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Response to the U.S. FDA LeadCare Testing Systems Recall and CDC Health Alert

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Abstract

On May 17, 2017, the Food and Drug Administration (FDA) issued a safety recall for the Magellan Diagnostics' LeadCare Testing Systems due to the potential for inaccurately low blood lead test results when used with venous blood samples, which has implications for the follow-up care of persons exposed to lead. Concurrent with the recall, the Centers for Disease Control and Prevention (CDC) issued a health alert regarding the use of LeadCare Testing Systems. CDC provided recommendations for specific high-risk populations so that persons potentially impacted by falsely low test results could be retested and receive appropriate follow-up care. Childhood lead poisoning prevention programs in state and local public health agencies collect blood lead test results for children and had a lead role in identifying children for retesting. CDC's Lead Poisoning Prevention Program sought to understand how the recall and recommendations impacted state and local public health agencies. Case studies are presented that highlight the experiences of four state childhood lead poisoning prevention programs in responding to the recall and recommendations. Collectively, the case studies point to several lessons learned, including the importance of: (1) having a well-functioning surveillance system in place prior to a serious incident; (2) having a clear understanding of the roles partners play in the continuum of care for children potentially exposed to lead; (3) ensuring effective communications with all staff, both internal and external, to public health agencies that have a role in responding to a serious incident. The ability to respond to public health emergencies or other serious incidents takes the combined effort of federal, state, and local public health agencies as well as others in the healthcare delivery system. CDC will continue to support state and local lead poisoning prevention programs so they have the information and tools they need to address and prevent the health effects of lead exposures in communities.

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Background

Blood lead testing to identify children with lead exposure and link them with recommended follow-up services is an essential component of a comprehensive lead poisoning prevention program.[1] While blood lead testing is at the core of secondary prevention of childhood lead poisoning, it also has a clear role in primary prevention efforts to identify and remove sources of lead in homes and the environment before any exposure occurs.[2] The collection of blood lead test results for surveillance activities helps public health agencies identify high-risk geographic areas and populations in order to effectively target scarce resources where needed most.

A blood lead test is recommended for initial screening purposes and, in the case of elevated screening blood lead levels, for confirmatory diagnostic evaluation and ongoing monitoring.[3–5] Capillary blood lead measurements may be used for initial screening purposes, but generally venous blood is recommended for diagnostic evaluation.[3–6] There are several laboratory analytical methods for the determination of lead in blood including anodic stripping voltammetry (ASV), graphite furnace atomic absorption spectroscopy (GFAAS), and inductively coupled plasma mass spectrometry (ICP-MS), the latter two of which use laboratory-developed tests to conduct high-complexity diagnostic tests.[7,8] The U.S. Food and Drug Administration (FDA) categorizes diagnostic tests based on seven Clinical Laboratory Improvement Amendments (CLIA) criteria categorized by complexity—from the least to the most complex: waived tests, moderate complexity tests, and high complexity tests.[9]

A family of instruments for blood lead analysis using anodic stripping voltammetry (ASV) methods, known as LeadCare® Testing Systems (i.e. LeadCare I, LeadCare II, LeadCare Plus, and LeadCare Ultra) manufactured by Magellan Diagnostics (North Billerica, MA), have been approved for marketing by the FDA. Both LeadCare Plus, designed to be used in small laboratories, and LeadCare Ultra, a high-throughput testing system designed for use in larger laboratories, are classified as a “moderate complexity” tests. The LeadCare II point-of-care (POC) instrument, a second-generation of LeadCare I (ESA Biosciences, Chelmsford, MA), has been approved for marketing by the FDA as a “CLIA-waived” device for use in non-laboratory settings such as doctors’ offices and clinics.[10] Diagnostic tests are categorized by FDA as “waived” if they are “simple to use and there is little chance the test will provide wrong information or cause harm if it is done incorrectly.[11]

On May 17, 2017, the FDA issued a safety communication regarding a Class I recall for all versions of LeadCare Testing Systems devices.[12,13] The FDA defines a Class I recall, the most serious type, as one in which there is a reasonable probability that use of the product “will cause serious adverse health consequences or death.”[14] The FDA warned that LeadCare Testing Systems “may underestimate blood lead levels (BLLs) and give inaccurate results when processing venous blood samples.”

