

Impact of Faulty Test Kits on LeadCare II Capillary Blood Lead Screening Performance in Michigan



Study conducted on Oct. 2, 2024
Lead and Other Hazards Unit

Executive Summary

- To investigate the impact on blood lead surveillance in Michigan resulting from the Magellan field action notice regarding faulty test kits for the LeadCare® II Point-of-Care (POC) blood lead analyzers, (affected lots produced beginning on April 8, 2022) we examined two metrics to identify changes that may reveal decreasing accuracy in LeadCare® II analyzers:
 - Capillary geometric mean blood lead levels.
 - Positive predictive value of capillary screening tests.
- **Findings:**
 - **Geometric mean blood lead levels:**
 - Trend analysis found increases in quarterly geometric means from 2021 to 2023, but this trend did not change during the notice period.
 - Parallel trend analysis found a difference in trends between LeadCare® II and other capillary blood lead analyzers.
 - **Positive predictive value (PPV) of capillary blood lead tests:**
 - Trend analysis found a significant declining trend in quarterly PPV from 2018-2021, and a steeper declining trend from 2021-2023.
 - Parallel trend analysis found no difference in trends between LeadCare® II and other capillary blood lead analyzers.
- **Conclusions:**
 - There is not strong evidence that the performance of LeadCare® II blood lead analyzer as a screening test was affected by the 2022 field action notice for faulty test kits, particularly when compared to parallel issues in other capillary screening test methods.
 - As test results cannot be linked to specific test kit lots in our data, it is impossible to tie these changes in performance to the faulty test kits directly.
- **Additional Considerations:**
 - Overall capillary screening results illustrate the need for the LeadCare® II analyzers in screening children *out* of further testing (over 92% of individuals tested).
 - The low and declining PPV of all capillary analyzers is of concern as it suggests children are being referred to confirmatory venous testing who may otherwise be screened out of venous testing with a more accurate screening approach.

Objective

The objective of this analysis was to evaluate the impact of faulty test kits manufactured by Magellan for LeadCare® II Point-of-Care (POC) blood lead analyzers on blood lead surveillance in Michigan.

Background

Magellan Diagnostics issued a voluntary field action notice regarding LeadCare® II blood lead test kits with specific lot numbers manufactured between April 8, 2022 and Aug. 31, 2023.¹ The involved testing kits had faulty treatment reagent tube caps, which may have resulted in a falsely elevated result if treatment reagent leaked via the faulty cap. Michigan's Childhood Lead Poisoning Prevention Program (CLPPP) was informed of the issue on Sept. 28, 2023, when a local health department contacted CLPPP regarding the notice and requested guidance on how to proceed with capillary screening using LeadCare® II analyzers. CLPPP staff discussed the issue with Magellan representatives on Sept. 29, 2023. The total number of tests impacted by the issue with the treatment reagent tube caps is unknown at this time.

Methods

Data Source

Records of blood lead tests with sample collection dates from Jan. 1, 2018, to Aug. 31, 2023, were selected from the CLPPP Blood Lead Surveillance database on Sept. 4, 2023.

Objectives

- Determine if the faulty test kits coincided with an increase in capillary blood lead levels.
- Determine if the faulty test kits coincided with a decrease in the performance of capillary screening tests.

Measures Used

Two measures were used to assess the impact of the faulty test kits on blood lead surveillance:

- Capillary geometric mean blood lead levels.
- Capillary screening test positive predictive value.

Capillary Geometric Mean Blood Lead Levels

Geometric means, defined as the n th root of the product of n values, were calculated using SAS PROC SURVEYMEANS², with standard errors and 95% confidence intervals. Capillary blood lead test results below the limit of detection (LoD) were replaced with the value of the laboratory method's LoD divided by the square root of two. For LeadCare® II analyzers, the LoD is 3.33 µg/dL, with a replacement value of 2.33 µg/dL. For other analyzers, the mean LoD is approximately 0.5 µg/dL with a replacement value of approximately 0.33 µg/dL. The geometric mean estimates were calculated for all ages and for children under the age of 6 years old.

