

CLIA Onsite Survey Experiences

2023 Summary Report



JANUARY 2024

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Background

APHL has received comments on member experiences regarding their recent CLIA (Clinical Laboratory Improvement Amendments) onsite survey. To better understand the scope and impact, the APHL Board of Directors established a taskforce to develop a member feedback survey. The survey was accessible from August 22 – September 12, 2023, and was distributed via the Laboratory Directors CoLABorate community (an online forum) with an additional reminder through the regional consortia. This survey was intended to be completed by the laboratory director or delegated to the quality manager/quality assurance officer.

All responses were anonymous and optional; it should be noted that **not all respondents answered all questions**. In accordance with APHL’s Data Use Policy, only de-identified aggregate data will be reported.

Data are based on public health laboratories’ experience with CLIA surveyors from the US Centers for Medicare & Medicaid Services (CMS) (data highlighted in orange in tables) and other CLIA-accrediting agencies.

Inspection Details

Respondents Demography

Out of APHL’s 110 member laboratories, 56 (51%) responded to the survey. The breakdown of responses received for each CMS region is shown below:

- Western & Central: 27/53 (51%)**
 Respondents: Alaska, Arizona, California, Guam, Hawaii, Idaho, Iowa, Kansas, Missouri, Nebraska, Colorado, Nevada, Montana, North Dakota, Northern Mariana Islands, Oregon, Samoa, South Dakota, Utah, Washington and Wyoming.
- Northeastern & Midwestern: 20/34 (59%)**
 Respondents: Connecticut, Delaware, Illinois, Indiana, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Michigan, Minnesota, Pennsylvania, Puerto Rico, Ohio, Rhode Island, US Virgin Islands, Vermont, Virginia, Washington DC, West Virginia and Wisconsin.
- Southern: 9/23 (39%)**
 Respondents: Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee and Texas.

Survey Frequency and Timing

Most of the CMS surveys occurred during 2022 and 2023, with the majority between January and May.

Table 1. 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	2021	1	-	-	1	-	-	-	-	-	-	-	-	2
	2022	-	2	1	1	5	1	2	2	1	-	2	3	20
	2023	4	-	7	4	3	1	1	2	-	-	-	-	22
	Total	5	2	8	6	8	2	3	4	1	0	2	3	44
CAP or Other	2021	-	-	-	-	-	-	1	-	-	1	-	-	2
	2022	-	1	1	2	-	1	-	-	-	-	-	-	5
	2023	-	-	-	-	1	2	1	-	-	-	-	-	4
	Total	0	1	1	2	1	3	2	0	0	1	-	-	11
Overall Total	5	3	9	8	9	5	5	4	1	1	2	3	55	

Surveyor/Inspector

44/55 (80%) of the surveys were performed directly by CMS while only 2/55 (3.6%) were surveyed by CAP, and 9/55 (16%) were surveyed by other accrediting agencies. The other agencies listed included the California Department of Public Health Laboratory Field Services, MO DHSS Auditor for CLIA Program, NYS CLEP and the State of Wisconsin Department of Health Services.

Table 2. Regional Distribution of Accrediting Agencies Conducting Assessments

Region	CAP	CMS	Other
Northeastern & Midwestern	-	17	2
Southern	1	8	-
Western & Central	1	19	7
Total	2	44	9

Test Volume

A total of 51.7 million tests were reported via CMS direct applications. The Southern Region had the highest average estimated annual test volume reported, which accounted for around 2.7 million tests. However, the Northeastern and Midwestern Region reported the maximum and minimum test volumes from a single public health laboratory.

Table 3. Comparative Analysis of Testing Volumes Across Accrediting Agencies and Regions

Agency	Region	Sum	Average	Maximum	Minimum
CMS	Northeastern & Midwestern	23,722,286	1,581,486	15,403,068	217
	Southern	21,496,441	2,687,055	7,869,433	98,615
	Western & Central	6,468,547	359,364	1,667,000	100
	CMS Overall	51,687,274	1,260,665	15,403,068	100
CAP or Other	Northeastern & Midwestern	10,713	5,357	10,713	-
	Southern	500,000	500,000	500,000	500,000
	Western & Central	7,261,978	1,037,425	6,500,000	20,000
	CAP or Other Overall	7,772,691	777,269	6,500,000	0

Laboratory Specialties/Subspecialties

Microbiology and Diagnostic Immunology were the most predominant specialties report directly on CMS applications, comprising 34% of the total. Chemistry was the third most common specialty, with 25.2% of respondents.

