Pediatric Lead Testing Capability and Capacity

2023 Survey Summary Report

APRIL 2024

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

CONTENTS

INTRODUCTION

According to the US Centers for Disease Control and Prevention (CDC), a blood lead test is the best way to find out if a child has lead poisoning. In October 2021, CDC reduced their blood lead reference value (BLRV) from 5 to 3.5 ug/dL in an attempt to identify lead poisoning at lower levels.

Pediatric Lead Testing: For this survey, pediatric lead testing is defined as any blood test on a child less than six years old.

State and local public health laboratories play a major role in blood lead testing in the US, but their involvement varies by jurisdiction. The Association of Public Health Laboratories (APHL) conducted their Pediatric Lead Testing Capability and Capacity Survey in the spring of 2023 to assess the analytical capability and capacity of public health laboratories to perform blood lead testing, the status of their pediatric testing programs, and the desire of public health laboratories to develop or expand childhood lead testing programs should funding become available. APHL was particularly interested in changes to pre-analytical, analytical and post-analytical practices following CDC's BLRV reduction.

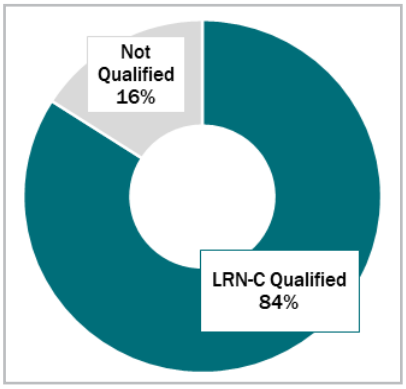
Parameter	Details
Survey Field Date	**March 22, 2023 – June 2, 2023**
Target Population	**112 APHL member public health laboratories**
Total Response Rate	**63% (70/112)**
State Laboratories Response Rate	**85% (44/52 [50 states, DC and American Samoa])**
Local Laboratories Response Rate	**41% (26/63)**

RESULTS

LRN-C Program Qualification Status for Blood Metals Panel Testing in Laboratories

Among the 44 state laboratory respondents, 37 (84%) indicated that they are currently qualified by the Laboratory Response Network for Chemical Threats (LRN-C) program to perform the LRN-C blood metals panel (**Figure 1**).

Figure 1. LRN-C Program Qualification Status for Blood Metals Panel Testing in Laboratories (n= 44 state laboratories)



Mandated Pediatric Lead Testing in Laboratory Jurisdictions

Over half of responding laboratories (42/70, 60%) reported that pediatric lead testing is mandated in their laboratory's jurisdiction. Explicit requirements for their testing are outlined in **Table 1**. Seven respondents (10%) cited other reasons for mandated testing in their jurisdictions:

- **Risk-Based Questionnaires:** A risk-based questionnaire can be used to assess the likelihood of lead exposure.
- **House's Age:** The age of the child's residence (e.g., built before 1978) can be a criterion for lead testing mandates.
- **Preschool Entry:** Lead testing may be required for children before entering childcare and/or school.
- Other reasons included geographic location and refugee status.

Table 1. Mandated pediatric lead testing in laboratory jurisdiction (n=70; 44 state, 26 local laboratories)

Mandated pediatric lead testing	#	%
Yes, for all children in a specified age range and/or geographic area	25	36%
Yes, only for children enrolled in Medicaid programs	10	14%
Yes, other reasons - please specify.	7	10%
I don't know	18	26%
No	10	14%
Total	**70**	**100%**

Pediatric Lead Testing Practices in Laboratories

Of the 70 laboratories surveyed, 36% (25) reported conducting routine pediatric lead testing, while 7% (5) only perform such testing in emergency situations and one laboratory (1%) provides reference laboratory service. Over half the laboratories (56%, 39/70) do not perform routine pediatric lead testing (**Figure 2**). **Table 2** provides a comprehensive breakdown of the responses, stratified by laboratory type.

Figure 2. Performance of routine pediatric lead testing (n=70; 44 state, 26 local laboratories)

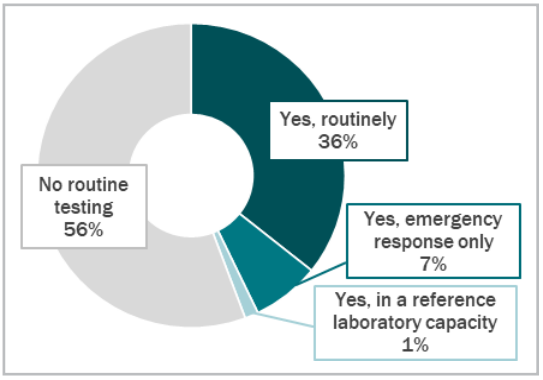


Table 2. Performance of routine pediatric lead testing by laboratory type (n=70; 44 state, 26 local laboratories)

Performing pediatric lead testing?	Laboratory Type	#	%
Yes, routinely	Local	10	14%
	State	15	21%
	Total	25	36%
Yes, emergency response only	Local	2	3%
	State	3	4%
	Total	5	7%
Yes, in a reference laboratory capacity	Local	0	0%
	State	1	1%
	Total	1	1%
No	Local	14	17%
	State	25	39%
	Total	39	56%
Total		**70**	**100%**

Historic Pediatric Lead Testing Practices in Laboratories

Of the 39 laboratories that do not currently perform lead testing, only 12 (31%) reported previously performing routine pediatric lead testing, while 69% (27/39) had either never conducted routine lead testing (56%, 22/39) or were uncertain about their historical practices (13%, 5/39).