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Concurrent with the FDA warning, CDC issued an advisory and provided recommendations for retesting potentially affected persons through its Health Alert Network (HAN).[15] The retesting recommendations apply to those with a venous blood test result of less than 10 micrograms per deciliter (μg/dL) analyzed prior to the recall using a Magellan Diagnostics' LeadCare Testing Systems instrument. Children less than 6 years of age at the time of the alert and currently pregnant or lactating women were identified by CDC as the highest risk priority group and, thus, the focus of the retesting recommendations. A flow diagram that summarizes CDC's retesting recommendations is presented in Figure 1.

The target audiences responsible for implementing the retesting recommendations include: public health officials, healthcare providers, and clinical laboratories. Most public health agencies have regulatory or statutory authority that requires reporting of blood lead test results for residents in their jurisdictions regardless of where the test was administered or analyzed. Blood lead surveillance is typically the responsibility of state and local Childhood Lead Poisoning Prevention Programs (CLPPPs). Consequently, CLPPPs were at the forefront in responding to the FDA's safety recall and CDC's retesting recommendations. CDC sought to understand how this extraordinary incident impacted state and local CLPPPs. For example, what challenges did programs face and what lessons were learned? To answer these questions, CDC utilized a two-pronged approach to collect information: case studies and semi-structured phone interviews. Case studies were written by state CLPPP staff who presented information on their experiences with the FDA recall and CDC retesting recommendations at CDC's Annual Lead Poisoning Prevention Program Cooperative Agreement Recipients' Meeting held in Atlanta in December 2017. The four case studies presented and described herein provide both common and unique experiences of public health agencies in responding to the recall and recommendations. Additionally, one staff member who played an active role in implementing the CDC recommendation from each of nine CLPPPs was invited to participate in an hour-long, semi-structured phone interview [**Editor's Note: See article by Trinh, et al. on page XX in this issue**].

Case Studies

Connecticut

The Connecticut Department of Public Health (CT DPH) became concerned about error rates and inconsistencies between LeadCare package inserts and the Advisory Committee for Childhood Lead Poisoning Prevention's (ACCLPP) POC recommendations for confirmatory tests. CT DPH consulted with scientists who informed the ACCLPP guidelines, about their concerns. In January 2016, CT DPH notified pediatricians and hospital laboratories via a "circular letter" that venous results from LeadCare instruments were not an acceptable form of confirmation.[16] Circular Letter 2016–02 also briefly described the differentiation of moderate and high complexity testing for confirmation.

As a result of their investigation, CT DPH found certain laboratories used as "reference labs" were, unbeknownst to pediatricians, using the moderate complexity LeadCare Ultra/Plus instruments for confirmatory analysis. Differences exist between the underlying analytic ASV method of the LeadCare II, intended for POC use, and the LeadCare Ultra/Plus instruments being used to confirm screening results.[17,18] These differences include: the

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number of channels, and therefore tests, for analysis at the same time, the freshness of sample matrix from time of draw, how samples are transferred to sensors, whether carbon particles are part of the analytical process, and the limits of detection. Additionally, CT DPH learned that due to quick turnaround time, providers were basing clinical decisions on whether or not to chelate using results derived from LeadCare instruments which do not meet the ACCLPP-recommended definition of confirmatory test utilizing high complexity analytic methods.[6]

On May 17, 2017, CT DPH learned of the Class I FDA recall through the CDC Health Advisory via the Association of State and Territorial Health Officials (ASTHO) email listserv. Following the recall of the LeadCare venous feature and CDC's subsequent retesting recommendations, CT DPH sent out a second circular letter that informed providers of the recall and recommendations and required all labs using LeadCare to inform referring pediatricians to determine if patients needed retesting. CT DPH also worked diligently with the Medical Director of the Department of Children and Families (DCF) to determine which children needed retesting. Additionally, CT DPH worked with hospitals to gather paired data on venous samples analyzed using both LeadCare and high complexity methods to further understand potential discrepancies. Analysis revealed differences for BLLs greater than 5 μg/dL (as measured by LeadCare II) ranging from −28 to +4.3 μg/dL between paired results for LeadCare II and high complexity methods (unpublished data). Therefore, differing medical courses of action may have been prescribed depending on which analytical method was used.