Newborn screening tests are conducted internally by 17/56 respondents (30%).

Table 4. Comparison of Laboratory Specialties and Subspecialties Across Accrediting Agencies and Regions

Specialty	Region	CMS	CAP or Other	Total
Microbiology	Northeastern & Midwestern	16	2	19
	Southern	8	1	9
	Western & Central	18	8	26
	Total	42	11	54
Diagnostic Immunology	Northeastern & Midwestern	16	2	19
	Southern	8	-	8
	Western & Central	18	8	26
	Total	42	10	53
Chemistry	Northeastern & Midwestern	13	-	14
	Southern	6	-	6
	Western & Central	12	3	15
	Total	31	3	35
Hematology	Northeastern & Midwestern	1	-	1
	Southern	4	-	4
	Western & Central	2	-	2
	Total	7	0	7
Immunohematology	Northeastern & Midwestern	1	-	1
	Southern	-	-	-
	Western & Central	-	-	-
	Total	1	0	1

Number of Surveyor(s)/Inspectors

Of CMS surveyors, 88/105 (83.8%) were identified as regional surveyors. The maximum number of surveyors/inspectors reported across all responses was five, with an average of two regional surveyors, two inspectors and one state surveyor.

Table 5. Distribution of Surveyors and Inspectors by Types of Accrediting Agencies

Surveyor/Inspector	CMS	CAP or Other	Total
Regional Surveyor(s)	88	-	88
State Surveyor(s)	17	-	17
Inspector(s)	-	19	19

Table 6. Distribution of Surveyors and Inspectors by Types of Accrediting Agencies and Regions

Speciality	Region	CMS	CAP or Other	Total
Northeastern & Midwestern	Regional Surveyor(s)	31	-	31
	State Surveyor(s)	6	-	6
	Inspector(s)	-	4	4
	Total	37	4	41
Southern	Northeastern & Midwestern	26	-	26
	Southern	8	-	8
	Western & Central	-	3	3
	Total	34	3	37
Western & Central	Northeastern & Midwestern	31	-	31
	Southern	3	-	3
	Western & Central	-	12	12
	Total	34	12	46

Days Surveyor(s) Remained Onsite

On average, CMS surveyors spent an average of 2.48 days onsite, compared to an average of 1.0 day for the other CLIA-accrediting agencies. For CMS, the Southern region had the longest onsite with an average 3.47 days; Northeastern & Midwestern and Western & Central regions stayed 2.35 and 2.18 days, respectively. When comparing all individual public health laboratory responses, surveyors spent a maximum of five days onsite and a minimum of one day.

Table 7. Average Days a Surveyor(s) Remained Onsite by Accrediting Agency and Region

Region	CMS	CAP or Other
Northeastern & Midwestern	2.35 days	1.50 days
Southern	3.47 days	1.50 days
Western & Central	2.18 days	0.81 days
Agency Average	2.48 days	1 day
Overall Average	2.19 days	

Citations and Level of Deficiency Received

This report specifically focuses on citations categorized as ‘condition level’ and ‘immediate jeopardy’ and does not include citations deemed as ‘standard’ deficiencies. Therefore, the data listed here do not represent total numbers of deficiencies cited. Of note:

- There were no “immediate jeopardy” citations reported by any respondents.
- Quality Systems (Subpart K) and Personnel (Subpart M) were the most cited areas by CMS and other CLIA-accrediting agencies. For CMS, Quality Systems (Subpart K) and Personnel (Subpart M) were the most cited areas with 64.4 and 21.1%, respectively.
- On average, CMS issues 1.77 citations per respondent, compared to other CLIA-accrediting agencies at 1.09 citations. When comparing citation rate per public health laboratory (responses to this survey) per region, the NM&MW region had the highest citation rate at 2.14 citations per public health laboratory.