As detailed in **Table 3**, laboratories that had discontinued routine pediatric lead testing did so primarily due to resource limitations and an insufficient demand for testing services. Other reasons included: lower costs in the private sector, instrumentation problems and multiple recalls of waived tests over a decade, which required significant effort for patient follow-up and recall.

Table 3. Reasons for Discontinuing Pediatric Lead Testing (n=38; 24 state, 14 local laboratories)

Reasons for Discontinuing Pediatric Lead Testing	#	%
Resource limitations	11	29%
Insufficient demand for testing services	10	26%
Reimbursement challenges, like Medicaid or medical billing	4	11%
Competing priorities	2	5%
Other	15	39%
I don't know	9	24%

Note: Respondents could select more than one reason.

Locational Requirements for Pediatric Lead Testing

When asked about requirements about where pediatric lead testing takes place within their jurisdiction, no respondents were aware of a specific requirement that testing must be performed at a public health laboratory, though two were unsure (**Table 4**). Despite not having a specific mandate, the majority of jurisdictions did conduct at least some of their pediatric lead testing at a public health laboratory (27/31), but physicians and commercial laboratories were also common testing locations (22/31 each). Other testing locations included clinic and hospital laboratories (**Table 5**).

Table 4. Requirement for pediatric lead testing to be performed at a public health laboratory (n=31)

Requirement to Conduct Pediatric Lead Testing at Public Health Laboratory	#	%
Yes	0	0%
No	29	94%
I don't know	2	6%
Total	**31**	**100%**

Table 5. Locations for Pediatric Lead Testing in Jurisdictions (n=31)

Location of Pediatric Lead Testing	#	%
Public health laboratories	27	69%
Physician offices	22	56%
Commercial laboratories	22	56%
Other	8	21%

Test Methods and Instrumentation

Only those laboratories that currently conduct routine pediatric lead testing (30 total*; 19 state, 11 local) provided data for this section.

Table 6 outlines the responding laboratories' average, minimum and maximum detection and reporting limits for a variety of testing platforms used for lead testing. **Figures 3-5** illustrate how the reported limits for each platform compare the CDC blood lead reference value of 3.5 µg/dL.

Table 6. Testing platform detection and reporting limits by laboratory type (n= 30; 19 state, 11 local)

Testing Platform	Laboratory Type	Detection Limit (ug/dL)			Reporting Limit (ug/dL)		
		Mean	Min.	Max.	Mean	Min.	Max.
Inductively Coupled Plasma/Mass Spectrometry (ICP/MS)	**State**	0.42	0.03	2.00	1.13	0.03	3.50
	Local	1.00	0.01	2.00	1.51	0.03	3.50
Graphite Furnace Atomic Absorption Spectroscopy (GFAAS)	**State**	1.02	0.20	2.00	1.60	0.20	3.00
	Local	1.00	1.00	1.00	2.50	1.00	3.50
LeadCare II® *, ** (CLIA waived, point of care instrument)	**Local**	3.30	3.30	3.30	3.37	3.30	3.50
LeadCare Plus® *, ** (benchtop instrument)	**Local**	3.30	3.30	3.30	3.50	3.50	3.50

* A single outlier was removed from the calculated values

** According to FDA, the detection limit and reporting limit for LeadCare II® is 3.3 ug/dL and LeadCare Plus® is 1.9 ug/dL