Informing healthcare providers and laboratories that venous results obtained using LeadCare instruments were not acceptable prior to the FDA recall likely reduced the number of children who required retesting in CT. To ensure confirmatory testing is appropriately done, health departments may want to consider educating providers and laboratories, particularly hospital labs, regarding the important differences, such as detection limits, between the various laboratory methods. In addition, healthcare providers can denote the blood sample type and whether the sample is for screening or confirmatory purposes to better advise the analyzing lab and health department responsible for collecting and following up on blood lead test results.

New Jersey

The New Jersey Department of Health (NJ DOH) identified 11 providers representing 24 user sites in New Jersey that reported blood lead test results on venous samples that were analyzed on either a LeadCare II or LeadCare Ultra instrument. Providers included: local health departments (LHDs), health care professional offices, hospitals, and independent laboratories. The NJ DOH contacted each user site by phone to instruct the laboratory director to cease analyzing venous samples on LeadCare instruments and to inform them that further guidance would be provided about the FDA recall and CDC health advisory. The NJ DOH faxed a FAQ information sheet, the FDA notification, the retesting protocol, and a sample patient notification letter to each user site. Additionally, the NJ DOH used a Family Health Warm Line to address FAQs from the public regarding the health advisory.

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Fifteen thousand children were identified by the NJ DOH as meeting the CDC retesting criteria. Two LHDs were impacted by the warning, resulting in 4,700 children requiring retesting according to the CDC recommendations. The NJ DOH provided a list of identified children to the impacted LHDs.

In reviewing blood lead test results for the impacted providers, the NJ DOH noted an abnormally high quantity of homogenous results for an independent laboratory. Of 956 reports to the NJ DOH between May 2011-June 2016, 944 (98.7%) were reported with a value of 3.0 μg/dL. The LeadCare II instrument has a limit of detection of 3.3 μg/dL; however, the results of 3μg/dL may be the result of rounding and highlight the importance of reporting non-integer test results to at least one digit to the right of the decimal point particularly for results below 10 μg/dL. When the NJ DOH attempted to contact the independent laboratory about the warning and advisory, the phone number was no longer in service. A web search for additional contact information revealed multiple news articles regarding a U.S. Federal Bureau of Investigation (FBI) investigation regarding the provider. The Child and Adolescent Health Program (CAHP) forwarded its concerns regarding the possible falsification of medical records to the NJ DOH's Office of Legal and Regulatory Compliance. Subsequently, the issue was forwarded to the NJ Deputy Attorney General, Division of Criminal Justice for further investigation. Ultimately, the owners of the independent laboratory pled guilty and forfeited assets in 2016. As of April 2017, the medical fraud case has led to 51 convictions, including 38 doctors, with more than a dozen people awaiting sentencing. News accounts report that it is the largest number of medical professionals ever prosecuted in a federal bribery case, with over $150 million in billed payments from Medicare and private insurance over eight years.[19]

The warning and advisory provided an opportunity for the NJ DOH to update its LeadCare user contact list and to reinforce regulatory reporting requirements. Another positive outcome arising from the recall is that NJ DOH's childhood lead surveillance data management plan has put quality assurance and improvement protocols to identify anomalies in place. An important lesson learned is that intra- and inter-departmental communication can facilitate efficient communication with impacted providers and the public and to address other concerns that affect public health outcomes.

Oklahoma

The Oklahoma Childhood Lead Poisoning Prevention Program (OCLPPP) was notified of the FDA advisory officially via email notices through the CDC Health Alert Network. The OCLPPP participated on a CDC conference call on May 18th describing the potential for falsely low venous test results and clarifying retesting recommendations.

