days). For CMS, the average decreased modestly from 13.95 days (2023) to 12.46 days (2025), while the reported range narrowed substantially—most notably, the maximum dropped from 126 days in 2023 to 30 days in 2025, suggesting fewer extreme delays among 2025 respondents; the minimum increased from 0 to 5 days, indicating that same-day receipt was not reported in 2025 for CMS.

For CAP/Other, the average also declined from 13.55 days (2023) to 10.38 days (2025), while the maximum increased from 30 to 60 days, indicating that some respondents still experienced longer waits even as the average improved. Taken together, these findings suggest modest improvement in typical report turnaround time in 2025, alongside continued variability, particularly for CAP/Other.

Table 14. Analysis of Waiting Time for Receiving Final Report (Year-over-year)

Agency	Average Days		Maximum Days		Minimum Days	
	2023	2025	2023	2025	2023	2025
CMS	13.95	**12.46**	126	30	0	5
CAP or Other	**13.55**	**10.38**	30	60	0	0
Total	**13.87**	**11.80**	**126**	**60**	**0**	**0**

CMS Report Clarity and Regulatory Traceability

For respondents with CMS surveys, the vast majority reported that the final report clearly explained the noncompliance and included a direct link to the cited regulation. Overall, 26 of 27 respondents (96%) answered Yes, while 1 respondent (4%) answered No.

Response Time to Address Deficiencies in Report

Respondents reported substantial time burden for corrective action, with clear year-over-year shifts across surveying entities. For CMS, the average hours required to respond to cited deficiencies decreased from 150.1 (2023) to 61.5 hours (2025), while the range remained wide (minimum hours of 0.3 to .5 hours; maximum of 3,000 to 700 hours), indicating that a subset of laboratories still experienced a very large workload in 2025 despite a lower overall average.

For CAP, the average dropped sharply from 305 hours (2023) to 23.5 hours (2025), and the range tightened considerably (maximum hours from 600 to 40), suggesting both lower burden and greater consistency among 2025 CAP respondents. The minimum hours increased from 10 to 15 hours.

For Other surveyors, the average increased from 11.6 hours (2023) to 26.3 hours (2025), with the maximum rising from 30 to 48 hours and the minimum remaining one hour. Overall, while average corrective-action hours declined in 2025 for CMS and CAP, the persistence of high CMS maxima indicates ongoing variability in the corrective-action workload experienced by respondents.

Table 15. Comparison of Response Time to Address Deficiencies in Report by Accrediting Agency (Year-over-year)

Agency	Average Hours		Maximum Hours		Minimum Hours	
	2023	2025	2023	2025	2023	2025
CMS	150.1	61.5	3,000	700	0.3	0.5
CAP	305	23.5	600	40	10	15
Other	11.6	26.3	30	48	1	1
Total	139.5	52.6	3,000	700	0.3	0.5

Challenging the Findings

At Closing Session

In 2025, among all respondents, five of 41 reported challenging a finding during the closing session, while 36 did not.

Within the small group who challenged a finding, most reported that the surveyor was receptive (4 Yes; 1 No), suggesting that when laboratories raised concerns about a cited issue, surveyors generally engaged with the discussion. However, the perceived outcome was mixed: only two of the five challengers reported that the discussion impacted the final report, while three reported no impact, indicating that receptiveness did not consistently translate into report changes.

Challenges were reported slightly more often under CAP/Other (3) than CMS (2), and while CAP/Other challengers uniformly perceived receptiveness (3 Yes), only one reported a resulting change in the final report (1 Yes; 2 No). Overall, the findings suggest that closing-session challenges are relatively rare and, when they occur, are often heard but do not consistently result in revisions to the final report.

Table 16. Challenging the Finding at Closing Session and the Outcome by Accrediting Agencies Type and Region

Agency	Region	Challenged Finding		Surveyor Receptive		Impacted Final Report	
		Yes	No	Yes	No	Yes	No
CMS	Northeastern & Midwestern	1	10	1	-	1	-
	Southern	-	6	-	-	-	-
	Western & Central	1	10	-	1	-	1
	Total	2	26	1	1	1	1
CAP or Other	Northeastern & Midwestern	1	2	1		1	
	Southern	-	2	-	-	-	-
	Western & Central	2	6	2	-	-	2
	Total	3	10	3	-	1	2
Overall		5	36	4	1	2	3

After Receiving the Final Report

Following receipt of the final report in 2025, reported post-report actions were concentrated entirely among CAP/Other respondents. Specifically, three CAP/Other laboratories indicated they challenged a finding, reported the surveyor was receptive, and stated that the issue impacted the final report; these responses were distributed evenly across regions (one each in Northeastern & Midwestern, Southern and Western & Central).