Figure 3. Average ICP/MS Detection and Reporting Limits

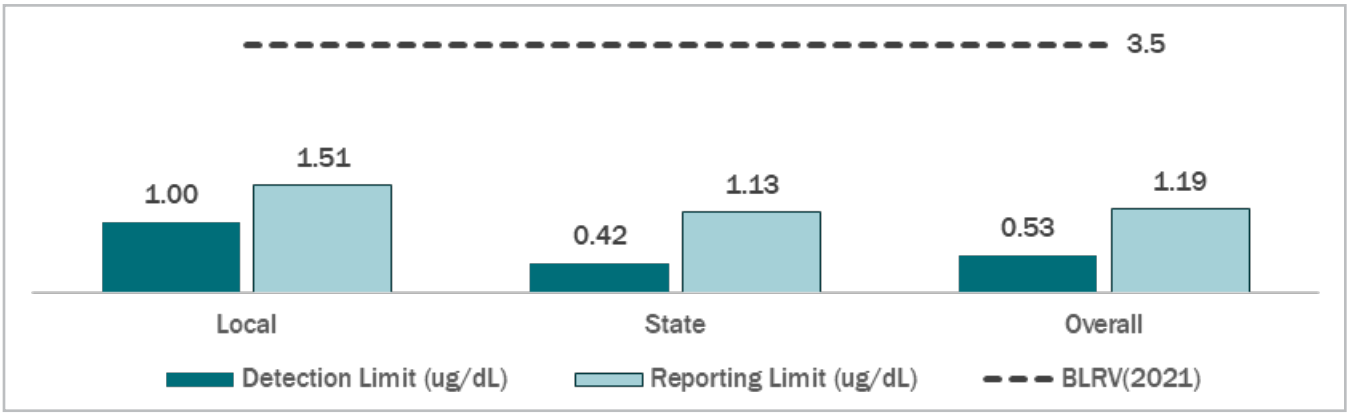


Figure 4. Average GFAAS Detection and Reporting Limits

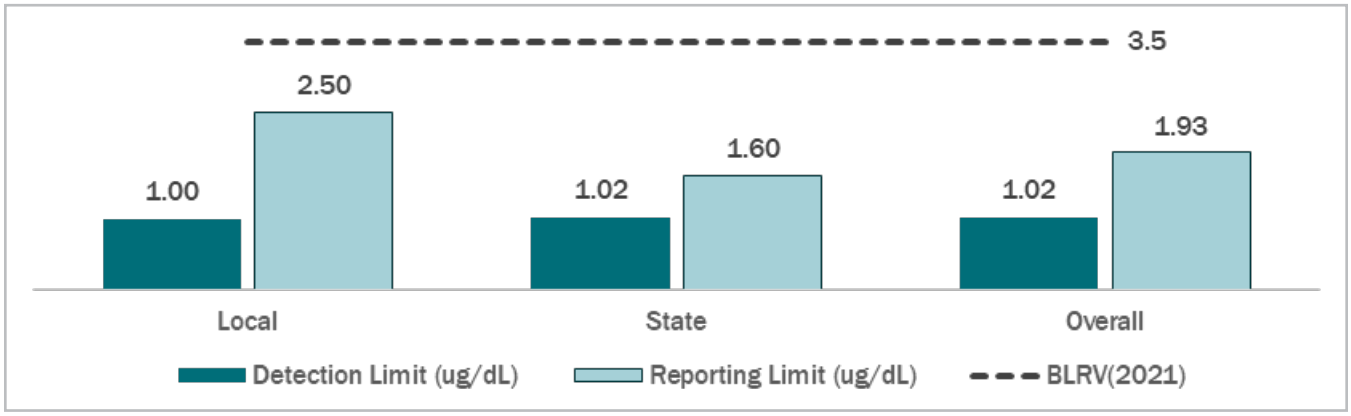
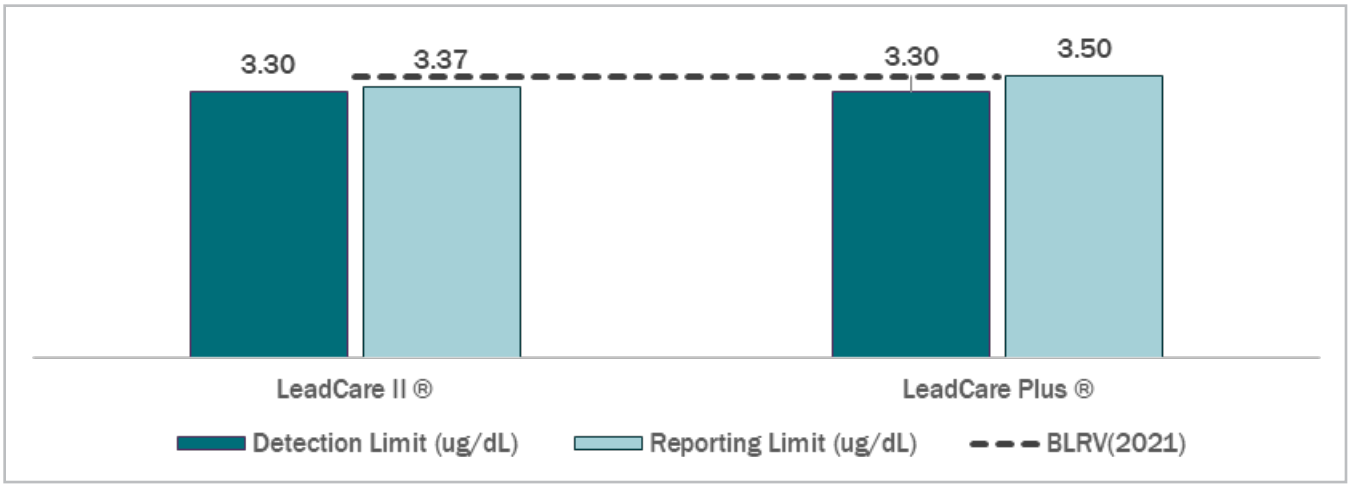


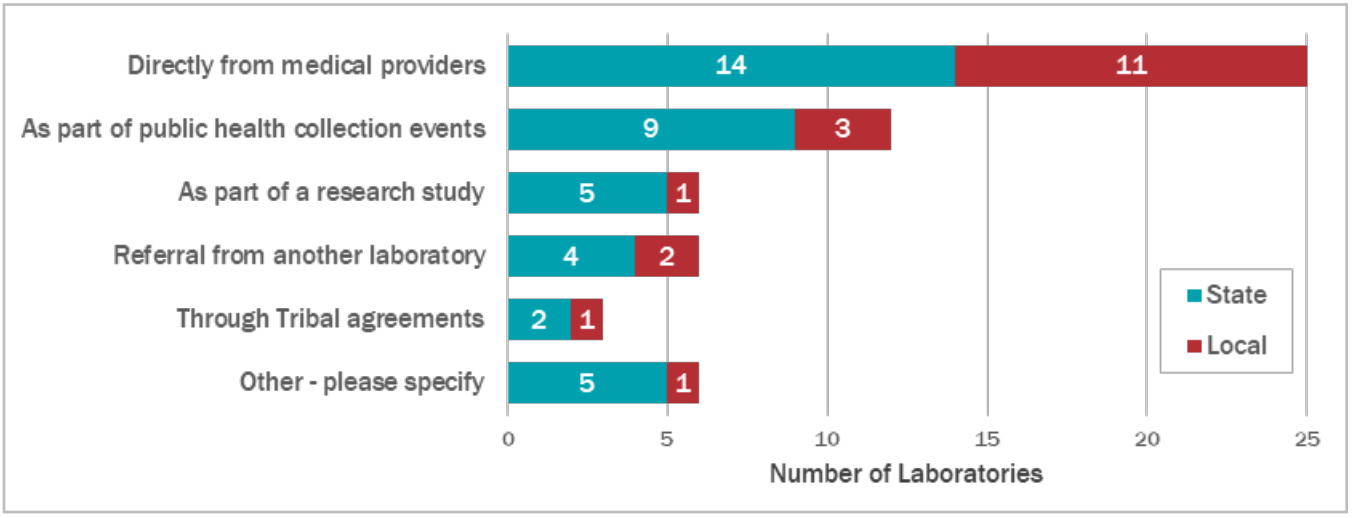
Figure 5. Average LeadCare II® Detection and Reporting Limits