Magellan Diagnostics mails the OCLPPP a monthly, updated list of organizations or providers who have purchased a LeadCare instrument in Oklahoma. The OCLPPP assists new users with reporting, onboarding, and follows up with non-reporters to identify if the instrument is still in use. Because these procedures were already in place, the OCLPPP had contact information for the LeadCare II users affected by the recall and a large hospital laboratory, which was using a LeadCare Ultra instrument. In OCLPPP's blood lead surveillance and case management system, blood lead test results analyzed using a LeadCare

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II instrument are identified by the laboratory name “In Office.” The OCLPPP was easily able to identify which patients were impacted by the FDA advisory and CDC’s recommended retesting protocol by analyzing the “In Office” and large hospital data. Relevant data were imported into SAS to identify patients who: (1) were born on or after May 17, 2011; and (2) had a venous specimen tested on a LeadCare instrument; and (3) either had no further blood lead testing or subsequent testing was also a venous specimen on a LeadCare instrument.

The OCLPPP mailed letters to the parents or guardian of the 6,442 children who met the retesting criteria. The letter detailed the advisory and potential for falsely low results in the previous blood lead test, recommended that the child receive a follow-up blood lead test, and provided contact information for the OCLPPP to answer any additional questions or provide assistance. In addition to the “parent” letter, the 383 unique health care providers who ordered the original blood lead tests on the 6,442 children were sent a letter asking them to contact the child’s guardian to schedule a retest. If a parent letter was returned, OCLPPP personnel queried additional databases to see if a newer address was on file and, if so, mailed the letter to the new address. The OCLPPP has not tracked the proportion of children who received the recommended follow-up test because querying the blood lead surveillance system for new blood lead testing data cannot definitively ascertain if the retest was collected due to the recall or as part of standard Oklahoma screening requirements.

CDC guidance was helpful in establishing the criteria for recommended retesting and allowed for standardization of how each state would handle the challenge and uniformity of response from all states. At this time, the OCLPPP is not pursuing additional steps in their response and considers that the matter has been resolved satisfactorily. No changes will be made to the reporting methodology as the current system easily identified LeadCare II test results and could do so again if a similar situation should arise.

Minnesota

In response to the CDC-issued health alert, the Minnesota Department of Health (MDH) issued a health advisory on May 18, 2017 to ensure health care providers and local and tribal health departments were aware of the recall and retesting recommendations. MDH also developed frequently asked questions (FAQ) for health care providers and parents. MDH identified laboratories with LeadCare instruments. Laboratories and local public health agencies were sent lists of patients meeting retesting criteria and were encouraged to ensure patients were retested. Individuals identified as meeting CDC’s retesting criteria through the surveillance system, as well as refugees 6–17 years of age, were recommended for retesting. Retesting was prioritized for persons with previous elevated blood lead levels [EBLLs (defined as ≥ 5 μg/dL)] MDH monitored retesting progress through routine blood lead surveillance and sent updated lists to partners. Logistic regression was used to examine trends in the proportion of individuals retested by the year of their pre-recall blood lead test.

MDH identified fifty-nine laboratories with LeadCare instruments that had analyzed 58,319 samples of venous blood or unknown sample type. Four of those laboratories were using LeadCare Ultra instruments. Of identified test results, 26,491 persons met retesting criteria, including: 18,152 children, 7,113 adults with unknown pregnancy status, and 1,226

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refugees; 1,528 had an elevated result from a capillary sample in the 12 months prior to having a venous sample analyzed on a LeadCare instrument (prior EBLL). As of April 30, 2018, MDH had received retests from 4,867 (18.4%) persons, including 3,994 (22.0%) of children, 796 (11.2%) of adult women, and 77 (6.3%) of refugees. Of those with prior EBLLs, 502 (32.9%) received a retest.