Capillary Screening Test Positive Predictive Value

To calculate capillary screening test positive predictive values, capillary-venous test pairs were created with a 90-day limit for the interval between screening and confirmatory tests – any test pairs with intervals >90 days were excluded. Capillary-venous test pairs were deduplicated down to one pair with the shortest time interval per individual per quarter. Each capillary test result in a pair was classified as

elevated if the blood lead level was greater than or equal to 3.5 µg/dL, the current Blood Lead Reference Value (BLRV).³ The BLRV is set by the CDC as the 97.5th percentile blood lead level for children ages one to five years old based on the National Health and Nutrition Examination Survey (NHANES) and adopted by Michigan on May 1, 2022.⁴

Capillary test positive predictive values were calculated using SAS PROC FREQ to classify test pairs by the status of the capillary screening test against the paired confirmatory venous test for all ages, with standard errors and 95% confidence intervals.⁵

Test pairs with an elevated capillary test (\geq BLRV) were classified into one of the following groups:

- **True Positives (TP):** An elevated (\geq BLRV) capillary screening test followed by an elevated (\geq BLRV) venous test within 90 days.
- **False Positives (FP):** An elevated (\geq BLRV) capillary screening test followed by a non-elevated ($<$ BLRV) venous test within 90 days.

Positive predictive values were calculated using the following equation:

Positive Predictive Value [TP/(TP + FP)]: The proportion of elevated capillary screening tests that were followed by an elevated venous test.

In a comprehensive screening test evaluation, sensitivity, specificity and negative predictive value would be evaluated as well as the positive predictive value using repeat measurement of the sample with a gold standard. In the place of a repeat measurement, we used a paired confirmatory venous test result as a stand-in gold standard. However, the likelihood of a non-elevated capillary test being followed by a confirmatory venous test is much lower in Michigan blood lead surveillance data because screening programs only confirm elevated capillary screening tests by design. This leads to a likely incomplete estimate for both true and false negatives and a corresponding bias in measures reliant on those values, including sensitivity, specificity and negative predictive value. This analysis therefore solely assessed positive predictive value to evaluate the performance of the LeadCare II screening tests.

Note about prevalence and PPV: Prevalence, or the proportion of the population who have a condition within a certain time period, is an important aspect to consider when evaluating a screening test based on the PPV. Without changing the sensitivity or specificity of a screening test, the PPV will decrease the lower the prevalence of the condition in the population.⁶

Analytic Approach

Analyses of the two metrics were conducted using two different approaches:

- **Descriptive statistics:** To detect changes in metrics related to the faulty test kit distribution, descriptive statistics were calculated and compared by dividing each metric (all ages) to before (Jan. 1, 2018 – April 8, 2022) and after (April 9, 2022 – Aug. 31, 2023) the faulty test kits were distributed and whether the capillary screening test was performed on a LeadCare® II analyzer or any other laboratory analytic method (hereafter: “other analyzers”).
 - Testing and prevalence data are provided to give additional context under the “Results: Descriptive Statistics” section titled “Blood Lead Testing,” which includes a table of the number of individuals with a capillary screening test (Table 1) and the annual percent of all individuals tested who had a venous elevated blood lead level (EBLL) (Figure 1).

- **Trend analyses:** To evaluate trends changing over time that coincide with the faulty test kit distribution, trend analyses were conducted on quarterly metric aggregates for all ages by type of blood lead test method (LeadCare® II, other analyzers) using JoinPoint v4.9.1.0 software.⁷
 - In joinpoint regression analysis, trends in a specified measure over time are fitted to the model that best identifies points (joinpoints) where statistically significant changes in trends are found.
 - From those points, linear regression models are created for each segment of the model. Joinpoint identifies the best-fitted model and calculates the percent change along each line segment between two joinpoints.
 - Comparisons between trends by type of analyzer (LeadCare® II, other analyzers) was also conducted in Joinpoint, which compares the modeled slope of the fitted joinpoint regression model segments of each group and determines if they are parallel to each other.
 - Data from 2023 Q3 was not included in any joinpoint trend analysis. This exclusion is due to the data collected from July 2023 to August 2023 being provisional in nature. Given the data's recency as of Sept. 4, 2023, 2023 Q3 falls within the three-month provisional buffer period.
 - For geometric means trend analysis, results for children < 6 years of age were used.

Results: Descriptive Statistics

Blood Lead Testing

- A total of 342,715 individuals had at least one capillary blood lead test in the pre-kit distribution period (Jan. 1, 2018 to April 7, 2022) and 99,087 had at least one capillary blood lead test during the kit distribution period (April 8, 2022 to Aug. 31, 2023) (Table 1).
- Most individuals (93.3%) had blood lead levels below 3.5 µg/dL. The percent of individuals with blood lead levels below 3.5 µg/dL decreased from 93.4% during the pre-notice period to 92.8% during the kit distribution period (Table 1).
- 71.6% of individuals were tested on the LeadCare® II analyzer (Table 1).
- Out of 324,924 individuals with a capillary test performed on LeadCare® II, 24,621 (7.6%) had an elevated result (Table 1).
- The percent of individuals tested by LeadCare® II analyzer with a capillary test result ≥ 3.5 µg/dL increased from before the kit distribution to during the kit distribution period (7.4% to 8.0%) and increased in other blood lead analyzers (4.4% to 5.2%) (Table 1).
- The annual prevalence of venous EBLLs (BLRV = 3.5 µg/dL) in the tested population remained steady through the timeframe of this analysis (Figure 1).