Specimen Collection and Submission Methods to Laboratories

The samples laboratories test may come from a variety of sources (**Figure 6**). The most common method of specimen submission among respondents was directly from medical providers (64%, 25/31). The second-most-common mechanism (31%, 12/31) was to receive specimens as part of public health collection events. Other responses included health providers, biomonitoring studies, public health/department of health clinics, county hospitals and courier services. Respondents were able to select all collection and submission methods that applied.

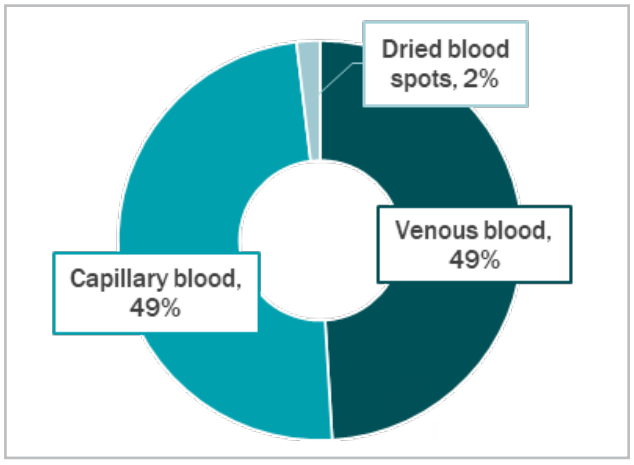
Figure 6. Specimen Collection and Submission Methods (n=31; 19 state, 12 local laboratories)



Types of Blood Specimens Routinely Analyzed in Laboratories

Among the respondents conducting routine blood lead testing, venous and capillary blood are analyzed with similar frequency (49%, 15/31). Only one laboratory reported routine analysis of dried blood spots (**Figure 7**).

Figure 7. Types of Blood Specimens Routinely Analyzed in Laboratories (n=31; 19 state, 12 local laboratories)



Contamination Control Practices in Pediatric Lead Testing Laboratories

Laboratories may use a variety of methods to control specimen when conducting pediatric lead testing (**Figure 8**). Most of the laboratories conducting routine testing (71%, 21/31) train staff members on contamination control practices, which indicates a significant focus on maintaining testing quality through proper training. Additionally, 21 laboratories (68%) reported using "trace-metal free" certified materials as a contamination control measure, while 18 laboratories (58%) use "trace-metal free" certified reagents. Specimen preparation in BSC or CFH, and pre-screening specimen collection supplies were also significant contamination control practices. Other responses included: employing dedicated space within the laboratory, adhering to state regulatory standards for blood lead testing, utilizing robotic liquid handling, using an auto-diluter and powder free gloves and implementing pre-screening testing supplies. Individual responses are on file with APHL.

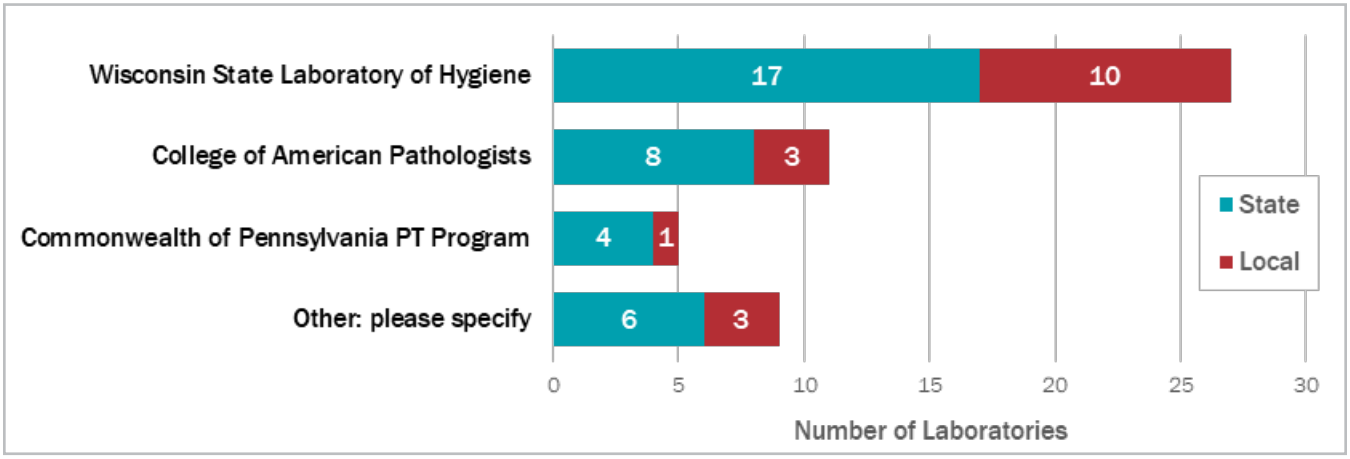
Figure 8. Contamination Control Practices in Pediatric Lead Testing Laboratories (n=31; 19 state, 12 local laboratories)

Participation in Blood Lead Proficiency Testing and Quality Assessment Programs

Proficiency testing (PT) and other quality assessment (QA) programs are a key mechanism for ensuring data and specimen integrity. The majority of laboratories conducting routine pediatric lead testing (87%, 27/31) reported participating in the PT/QA program offered by the Wisconsin State Laboratory of Hygiene (**Figure 9**). Over a third (39%, 12/31) participated in programs by the College of American Pathologists, and 16% (5/31) utilized the Commonwealth of Pennsylvania PT Program.