In contrast, no CMS respondents reported challenging a finding after receiving the final report (all 28 CMS responses fall under "No" for the challenged-finding item, with no corresponding "Yes" entries for receptiveness or impact). Overall, these results suggest that, among respondents, post-report challenges were rare and—when they occurred—were reported only in CAP/Other settings and were consistently associated with a receptive response and a perceived change to the final report.

Table 17. Challenging the Finding After Receiving the Final Report and its Outcome by Accrediting Agencies Type and Region

Agency	Region	Challenged Finding		Surveyor Receptive		Impacted Final Report	
		Yes	No	Yes	No	Yes	No
CMS	Northeastern & Midwestern	-	11	-	-	-	-
	Southern	-	6	-	-	-	-
	Western & Central	-	11	-	-	-	-
	Total	**0**	**28**	**0**	**0**	**0**	**0**
CAP or Other	Northeastern & Midwestern	1	2	1	-	1	-
	Southern	**1**	**1**	**1**	-	**1**	-
	Western & Central	**1**	7	**1**	-	**1**	-
	Total	**3**	**10**	**3**	**0**	**3**	**0**
Overall		**3**	**38**	**3**	**0**	**3**	**0**

Assessment of Surveyors' Performance

Overall Impressions

The following analysis represents a comparative review of respondent agreement levels from 2023 to 2025 regarding the conduct and expertise of the survey/inspection teams. Percentage scores were calculated by aggregating "Strongly Agree" and "Agree" responses and dividing by the total number of Likert-scale entries (n) for each respective category. This metric provides a clear "Net Agreement" score to evaluate performance trends across eight core competencies.

While performance remains generally high, 2025 saw a divergence in trends: State Surveyors reached a perfect 100% across nearly all metrics, while CMS Surveyors and Inspectors experienced noticeable declines in several key areas.

- **Professionalism & Conduct:** This remains a strong domain, though it saw a slight downward trend for two cohorts. **CMS Surveyors** dropped from **98.9% in 2023 to 95.5% in 2025**, and **Inspectors** shifted from a perfect **100% down to 97.1%**. Conversely, **State Surveyors** maintained a flawless 100% rating year-over-year. Despite these minor dips, professionalism during and after the onsite survey remains the most consistently high-performing category.

- **Regulatory Knowledge:** Perception of regulatory expertise showed significant shifts. **CMS Surveyors** saw a slight decrease from **96.6% to 93.8%**, but they now hold a substantial advantage over the Inspector cohort. The **Inspector** group experienced a sharp decline, falling from **100% in 2023 to 82.9%** in 2025 ($17.1% decrease). In contrast, **State Surveyors** showed the most improvement in this area, rising from **87.5% to 100%**.

- **Deficiency Communication:** A significant divergence was observed in closing session metrics between 2023 and 2025. **CMS Surveyors** saw their effectiveness in communicating what deficiencies were observed drop from **97.1% to 86.2%**. **Inspectors** remained highly effective at communicating what was observed (**96.9%**), yet they struggled to explain why deficiencies were cited, dropping from **93.3% in 2023 to 81.3% in 2025**. Meanwhile, **State Surveyors** made massive gains, moving from **80.0% to 100%** in communicating "What" and from **85.7% to 100%** in communicating "Why."

- **Technical Assistance (How to Address Deficiencies):** This category represents the most significant area for growth. While **CMS Surveyors** remained relatively stable (**92.6% to 91.2%**), the **Inspector** cohort saw a major decline, plummeting from 9**3.8% in 2023 to 74.1% in 2025**. This 19.7% drop suggests a growing gap in the Inspector cohort's ability to provide actionable remediation guidance. In contrast, **State Surveyors** achieved and maintained a perfect 100% in this category for 2025.

The data indicates that while **State Surveyors** have successfully closed all previous performance gaps to reach 100% agreement, the **Inspector** cohort is facing a downward trend in technical domains, particularly in regulatory knowledge and remediation guidance. **CMS Surveyors** remain the most consistent overall, though the 2025 data suggests a need to refocus on the clarity of communication during closing sessions to reverse the ~10% drop in "What" and "Why" deficiency reporting.