Geometric Mean Blood Lead Levels

Including Imputed Results below LoD:

- A total of 459,479 capillary blood lead tests were reported to MDHHS CLPPP from Jan. 1, 2018 to Aug. 31, 2023 (Table 2a).
 - 328,583 (71.5%) were analyzed by LeadCare® II.
 - 130,896 (28.5%) were analyzed by other analyzing laboratories.
- The majority (~91%) of test results from LeadCare® II analyzers were below the LoD of 3.3 µg/dL, which was higher than from other capillary blood lead analyzers (48% - 50%).
- There were differences in geometric mean capillary blood lead levels between LeadCare® II analyzers and other blood lead analyzers (Table 2a), driven by the analyzer LoD values:
 - The LeadCare® II analyzer LoD is 3.3 µg/dL, so the minimum capillary test result by the LeadCare® II analyzer is 2.33 µg/dL.
 - The other analyzers mean LoD is approximately 0.5 µg/dL, so the minimum capillary test result by other analyzers approximately 0.33 µg/dL.
- There were very small but statistically significant differences in geometric mean capillary blood lead levels (0.01 µg/dL) from LeadCare® II analyzer for all ages and for children under 6 years of age before and after the test kit notice (Table 2a).

Results above LoD:

- A total of 459,479 capillary blood lead tests were reported to MDHHS CLPPP from Jan. 1, 2018 to Aug. 31, 2023 (Table 2a).
 - 328,583 (71.5%) were analyzed by LeadCare® II.
- The majority (~91%) of test results from LeadCare® II analyzers were below the LoD of 3.3 µg/dL, which was higher than from other capillary blood lead analyzers (48% - 50%).

- There were differences in geometric mean capillary blood lead levels between LeadCare® II analyzers and other blood lead analyzers (Table 2b):
 - The geometric mean blood lead level of detectable test results (results \geq laboratory LoD) for LeadCare test kits was approximately 4.8 $\mu\text{g}/\text{dL}$.
 - The geometric mean blood lead level of detectable test results from other analyzers was approximately 1.5 $\mu\text{g}/\text{dL}$.
- There were very small but statistically significant differences in geometric mean capillary blood lead levels (0.04 $\mu\text{g}/\text{dL}$) from LeadCare® II analyzer for all ages and for children under 6 years of age before and after the test kit notice (Table 2b).
- The magnitude and direction of effects observed when omitting results below the LoD closely paralleled those when using imputation described above, suggesting that imputing the ~91% of results below the LoD was not obscuring any impacts on test results due to the notice.
 - To preserve a large sample size, all remaining analyses were performed using the imputed dataset.

LeadCare II Test Positive Predictive Value

- Among the 26,934 individuals tested with LeadCare® II who had a paired venous test, there was a statistically significant decrease (11.2%) in the LeadCare® II screening test positive predictive value during the kit distribution period start-date of April 8, 2022 at the 3.5 $\mu\text{g}/\text{dL}$ BLRV (Table 3), from 0.30 to 0.19. A similar statistically significant decrease (14%) was observed in other blood lead analyzers, from 0.43 to 0.29 (Table 3).
- Out of all venous-paired LeadCare® II positives, 73.6% were false positives (Table 3). Using the count of all individuals tested on LeadCare® II (24,621), an estimated 18,121 individuals were impacted by a false positive, which is 5.6% of the total population tested (Table 1).