"Other" responses included participation in the CDC Lead and Multi-element Proficiency (LAMP) program, New York State PT Program for Biomonitoring Trace Elements, and programs offered by Quebec CTQ (PCI and QMEQAS), UK TEQAS, G-EQUAS, and Spanish PICC. Individual responses are on file with APHL.

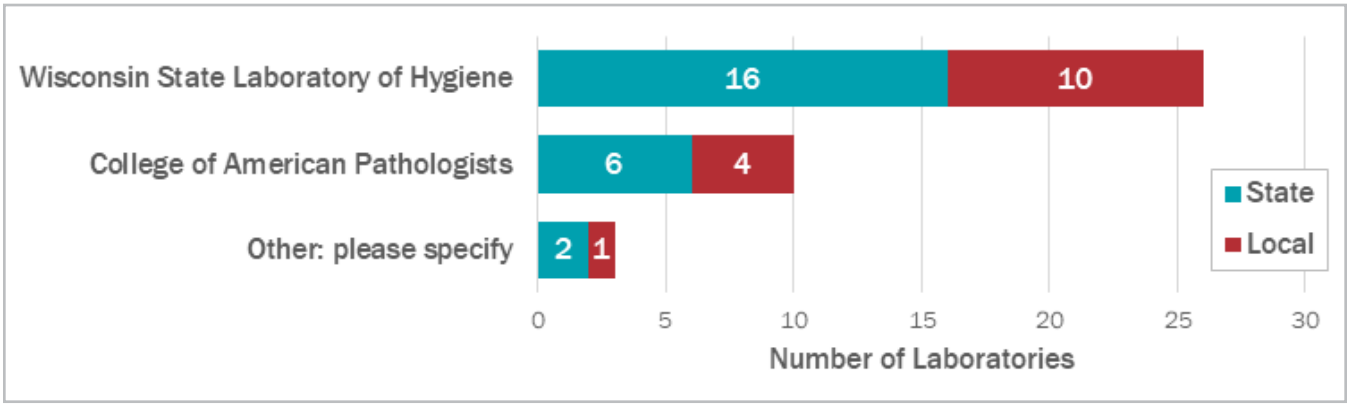
Figure 9. Participation in Blood Lead Proficiency Testing and Quality Assessment Programs (n=31; 19 state, 12 local laboratories)



Reporting Proficiency Testing Program Results for CLIA Compliance

As shown in **Figure 10**, 84% of testing laboratories (26/31) reported that they report PT program results to the US Centers for Medicare and Medicaid Services (CMS) for CLIA compliance through the Wisconsin State Laboratory of Hygiene. Individual responses are on file with APHL.

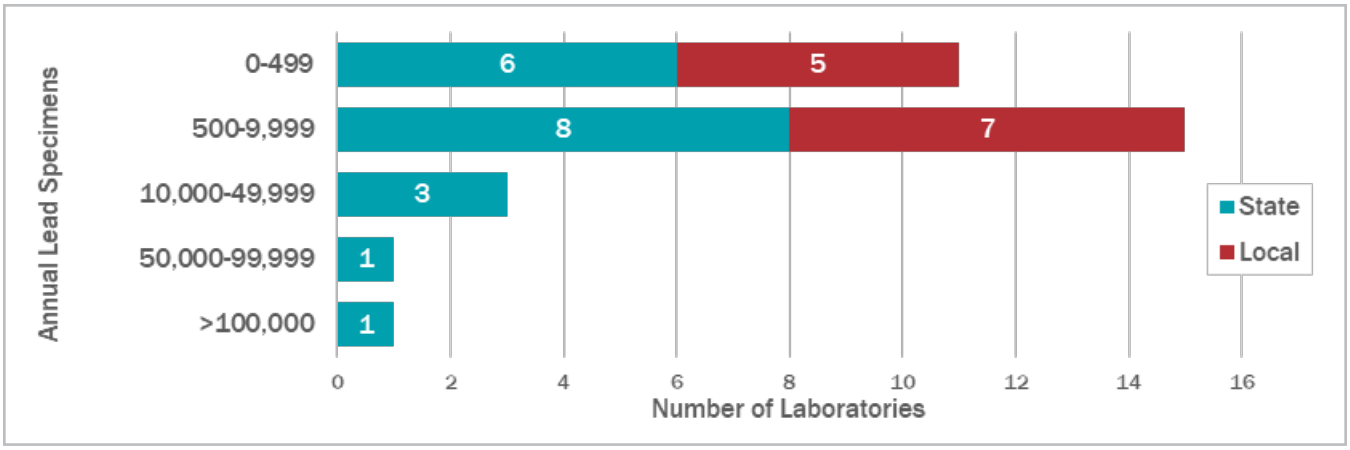
Figure 10. Reporting Proficiency Testing Program Results for CLIA Compliance (n=31; 19 state, 12 local laboratories)



Estimated Annual Number of Pediatric Lead Specimens Tested

Almost half of the testing laboratories (48%, 15/31) reported testing between 500 and 9,999 pediatric lead specimens annually (**Figure 11**).