Table 8. CMS Citations by Region

Region	Number of PHLs	Total Citations	Citations per PHL
Northeastern & Midwestern	17	47	2.14
Southern	8	9	1.12
Western & Central	19	22	1.16

Table 9. Comparison of Citations by Type of Accrediting Agency

Citation Type	CMS	CAP or Other	Total
Facility Administration (Subpart J)	2	1	3
General Administration (Subpart F)	-	1	1
Other (please describe)	3	-	3
Personnel (Subpart M)	14	5	19
Proficiency testing (Subparts H or I)	4	2	6
Quality Systems (Subpart K)	55	3	58
Total Citations	78	12	90
Number of Responses	44	11	55
Average Citation Per Agency Type	1.77	1.09	1.63

Table 10. Disparities in Citations and Deficiency Levels by Accrediting Agency and Region

Citation Type	Region	CMS	CAP or Other	Total
Facility Administration (Subpart J)	Northeastern & Midwestern	2	-	2
	Southern	-	-	0
	Western & Central	-	1	1
	Total	2	1	3
General Administration (Subpart F)	Northeastern & Midwestern	-	-	0
	Southern	-	1	1
	Western & Central	-	-	0
	Total	0	1	1
Personnel (Subpart M)	Northeastern & Midwestern	10	-	10
	Southern	1	1	2
	Western & Central	3	4	7
	Total	14	5	19
Proficiency testing (Subparts H or I)	Northeastern & Midwestern	3	2	5
	Southern	1	-	1
	Western & Central	-	-	0
	Total	4	2	6
Quality Systems (Subpart K)	Northeastern & Midwestern	30	-	30
	Southern	7	2	9
	Western & Central	18	1	19
	Total	55	3	58
Other	Northeastern & Midwestern	2	-	2
	Southern	-	-	0
	Western & Central	1	-	1
	Total	3	0	3
Overall Total		78	12	90

Managing Data and Information Requests Following an Onsite Survey

11/55 (20%) survey respondents reported that they needed to address additional surveyor questions with data or information following the onsite survey. Moreover, when the data is compared by an accrediting agency, 10 of the 11 requests came from the CMS.

Post-survey data requests requires time, both from the accrediting agencies and the laboratories. On average, CMS dedicated 14.8 hours to post-survey data requests, while other CLIA- accrediting agencies spent approximately 1.0 hour. On average, the laboratories from the Western & Central and Southern regions reported spending the most hours on post-survey data requests, with 34.67 and 12.67 hours, respectively; maximum hours for the Northeastern & Midwestern, Southern and Western & Central regions were 4.0, 30.0 and 80.0 hours, respectively.

Table 11. Average Hours Spent on Post-survey Data Request by Accrediting Agency

Agency	Average Hours	Maximum Hours	Minimum Hours
CMS	14.80	80.00	1.00
CAP or Other	1.00	1.00	1.00
Overall	13.55	80.00	1.00

Table 12. Average Hours Spent on Post-survey Data Request by Accrediting Agency and Region

Agency	Region	Average Hours
CMS	Northeastern & Midwestern	1.50
	Southern	12.67
	Western & Central	34.67
	CMS Overall	14.80
CAP or Other	Northeastern & Midwestern	-
	Southern	-
	Western & Central	1.00
	CAP or Other Overall	1.00
Overall		13.55

Days for Receiving Final Inspection Reports

Overall, average days to receiving final reports were similar between CMS and other CLIA- accrediting agencies:

- **Northeastern & Midwestern Region:** The average time to receive the final inspection report is relatively shorter, with the fastest report received within two days and the longest taking up to 30 days.
- **Southern Region:** Conversely, the Southern region shows a longer average time for receiving the final inspection report, ranging from five to 34 days.
- **Western & Central Region:** The average time for report delivery is moderate, with a notable outlier of 126 days for the maximum time taken to one day of minimum time.