Table 18. Summary of Respondents' Impressions, Perceptions and Experiences by Surveyor and Year

Impressions	CMS Surveyor		Inspector		State Surveyor	
	2023	2025	2023	2025	2023	2025
The surveyor was professional throughout the onsite inspection.	99%	96%	100%	97%	100%	100%
The surveyor accurately demonstrated their knowledge of the regulations.	97%	92%	100%	**83%**	**88%**	100%
The surveyor demonstrated a clear understanding of my laboratory's Quality Management System.	97%	93%	100%	**83%**	100%	100%
The surveyor answered questions about the interpretation of regulations.	90%	90%	100%	**79%**	93%	100%
The surveyor answered questions on how to address deficiencies.	93%	91%	94%	**74%**	100%	100%
During the closing session, the surveyor clearly communicated WHAT deficiencies were observed.	97%	**86%**	100%	97%	**80%**	100%
During the closing session, the surveyor clearly communicated WHY the deficiencies will be cited.	99%	**89%**	93%	**81%**	**86%**	100%
The surveyor was professional in follow-up communications after the onsite survey.	97%	95%	100%	100%	100%	100%

The regional data highlights a distinct divergence in performance trends across the three geographic sectors from 2023 to 2025. While the **Northeastern and Midwestern** region showed remarkable improvement in the "CAP Other" category—specifically regarding technical assistance on deficiencies, which doubled from **50% to 100%**, the **Southern** and **Western & Central** regions experienced notable declines in "CAP Other" performance. For example, in the Southern region, "CAP Other" agreement on answering regulatory interpretation questions plummeted from **100% to 60%**. Meanwhile, **CMS** performance remained relatively stable across all regions, generally maintaining high scores in the **80-100%** range, though professional conduct scores saw a slight dip in the **Northeastern & Midwestern** sectors.

Communication during the closing session emerged as a regional pain point in 2025, particularly regarding the rationale behind citations. In the **Western & Central** region, the "CAP Other" cohort saw a significant drop in communicating "Why" deficiencies were cited, falling from **100% to 68.8%**. This trend was mirrored in the Southern region, where the same metric dropped to 80.0%. These regional fluctuations suggest that while **CMS** surveyors maintain a consistent national standard, "CAP Other" inspectors face localized challenges in technical communication and regulatory guidance. A full breakdown of these regional metrics, including year-over-year percentage changes for every competency, is available in Table 19 on page 20.

Final Comments

Critical Areas of Laboratory Operations in Surveys

The following report summarizes feedback from laboratory professionals regarding the most critical areas that should be examined during every survey. This qualitative data highlights a strong emphasis on workforce competency, quality management systems and procedural integrity.

Note: Responses were analyzed using a multi-label thematic coding approach, allowing a single response to be associated with multiple themes. A total of 38 responses were examined, with 36 containing substantive content and two classified as "N/A / no opinion." The counts reflect the frequency of theme mentions rather than their level of prioritization.

Analysis of open-ended responses indicates that laboratory staff view Personnel Qualifications and Competency as the single most vital component of survey oversight. This is closely followed by a focus on Quality Systems (specifically Subpart K), which includes validation, verification, and corrective actions. Professionals also emphasized the importance of ensuring that Quality Management Systems (QMS) meet both federal CFR requirements and the specific operational needs of the laboratory's jurisdiction.

Key Themes and Priority Areas

- **Workforce Competency and Personnel (Subpart M) (24 mentions):** A significant majority of respondents identified personnel-related factors as a top priority for survey examination.
- **Quality Systems and Analytic Integrity (Subpart K) (24 mentions):** Respondents frequently cited elements of the analytical process and quality control as essential survey targets.
- **Proficiency Testing (PT) (10 mentions):** PT was identified as a critical external measure of laboratory performance that must be scrutinized.
- **Operational Adherence to SOPs (8 mentions):** Consistency between written policy and actual practice was a recurring theme.
- **Pre/Post-Analytic Process (9 mentions):** Specimen receiving, temperature logs, and final reporting.
- **Other (Safety/General) (6 mentions)**

Additional Information

This section of the report synthesizes qualitative feedback from respondents regarding their most recent inspection experiences. The responses highlight a shift toward specimen integrity and environmental monitoring and data accessibility, alongside concerns regarding the consistency and tone of federal oversight.