Figure 11. Estimated Annual Number of Pediatric Lead Specimens Tested (n=31; 19 state, 12 local laboratories)



Modifications Made Following the Reduction in CDC Blood Lead Reference Value to 3.5 µg/dL

In response to the CDC blood lead reference value reduction, the survey found that 18 out of 31 laboratories (58%) made changes to their laboratory reports and 14 laboratories (45%) enhanced their communication with public health partners and clinicians.

Beyond the modifications outlined in **Table 7**, other modifications included the implementation of online training via a public website for correct specimen collection, packaging, and shipping; a shift in testing methodology from GFAAS to ICP-MS; and one laboratory reported that adjustments have not yet been made due to coordination with public health nurses and logistical considerations, with a potential implementation date of Summer 2023. Individual responses are on file with APHL.

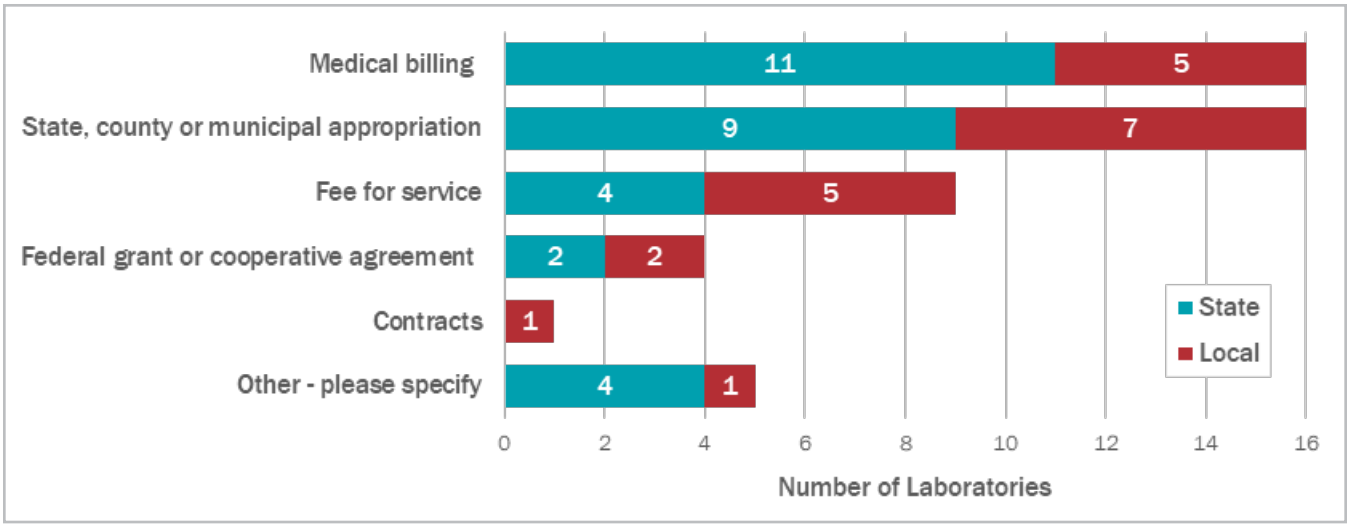
Table 7. Modifications post-CDC reference value reduction (n=31; 19 state, 12 local laboratories)

Modifications	State	Local	Total
Modifications to laboratory reports	10	8	18
Enhanced partner communication with public health partners and clinicians.	10	4	14
Revised results interpretation and guidance	9	2	11
Lowered reporting limits	5	5	10
Enhanced contamination control practices	5	1	6
Analytical method changes	5	0	5
Updated specimen collection guidance	3	1	4
Other	2	1	3
None	2	1	3

Funding Sources for Pediatric Lead Testing Laboratory Programs

The most common sources of pediatric lead testing laboratory program funding were state, county or municipal appropriations, and medical billing, with 51% (16/31) of testing laboratories claiming funds from both (**Figure 12**). Other responses regarding funding for pediatric lead testing included: participation in a CDC-funded biomonitoring study, receiving in-kind state support (not appropriated), funding through the state childhood lead poisoning prevention fee and partial funding from Medicaid. Individual responses are on file with APHL.

Figure 12. Funding Sources for Pediatric Lead Testing Laboratory Programs (n=31; 19 state, 12 local laboratories)