Table 13. Accrediting Agency and Regional Analysis of Average Waiting Time for Receiving Report

Agency	Region	Average Days	Maximum Days	Minimum Days
CMS	Northeastern & Midwestern	10.65	21	2
	Southern	21.00	34	5
	Western & Central	14.32	126	1
	CMS Overall	13.95	126	1
CAP or Other	Northeastern & Midwestern	16.00	30	2
	Southern	30.00	30	30
	Western & Central	10.88	30	1
	CAP or Other Overall	13.55	30	1
Overall		13.87	126	1

Hours Response Time to Address Deficiencies in Report

Overall, respondents spent on average of over 103 hours responding to CMS deficiencies, as compared to other CLIA-accrediting agencies at about 60 hrs.

- **Northeastern & Midwestern Region:** Respondents took an average of 27.26 hours to respond to deficiencies cited in the final report. The maximum response time recorded in this region was 210 hours.
- **Southern Region:** The average response time was significantly higher at 532.14 hours. The maximum response time observed in the Southern region was 3,000 hours, indicating substantial variations in response times.
- **Western & Central Region:** Respondents had an average response time of 28.81 hours. The maximum response time recorded in this region was 240.00 hours, which is relatively lower than the Southern region's maximum response time.

Table 14. Comparison of Response Time to Address Deficiencies in Report by Accrediting Agency

Agency	Average Hours	Maximum Hours	Minimum Hours
CMS	103.64	3,000	1
CAP or Other	60.73	600	1
Overall	94.74	3,000	1

Table 15. Analysis of Response Times to Address Report Deficiencies by Accrediting Agency and Region

Agency	Region	Average Hours	Maximum Hours	Minimum Hours
CMS	Northeastern & Midwestern	27.53	210	2
	Southern	520.83	3,000	10
	Western & Central	40	240	12
	CMS Overall	103.64	3,000	2
CAP or Other	Northeastern & Midwestern	25	30	20
	Southern	600	600	600
	Western & Central	2.25	10	1
	CAP or Other Overall	60.73	600	1
Overall		94.74	3,000	1

Assessment of Surveyors' Performance

Overall Impressions

The tables below represent the findings and analysis of survey responses regarding the performance of regional surveyors, state surveyors and inspectors based on their most recent onsite surveys. Respondents were asked to rate their level of agreement with various statements related to the surveyors' professionalism, knowledge and communication skills. Percent responses are based on respondents who selected "Strongly Agree" and "Agree" to obtain the summary level of agreement.

- Performance by surveyor type:
 - Overall, state surveyors received lower scores than regional surveyors and inspectors in the areas of knowledge of regulations, clarity in communicating observed deficiencies and providing clear reasons for citing the deficiencies.
 - Regional surveyors, when compared to state surveyors and inspectors, had room for improvement in providing clarity on the interpretation of regulations and guidance on addressing deficiencies.
- Performance by region and agency:
 - Southern and Western & Central regions: CMS surveyors in these regions were rated lower than those from other CLIA-accrediting agencies.
 - Southern region: CMS surveyors scored lower than CMS surveyors from the Northeastern & Midwestern and Western & Central regions.
- Opportunities for improvement:
 - Opportunities for improvement are evident for CMS across all regions. These include the need for a more accurate demonstration of their knowledge regarding regulations. Additionally, there are areas where improvement can be made, such as providing clear responses to questions related to the interpretation of regulations, offering guidance on addressing deficiencies, articulating both what deficiencies were observed and explaining why these deficiencies will be cited.
 - In the context of CLIA-accrediting agencies within the Northeastern & Midwestern region, there are notable areas where improvement opportunities exist. These opportunities pertain to addressing deficiencies comprehensively and enhancing the clarity of communication regarding the reasons behind citing deficiencies. It's noteworthy that both of these aspects received a score of 50%.