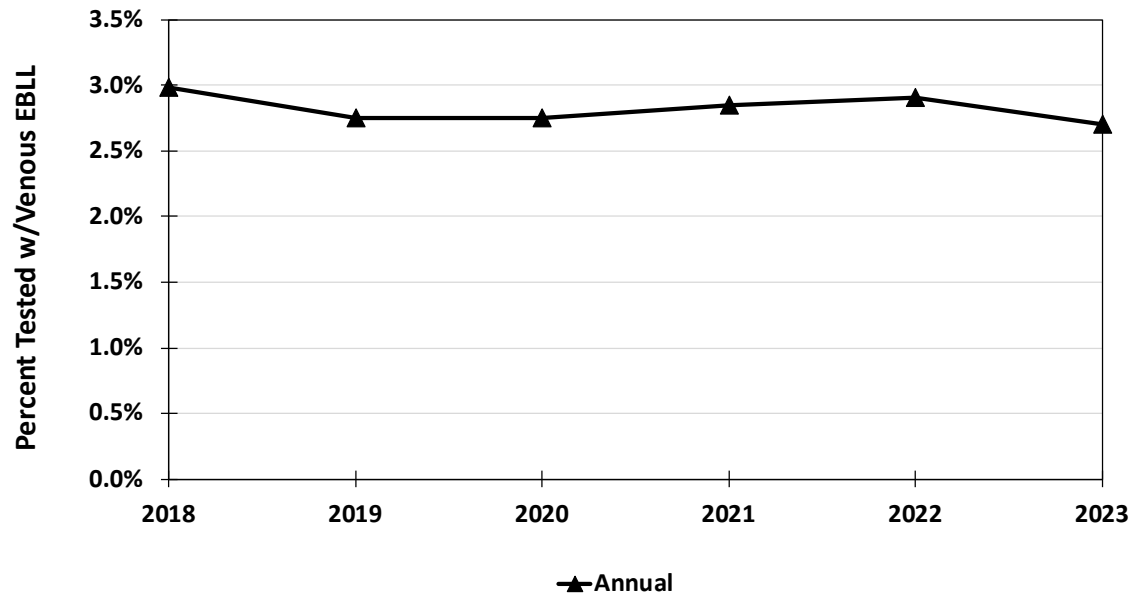
Table 1. Number of Individuals with a Capillary Test¹ by Capillary Test Type of Blood Lead Analyzer and Time Period of Capillary Test², All Ages, 2018-2023

Type of Analyzer	Time Period ²	Capillary Test Result	Number	Percent	
LeadCare® POC II Blood Lead Analyzer	Pre-Kit Distribution	< 3.5 µg/dL	226,228	92.6%	
		≥ 3.5 µg/dL	18,183	7.4%	
		Total	244,411	75.2%	
	During Kit Distribution	< 3.5 µg/dL	74,075	92.0%	
		≥ 3.5 µg/dL	6,438	8.0%	
		Total	80,513	24.8%	
	Total		324,924	71.6%	
	Other Capillary Blood Lead Analyzers	Pre-Kit Distribution	< 3.5 µg/dL	93,944	95.6%
			≥ 3.5 µg/dL	4,360	4.4%
Total			98,304	76.2%	
During Kit Distribution		< 3.5 µg/dL	29,089	94.8%	
		≥ 3.5 µg/dL	1,585	5.2%	
		Total	30,674	23.8%	
Total			128,978	28.4%	
All Analyzers				453,902	100%

¹ Data Source: CLPPP Blood Lead Surveillance Database

² Time Period: Pre-Kit Distribution (Jan. 1, 2018 to April 7, 2022), During Kit Distribution (April 8, 2022 to Aug. 31, 2023)

Figure 1. Annual Percent of Individuals Tested with a Venous Confirmed EBLL¹ in Michigan², All Ages, 2018-2023



¹ Blood Lead Reference Value of 3.5 $\mu\text{g}/\text{dL}$

² Data Source: CLPPP Blood Lead Surveillance Database

Table 2a. Geometric Mean Blood Lead Levels¹ by Type of Analyzer and Time Period Before or During Distribution of Faulty Test Kits², All Ages and Children <6, 2018-2023

Age Category	Type of Analyzer	Time Period ²	Number of Tests	Percent of Tests Below LOD ³	Geometric Mean (µg/dL)	95% lower CI ⁴	95% upper CI ⁴
All Ages	LeadCare® POC II Blood Lead Analyzer	Pre-Kit Distribution	247,258	90.9 %	2.492	2.489	2.495
		During Kit Distribution	81,325	90.7 %	2.498	2.493	2.503
	Other Capillary Blood Lead Analyzers	Pre-Kit Distribution	99,810	50.4 %	0.431	0.426	0.436
		During Kit Distribution	31,086	47.6 %	0.321	0.314	0.329
Children <6	LeadCare® POC II Blood Lead Analyzer	Pre-Kit Distribution	239,447	90.9 %	2.492	2.490	2.495
		During Kit Distribution	79,794	90.8 %	2.496	2.492	2.500
	Other Capillary Blood Lead Analyzers	Pre-Kit Distribution	97,847	50.4 %	0.430	0.426	0.435
		During Kit Distribution	30,722	47.6 %	0.321	0.314	0.329