Capacity for Expanding Pediatric Lead Testing Program with Additional Resources

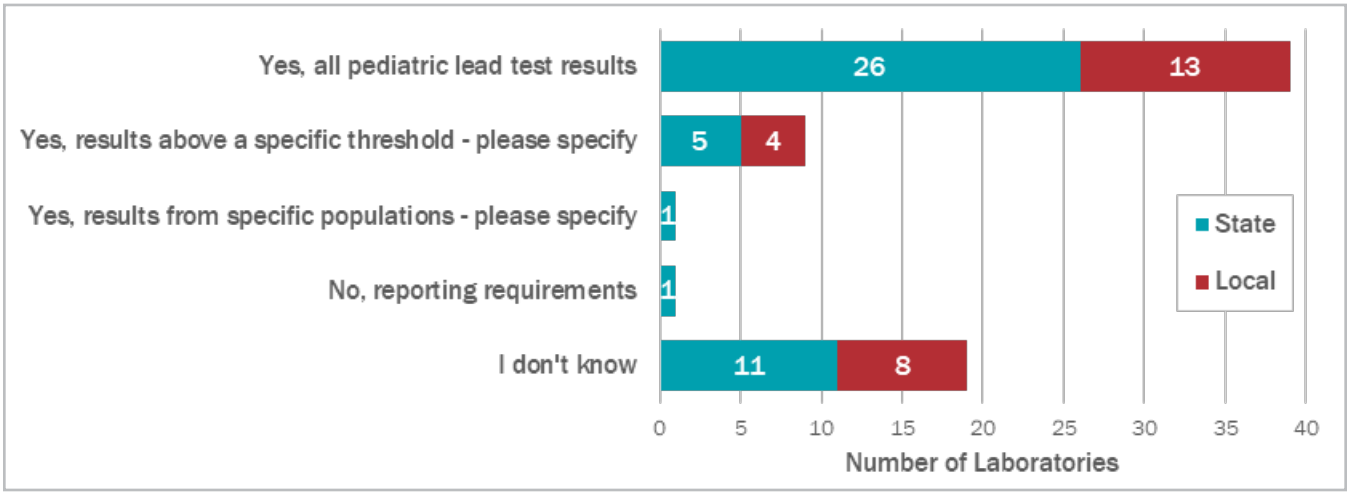
All 31 laboratories currently conducting routine testing indicated that their laboratories have the capacity to provide additional testing for their pediatric lead testing program if additional resources were made available.

Reporting Requirements for Pediatric Lead Tests to the Health Department

Jurisdictions have varying requirements about public health, clinical, commercial and/or physician office laboratories reporting pediatric lead test results to the health department. When asked about their own jurisdictions, most respondents (71%, 49/69) indicated that there were at least some situations that required laboratories to report pediatric lead tests to the health department (**Figure 13**); only one state had no reporting requirements and 19 were not sure about the requirements.

Of those with at least some required reporting of pediatric lead tests to the health department, 80% (39/49) were required to report all test results. A smaller group (18%, 9/49) were required to submit results above a specific threshold; levels mentioned for children under 18 included 2.3 µg/dL, 3.5 µg/dL, 45 µg/dL, and 5µg/dL). One jurisdiction only considered lead a reportable condition for specific populations.

Figure 13. Reporting Requirements for Pediatric Lead Tests to the Health Department (n=69; 44 state, 25 local laboratories)



Adoption of Lower CDC Blood Lead Reference Value

CDC's recommended BLRV was reduced from 5 ug/dL to 3.5 ug/dL in October 2021. Over half (58%, 40/67) of the respondents said that their organization had either adopted the new BLRV or were in the process of adoption, while another 32% were unsure. Only seven state laboratories confirmed that they had not begun adoption of the new BLRV (**Figure 14**).

Figure 14. Adoption of CDC's 3.5 ug/dL BLRV since 2021 (BLRV(2021)) (n=69; 44 state and 25 local laboratories)

Adoption of BLRV(2021)	State	Local	Total #	Total %
Yes	20	14	34	49%
In progress	4	2	6	9%
No	7	-	7	10%
I don't know	13	9	22	32%
Total	**44**	**25**	**69**	**100%**

Collaborative Efforts with Childhood Lead Poisoning Prevention Partners

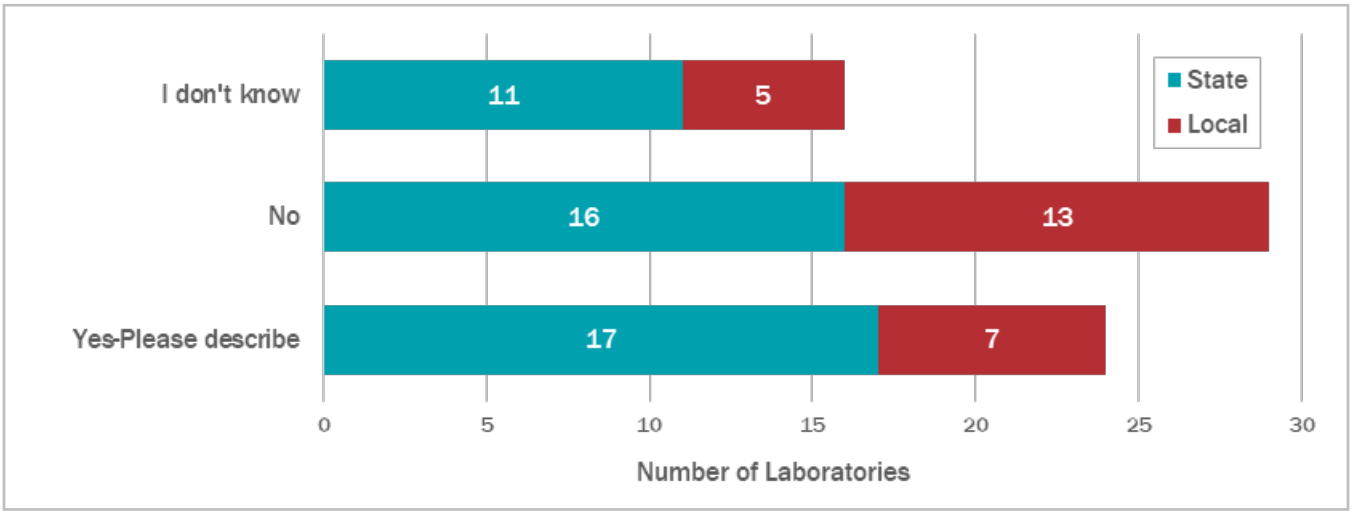
The CDC Childhood Lead Poisoning Prevention Program (CLPPP) works to strengthen blood lead testing, reporting and surveillance. When respondents were asked about their collaborative efforts with CLPPP and its partners to communicate about the new BLRV, testing options and interpretation of results, 35% (24/69) confirmed collaboration with CLPPP partners. Meanwhile, 42% (29/69) reported no such collaboration and 23% (16/69) were unsure of their collaborative status (**Figure 15**).