Table 16. Summary of Respondents' Impressions, Perceptions and Experiences

Impressions	Regional Surveyors	State Surveyors	Inspectors
The surveyor was professional throughout the onsite inspection.	98%	100%	100%
The surveyor accurately demonstrated their knowledge of the regulations.	93%	88%	100%
The surveyor answered questions about the interpretation of regulations.	90%	93%	100%
The surveyor answered questions on how to address deficiencies.	90%	100%	94%
During the closing session, the surveyor clearly communicated WHAT deficiencies were observed.	94%	80%	100%
During the closing session, the surveyor clearly communicated WHY the deficiencies will be cited.	97%	86%	93%
The surveyor was professional in follow-up communications after the onsite survey.	95%	100%	100%
The surveyor demonstrated a clear understanding of my laboratory's Quality Management System.	95%	100%	100%

Table 17. Regional Summaries of Respondents' Impressions

Impressions	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.	100%	100%	100%	100%	97%	100%
The surveyor accurately demonstrated their knowledge of the regulations.	89%	100%	100%	100%	97%	100%
The surveyor answered questions about the interpretation of regulations.	94%	100%	85%	100%	91%	100%
The surveyor answered questions on how to address deficiencies.	85%	50%	100%	100%	100%	100%
During the closing session, the surveyor clearly communicated WHAT deficiencies were observed.	94%	100%	90%	100%	100%	100%
During the closing session, the surveyor clearly communicated WHY the deficiencies will be cited.	100%	50%	90%	100%	100%	100%
The surveyor was professional in follow-up communications after the onsite survey.	97%	100%	100%	100%	97%	100%
The surveyor demonstrated a clear understanding of my laboratory's Quality Management System.	97%	100%	100%	100%	94%	100%

Challenging the Findings

At Closing Session

Overall, only 5/55 (9%) respondents challenged the findings. Most of these respondents stated that the surveyor was understanding of their concerns however it did not impact their final report.

Two respondents who used the other CLIA-accrediting agencies reported challenging findings and the results positively impacted their final report:

- *“Discussed how/where we tracked data and why it wouldn’t be in the location expected by the regulator. Quickly showed the surveyor where we locate the requested information.”*
- *“There was a deficiency that was cited that was discussed by the inspection team leader with the quality manager prior to the closing meeting. I was able to provide the requested records and demonstrate the lab’s compliance with the requirement at the eleventh hour. This citation was removed.”*

Table 18. 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	16	-	1	1	-
	Southern	1	7	1	-	1	-
	Western & Central	1	18	1	-	1	-
	Total	3	41	2	1	3	0
CAP or Other	Northeastern & Midwestern	-	2	-	-	-	-
	Southern	-	1	-	-	-	-
	Western & Central	2	6	2	2	-	-
	Total	2	9	2	0	2	0
Overall		5	50	4	1	5	0

After Receiving the Final Report

Overall, only 3/55 (5%) respondents disputed the findings after receiving the final report. Two of these respondents did not believe the surveyor was open to their challenge. Only one of the three respondents who questioned the results and who used the other CLIA-accredited agencies mentioned that their challenge had any impact on the final report: *“With CAP inspections, most disagreements in an inspection report are not addressed during the inspection. We challenged three of our deficiencies and two of them were removed from our record with CAP.”*

Table 19. Challenging the Finding After Receiving 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	-	17	-	-	-	-
	Southern	-	8	-	-	-	-
	Western & Central	2	17	1	1	1	2
	Total	2	42	1	1	1	2
CAP or Other	Northeastern & Midwestern	-	2	-	-	-	-
	Southern	-	1	-	-	-	-
	Western & Central	1	7	1	-	1	-
	Total	1	10	1	0	1	0
Overall		3	52	2	1	2	2

Unexpected Findings in the Final Report

3/55 (5%) respondents reported that they had found unexpected findings in the final report, all from the CMS and one across each region.