Analysis of open-ended questions on additional information about the onsite inspection reveals that while many laboratories view surveys as a professional and constructive "quality improvement partnership," there is significant

anxiety regarding **subjective interpretations** of regulations. Specifically, laboratories noted a heightened focus on **Environmental and Temperature Monitoring**, which has recently led to more stringent specimen rejection requirements.

Key Themes and Frequency of Mention

The following table categorizes 31 distinct responses to identify the most prevalent issues facing public health laboratories (PHLs) during inspections.

Theme	Frequency	Description of Feedback
Surveyor Professionalism and Tone	11	Descriptions range from "very professional" and "insightful" to "unorganized" or focused on a "gotcha" audit tone.
Consistency and Subjectivity	9	Concerns over differing interpretations among the 10 nationwide surveyors and a lack of communication between CMS and state offices.
Temperature and Environment	7	A "hot topic" involving increased scrutiny of humidity and temperature monitoring systems for equipment and specimens.
Documentation and System Access	5	Challenges with providing electronic documents quickly and surveyors requesting extended access to document control systems.
Process Improvement/ Learning	5	Requests for CMS to adopt more "supportive enforcement" or "learning experience" strategies rather than immediate citations.
Peer Review and CAP Benefits	4	Suggestions that CAP using peer-to-peer (PHL to PHL) inspections provide more relevant, specialized context.

Detailed Findings

1. The Consistency Challenge

Respondents noted that CMS surveyors may not meet internally to align their interpretations, leading to “different interpretations/opinions” on how tasks should be performed. This lack of standardization makes it difficult for laboratories to prepare effectively.

2. Increased Rigor in Specimen Temperature Monitoring

A critical area of recent friction involves Specimen Rejection Policy. Laboratories reported being told to reject any specimens arriving outside of temperature range, regardless of disclaimers—a shift that one respondent noted was implemented “to the anguish of many colleagues”.

3. Digital Vulnerabilities

As laboratories move to electronic systems, surveyors are requesting deeper and longer access to these databases. One respondent expressed feeling in a “vulnerable position” when asked to provide access beyond the onsite survey duration, highlighting a need for clearer boundaries in the digital age.

4. Constructive Engagement

Despite technical challenges, several laboratories reported highly positive experiences where surveyors acted as a “quality improvement partnership”. These labs emphasized that using the APHL CLIA Checklist prior to the survey was key to achieving minimal findings.

Appendix

Table 19. Summary of Respondents' Impressions, Perceptions and Experiences by Surveyor, Year and Region

Impressions	Year	Northeastern & Midwestern		Southern		Western & Central	
		CMS	CAP or Other	CMS	CAP or Other	CMS	CAP or Other
The surveyor was professional throughout the onsite inspection.	2023	100%	100%	100%	100%	97%	100%
	2025	91%	100%	100%	**86%**	97%	100%
The surveyor accurately demonstrated their knowledge of the regulations.	2023	**89%**	100%	100%	100%	97%	100%
	2025	**86%**	100%	95%	**86%**	97%	**71%**
The surveyor demonstrated a clear understanding of my laboratory's Quality Management System.	2023	97%	100%	100%	100%	94%	100%
	2025	91%	100%	91%	**71%**	97%	**77%**
The surveyor answered questions about the interpretation of regulations.	2023	94%	100%	**85%**	100%	**91%**	100%
	2025	90%	100%	94%	**60%**	**89%**	**71%**
The surveyor answered questions on how to address deficiencies.	2023	**85%**	**50%**	100%	100%	100%	100%
	2025	**90%**	100%	100%	**60%**	**89%**	**69%**
During the closing session, the surveyor clearly communicated WHAT deficiencies were observed.	2023	94%	100%	**90%**	100%	100%	100%
	2025	**80%**	100%	**89%**	**80%**	90%	100%
During the closing session, the surveyor clearly communicated WHY the deficiencies will be cited.	2023	100%	**50%**	**90%**	100%	100%	100%
	2025	**80%**	**100%**	**89%**	**80%**	97%	**69%**
The surveyor was professional in follow-up communications after the onsite survey.	2023	97%	100%	100%	100%	97%	100%
	2025	90%	100%	100%	100%	97%	100%

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other health threats.

7700 Wisconsin Avenue, Suite 1000 Bethesda, MD 20814 | 240.485.2745 | aphl.org

This project was 100% funded with federal funds and supported under the Cooperative Agreement #NU60OE000103 between the US Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.