¹ Data Source: CLPPP Blood Lead Surveillance Database

² Time Period: Pre-Kit Distribution (Jan. 1, 2018 to April 7, 2022), During Kit Distribution (April 8, 2022 to Aug. 31, 2023)

³ LOD: Limit of Detection

⁴ CI: Confidence Interval

Table 2b. Geometric Mean Blood Lead Levels¹ by Type of Analyzer and Time Period Before or During Distribution of Faulty Test Kits², All Ages and Children <6, 2018-2023, Omitting Results Below Laboratory Limits of Detection (LoD)³

Age Category	Type of Analyzer	Time Period ²	Total Tests	Tests > LoD ³	Geometric Mean (µg/dL)	95% lower CI ⁴	95% upper CI ⁴
All Ages	LeadCare® POC II Blood Lead Analyzer	Pre-Kit Distribution	247,258	22,427	4.82	4.79	4.86
		During Kit Distribution	81,325	7,572	4.86	4.80	4.92
	Other Capillary Blood Lead Analyzers	Pre-Kit Distribution	99,810	49,528	1.50	1.49	1.51
		During Kit Distribution	31,086	16,279	1.45	1.44	1.47
Children < 6	LeadCare® POC II Blood Lead Analyzer	Pre-Kit Distribution	239,447	21,774	4.82	4.78	4.85
		During Kit Distribution	79,794	7,343	4.86	4.79	4.92
	Other Capillary Blood Lead Analyzers	Pre-Kit Distribution	97,847	48,551	1.50	1.49	1.51
		During Kit Distribution	30,722	16,098	1.45	1.44	1.47

¹ Data Source: CLPPP Blood Lead Surveillance Database

² Time Period: Pre-Kit Distribution (Jan. 1, 2018 to April 7, 2022), During Kit Distribution (April 8, 2022 to Aug. 31, 2023)

³ LOD: Limit of Detection

⁴ CI: Confidence Interval

Table 3. Capillary Blood Lead Screening Test¹ Positive Predictive Value by Time Period of Test and Type of Analyzer, All Ages, 2018-2023

Type of Analyzer	Time Period ²	Number of Test Pairs ³	Number of True Positives ⁴	Number of False Positives ⁵	% False Positives ⁵	Positive Predictive Value	95% lower CI ⁶	95% upper CI ⁶
LeadCare® POC II Blood Lead Analyzer	Pre-Kit Distribution	22,532	2,087	4,847	70.0%	0.30	0.29	0.31
	During Kit Distribution	4,402	608	2,670	81.5%	0.19	0.17	0.20
	All Periods	26,934	2,695	7,517	73.6%	0.26	0.25	0.27
Other Capillary Blood Lead Analyzers	Pre-Kit Distribution	9,394	761	1,105	59.2%	0.41	0.39	0.43
	During Kit Distribution	1,409	235	666	73.9%	0.26	0.23	0.29
	All Periods	10,803	996	1,771	64.0%	0.36	0.34	0.38

¹ Data Source: CLPPP Blood Lead Surveillance Database

² Time Period: Pre-Kit Distribution (Jan. 1, 2018 to April 7, 2022) or During Kit Distribution (April 8, 2022 to Aug. 31, 2023)

³ Test Pairs: individuals with a capillary screening test paired with a confirmatory venous test within 90 days.

⁴ True positives: number of elevated capillary tests (positive) followed by an elevated confirmatory venous test (positive)

⁵ False positives: number of elevated capillary tests (positive) with a confirmatory venous test that was not elevated (negative)