To communicate about the new BLRV, various collaborative activities with CLPPP partners were listed by laboratory respondents, including:

- Sent letter to all public health partners explaining the change to the BLRV.
- Established meetings to devise a plan to roll out the new BLRV for state.
- Virtual meetings and sharing of information via email and Health Alert Network (HAN).
- Reporting of laboratory test results to CLPPPs and/or Healthy Homes programs.
- Created a new biomonitoring project together (PHL/CLPPP/Healthy Homes).
- Working together to flag elevated results, follow-up on cases, and complete outreach.
- Running TV and radio commercials to educate the public about the new BLRV
- Meeting quarterly to discuss changes to lead testing practices and to provide advice to CLPPPs on implications for permitted labs
- Notifying clinical stakeholders and providing links to CDC CLPPP resources
- Regular communication with coordination of testing for home investigations (e.g., spices, makeup, drinking water)
- Meeting with partners before providing testing to explain what laboratory can and cannot do, interpreting results, and communicating results locally and to the state
- Working with regional cooperatives, organizations, and medical professionals to raise awareness

Other individual responses are on file with APHL.

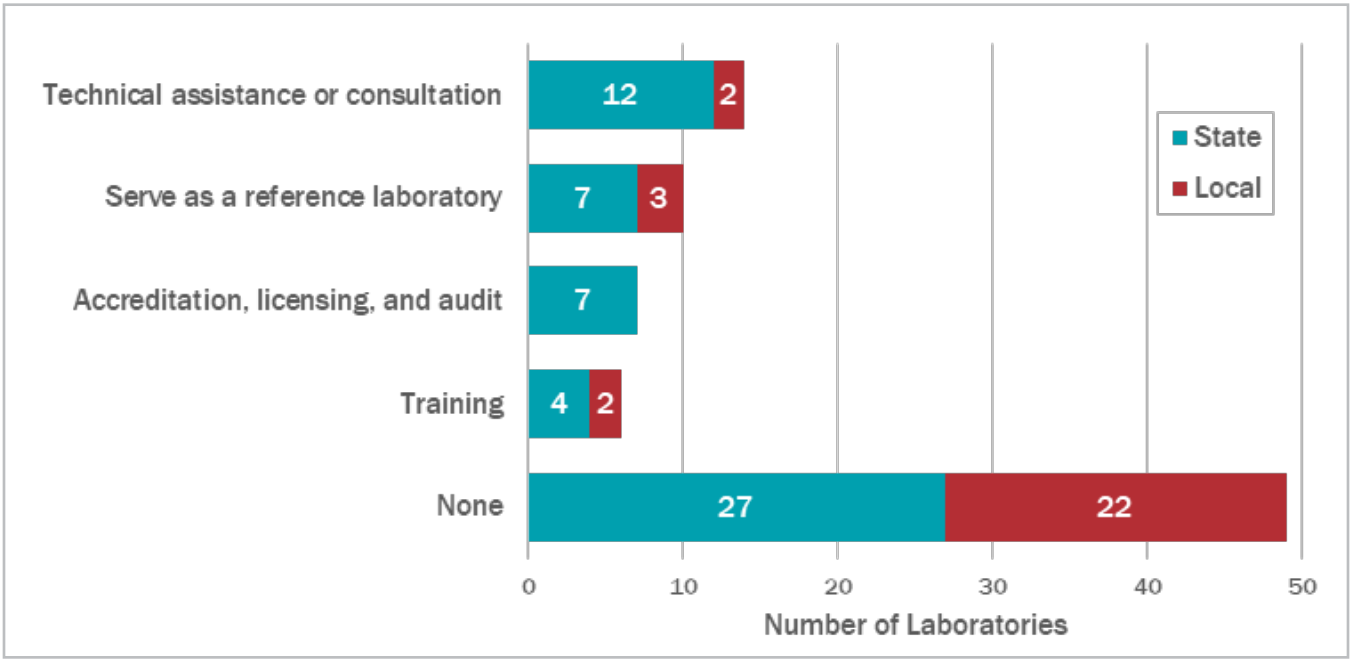
Figure 15. Collaborative Efforts with Childhood Lead Poisoning Prevention Partners (n=69; 44 state, 25 local laboratories)



Laboratories' Roles in Quality Assurance of Blood Lead Testing

Survey respondents were asked about their involvement in assuring the quality of test results for blood lead testing in their jurisdiction. While 71% (49/69) of the laboratories don't have a role in the quality assurance process at all, there were a number of ways the remaining 29% are involved. Six laboratories assist with training; 14 offer technical assistance or consultation; seven state laboratories perform accreditation, licensing and auditing roles; and 10 function as reference laboratories. See **Figure 16** for a breakdown of state and local activities.

Figure 16. Laboratory Involvement in Quality Assurance of Blood Lead Testing Results within Jurisdictions (n=69; 44 state, 25 local laboratories)



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.

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