Table 20. Number of Public Health Laboratories with Unexpected Findings in the Final Report

Agency	Region	Yes	No
CMS	Northeastern & Midwestern	1	16
	Southern	1	7
	Western & Central	1	18
	Total	3	41
CAP or Other	Northeastern & Midwestern	-	2
	Southern	-	1
	Western & Central	-	8
	Total	0	11
Overall		3	52

Final Comments

Critical Areas of Laboratory Operations in Surveys

Responding to the question about the critical areas of laboratory operations that should be examined in every survey, the respondents mentioned a wide range of topics. Below is a summary of these topics, along with the number of mentions for each:

- Pre-Analytical, Analytical and Post-Analytical Processes (12)
- Competency, Proficiency and Personnel Records (11)
- Quality Management System (QMS) and Quality Control (QC) (11)
- Validation and Verification (10)
- Standard Operating Procedures (SOPs) and Documentation (9)
- Proficiency Testing (PT) (9)
- Nonconformance, Corrective Actions and Complaint Handling (8)
- Laboratory Information Management System (LIMS) (4)
- Equipment Maintenance and Performance Monitoring (3)
- Turnaround Time (TAT) and Sample Handling (3)
- Specimen Receiving and Handling (3)
- Microbiology and Virology Departments (2)
- System-Level Assessment (2)
- Regulatory Compliance (2)
- Random Test Sample Selection and QA (2)
- Record Management (2)
- Specimen Temperature Control (1)
- Educational Requirements (1)
- Instruments Preventive Maintenance (PM) (1)
- Those Traditionally Examined by CMS in CLIA Inspections (1)

Additional Information

This summary below is based on an analysis of open-ended responses provided by respondents regarding their laboratory's most recent CLIA survey or other onsite inspection. While many respondents had positive experiences and appreciated the collaboration with surveyors, concerns were raised regarding CLIA requirements, regulations interpretation and the impact on laboratory personnel. These insights can inform discussions and potential improvements in the CLIA survey process, with a focus on consistency in interpretation, clearer communication and addressing specific challenges faced by laboratories, especially in remote or unique settings.

Note: The number of mentions for each topic is based on the frequency respondents raised the issue in their open-ended responses.

- **Positive Surveyor Experience (10):** Respondents highlighted many positive aspects of their onsite inspection experiences with their surveyors that included respect and professionalism, with clear communications and expectations. Many recognized and valued surveyor recommendations for improvements and sharing of best practices, as well as actual laboratory experience and demonstrated in-depth knowledge of CLIA regulations. All respondents acknowledged the collaborative nature, with inspections treated as a partnership where we both had a vested interest and desire for the laboratory to conduct high-quality testing. One respondent noted that the inspections have led to improvements in their laboratory and decrease in deficiencies over time.
- **Concerns with Personnel Qualifications (5):** Several respondents expressed concerns about specific CLIA requirements and excessive focus on Personnel Qualifications. Several respondents noted those related to the qualifications of Laboratory Directors as being too specific. Others commented on inconsistencies in surveyor comments regarding competencies as compared to CMS publications or inconsistencies in what was acceptable from previous surveyors related to personnel education and experience that are now not accepted. Some questioned why experience in a CLIA laboratory is not considered valuable, while others questioned why surveyors do not accept some classes or community college certificates. One respondent noted that the surveyor's findings on their personnel had a significant negative impact on morale and will influence the ability to hire.
- **Concerns with Interpretation of Other Regulations (8):** Respondents shared how surveyors interpretation of findings affected their inspection. Three respondents noted inconsistencies in interpreting CLIA regulations regarding QA, one noted the subjectivity in temperature/humidity of samples and one note inconsistencies of surveyors on deficiencies for previously accepted policies and procedures. Several respondents commented on their concern of the subjectivity of interpretation and the need of surveyors to focus on asking labs how they comply rather than prescribing compliance methods. One respondent suggested the need for checklists to make inspections more educational and less investigative.
- **Document Control and Inspection Logistics (2):** Two respondents mentioned logistical aspects of inspections, such as inspectors requesting additional time to review document control systems and the presence of multiple surveyors during inspections.
- **APHL Survey Improvement (1):** One respondent suggested changes in the APHL survey to improve the deficiency matrix reporting table.
- **CAP vs. CMS (1):** One respondent commented that their experience with CAP was a more collaborative inspection process than CMS and recommended this accrediting agency, citing additional benefits to share knowledge between public health laboratory professionals to support each.

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 diverse health threats.

This publication was supported by Cooperative Agreement number #NU600E000104, funded by the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or the Department of Health and Human Services.



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