⁶ CI: Confidence Interval

Results: Trend Analyses

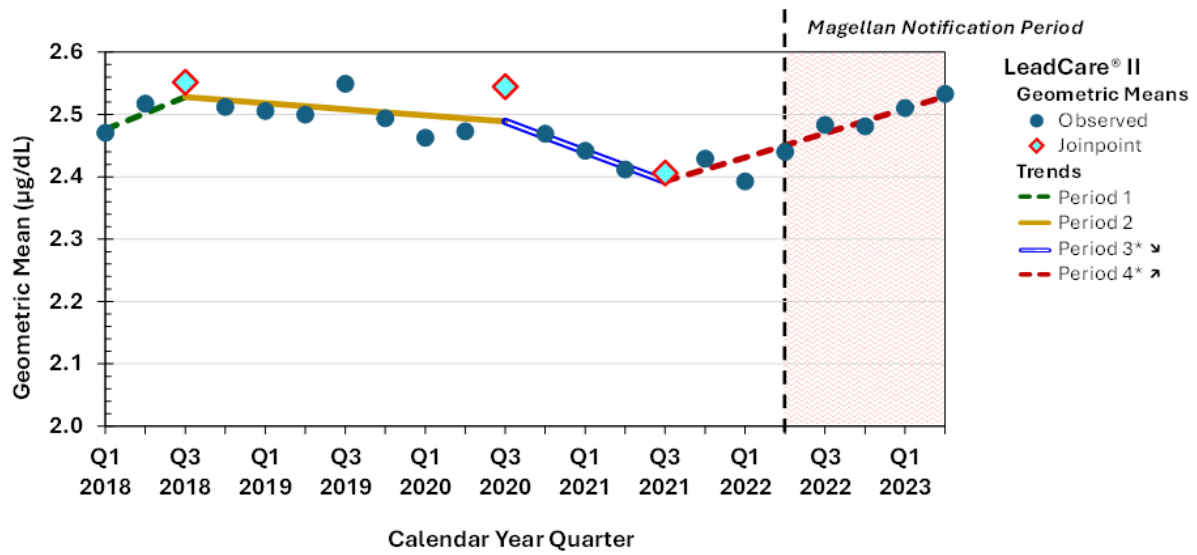
Geometric Mean Blood Lead Levels

- The best joinpoint trend model contained three joinpoints, of which two points led to a statistically significant change in trends (2020 Q3 and 2021 Q3) (Figure 2).
- There was a statistically significant decreasing trend from 2020 Q3 to 2021 Q3, followed by an increasing trend beginning in 2021 Q4. This increasing trend began before faulty test kits were distributed in April 2022 and did not change during the notice period (Figure 2).
- Parallel trend analysis found that trends in geometric mean capillary blood lead levels by LeadCare II analyzers were not in parallel with trends by other blood lead analyzers, due to the steady decrease in geometric means by other analyzers (Figure 3).

LeadCare II Test Positive Predictive Value

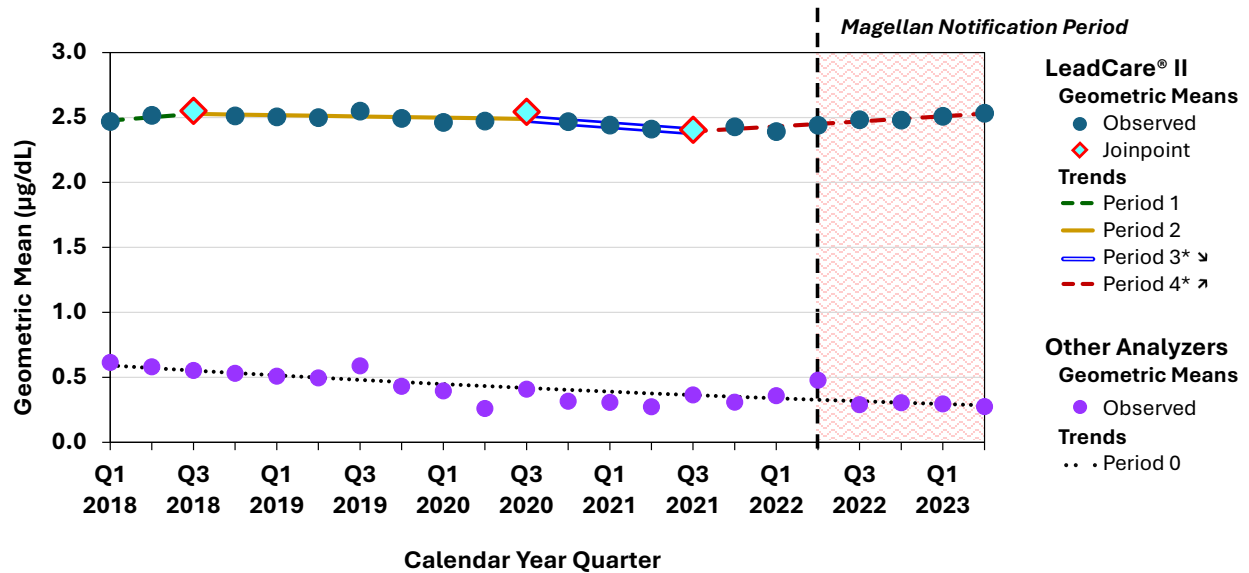
- The best joinpoint trend analysis model selected contained two joinpoints: one in 2020 Q4 and one in 2021 Q3 (Figure 4).
- There was a statistically significant declining trend in PPV from 2018 Q1 to 2020 Q4, turning into a more steeply declining and statistically significant trend following 2021 Q3. This latter joinpoint roughly coincided with the period when faulty test kits were distributed starting in 2022 Q2 (Figure 4).
- Parallel analysis of capillary blood lead screening test positive predictive value demonstrated that the trends seen in both the LeadCare® II analyzer and other analyzer groups were parallel with positive predictive values decreasing across all test modalities across the analysis period. Parallel trend analysis also identified a common joinpoint in 2021 Q4 in both groups (Figure 5).

Figure 2. Joinpoint Trend Analysis for Geometric Mean Capillary Blood Lead Levels by LeadCare® II POC Analyzers, Children < 6, 2018 Q1–2023 Q2



* Quarter Percent Change (QPC) is significantly different from zero at the alpha = 0.05 level.

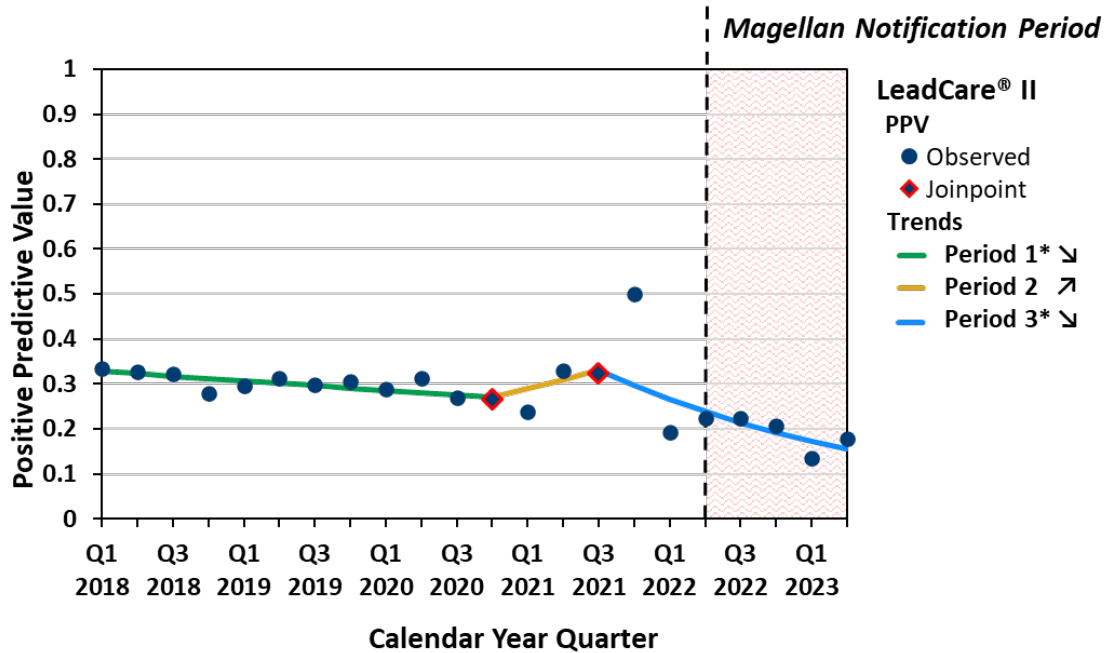
Figure 3. Joinpoint Parallel¹ Trend Analysis for Geometric Mean Capillary Blood Lead Levels by LeadCare® II and Other Blood Lead Analyzers, Children < 6, 2018 Q1–2023 Q2



¹ Trends are not parallel (p < 0.0001).

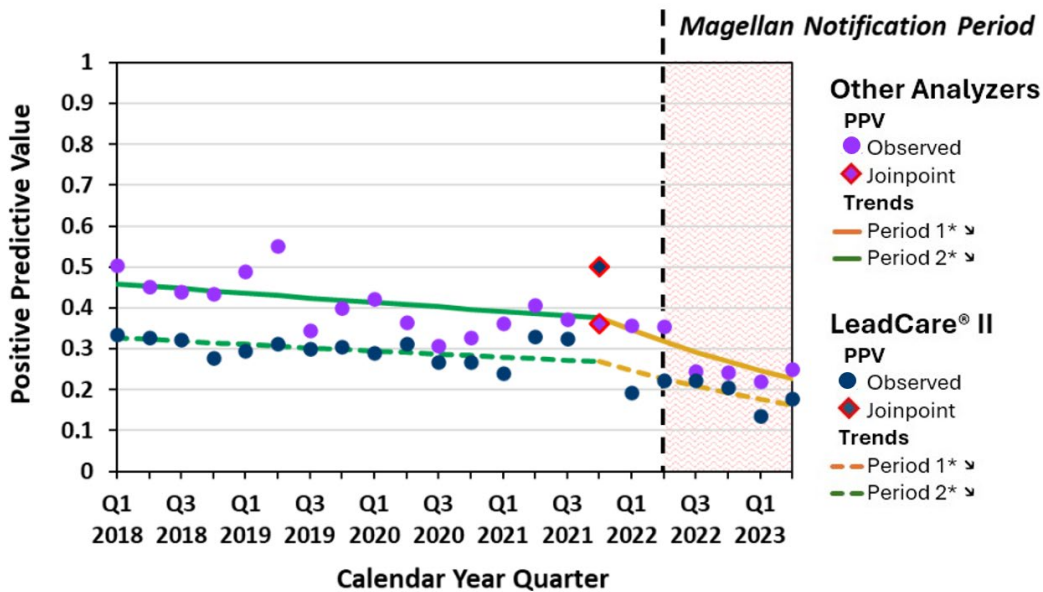
* Quarter Percent Change (QPC) is significantly different from zero at the alpha = 0.05 level.

Figure 4. Joinpoint Trend Analysis for LeadCare® II Analyzer Capillary Blood Lead Screening Test Positive Predictive Values (PPV), All Ages, 2018 Q1–2023 Q2



* Quarter Percent Change (QPC) is significantly different from zero at the alpha = 0.05 level.

Figure 5. Joinpoint Parallel¹ Analysis for Capillary Blood Lead Screening Test Positive Predictive Values in All Ages by Type of Analyzer, All Ages, 2018 Q1–2023 Q2



¹Trends Parallel (p = 0.397)

* Quarter Percent Change (QPC) is significantly different from zero at the alpha = 0.05 level.

Discussion

The results of this analysis indicate low and declining performance of the LeadCare® II analyzer for the screening of elevated blood lead levels, as assessed by positive predictive value (PPV). Though the PPV began declining more steeply around the time of the recent Magellan test kit notice, a parallel trend was observed in non-LeadCare screening modalities, suggesting that there is not strong evidence that the test kit issue was the driver for this declining performance. Based on the location of the joinpoint identified in both LeadCare® II and other analyzers in 2021 Q4, the sharper decline in PPV may be, in part, associated with the adoption of the new BLRV on May 1, 2022. The prevalence of elevated blood lead levels (EBLLs) in the population is another factor driving the low PPV; the lower the prevalence in the at-risk population the condition is, the lower the PPV of the screening test, regardless of its performance characteristics.

CLPPP currently does not have a comprehensive list of healthcare providers that received the faulty test kits from Magellan, and the surveillance database does not have the capacity to identify test kit lots. Since results from affected tests cannot be identified, and the affected test kits comprised less than 10% of test kits shipped by Magellan during the affected time, it is impossible to definitively determine if any of the observed changes in the metrics examined here were directly caused by faulty test kits.

The slight increasing trend in geometric mean blood lead levels for LeadCare® II analyzers did not follow the overall decreasing trend in geometric mean blood lead levels for other capillary blood lead analyzers (Figure 3). It should be noted that this trend began in 2021 Q3, approximately nine months before the period when faulty test kits were shipped to clients.

The parallel trends in PPV performance across capillary screening modalities suggests that the root causes underlying the low performance are also common across modalities. These results mirror those seen in a similar analysis conducted in Minnesota, which found a 60% false positive rate across all capillary testing when using an elevated blood lead level case definition of 5 µg/dL.⁸

To minimize the risk of false positives, test administrators must adhere to proper test collection hygiene following recommendations from both the manufacturer and the CDC. This proactive approach will improve the reliability of results from the LeadCare II in the ongoing effort to identify and address lead exposure in children.

It is imperative that the public and health care providers recognize the LeadCare® II blood lead analyzer as a screening tool, not a definitive indicator of elevated blood lead levels. Even though this analysis was not able to estimate the specificity or negative predictive value of the LeadCare II analyzer, over 92% of individuals screened by LeadCare II analyzers had results below the BLRV (Table 1) and did not require more invasive testing.

As with any screening tool used, it is vital that any suspected case of lead exposure or poisoning be confirmed by a venous test.

Conclusion and Overall Recommendation

The analyses in this brief do not suggest that the overall performance of LeadCare® II was impacted by the distribution of the faulty test kits and illustrates the ongoing utility of LeadCare® II analyzers as a sufficient screening tool for EBLLs. The CLPPP epidemiology team recommends that MDHHS continue to support the usage of LeadCare II instruments for blood lead screening.

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