The proportion of individuals who received a retest was associated with the year of their pre-recall blood lead test ($p<0.01$). Only 1.6% (16/1,023) of individuals who had been tested during 2007–2011 received a retest, compared to 10.4% (1,224/11,754) of individuals with a pre-recall test during 2012–2015, and 26.4% (3,627/13,714) of individuals with a pre-recall test during 2016–2017. Of retested persons, 80 (1.6%) had at least one elevated blood lead test result following the recall. Of those, 39 (48.8%) had confirmed EBLLs; 7 (8.8%) had elevated capillary results and have not yet received confirmatory testing; and the remainder were found to be non-cases.

As a group, refugees had the lowest retest rates (6.3%). Because many of these patients were originally tested at their intake examination and did not continue to receive primary care from the same health care provider, it was difficult for the clinics to contact these individuals. Additionally, it was difficult to determine the pregnancy status of adult women, as clinics often do not know whether a patient has become pregnant unless she is receiving regular, ongoing care. Retesting was also minimally successful for individuals tested prior to 2012.

Several factors were instrumental to this response. Purchase records from the manufacturer allowed identification of laboratories that used LeadCare instruments. However, the type of instrument used by each laboratory that submits data to MDH had to be validated because purchase records did not include instruments purchased prior to 2007 or laboratories that are located outside of Minnesota. Quality data in MDH's surveillance system facilitated generating lists of persons to retest. Voluntary cooperation from laboratories and local public health agencies was invaluable for contacting patients.

MDH was contacted about several instances when a patient attempted to schedule a retesting appointment and experienced difficulty because their clinic schedules appointments using a centralized switchboard, and the operators were unaware of the recall. Several health care providers reportedly told their patients that they did not need to be retested. In addition, some patients received confusing or contradictory messages about who would pay for the retesting appointment. In each of these circumstances, MDH staff attempted to intervene and educate health care providers and clinic staff on the importance of retesting. These difficulties highlight the importance of communicating with all levels of the health care delivery system, including local and tribal health departments, health care providers, staff who schedule appointments for clinics, and health insurance providers and managed care plans. MDH continues to monitor test results received to ensure that laboratories utilizing LeadCare instruments do not test venous samples.

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Discussion and Conclusions

Between January 1, 2014 and May 22, 2017, there were over 8 million blood lead tests analyzed on LeadCare Testing Systems kits distributed in the U.S.[13,20] Based on the CDC reference value of 5 μg/dL, Magellan Diagnostics estimated that 2.5% of the 8 million tests, or 200,000 results may have been affected by the potential for falsely low blood lead results.[21] However, there is no way to estimate how many tests were actually affected. In May 2005, a voluntary recall of eight specific lots of LeadCare testing kits identified defective sensors as the root cause of a negative bias that potentially affected 500,000 blood lead tests from kits distributed between September 2003 and April 2005.[22] This recall also resulted in a recommendation to retest affected persons.[23]

The LeadCare II POC instrument, designed to be used with two drops of capillary blood from a finger stick, offers several benefits over more complex methods including: rapid results, no specialized skill required for use, portability, and relative affordability.[24] However, capillary blood specimens may provide falsely elevated lead levels that can be the result of inappropriate blood collection procedures (e.g., finger stick collection from a lead-contaminated finger) or due to contaminated materials used to collect and transport the specimen.[5,25,26] Given that, in 2013, the CDC Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) recommended that blood lead levels greater than or equal to 5 μg/dL analyzed on POC instruments on children less than 6 years of age be confirmed using a venous blood sample analyzed by CLIA-certified high complexity method.[6] At that time, LeadCare II was (and still is) the only POC instrument approved for blood lead testing.[6] The subsequent approval and marketing of the LeadCare Ultra and LeadCare Plus instruments increased the availability of moderate complexity tests, which have been shown to compare well with high complexity methods.[17,18] However, given the low detection limits, precision, and high through put capabilities of ICP-MS and GFAAS, high complexity tests from laboratories that meet CLIA proficiency standards of ±10% or ±4 μg/dL are recommended for confirmatory blood lead analysis.[6,27–30]

Falsely low blood lead tests from the use of LeadCare Testing Systems with venous blood may have resulted in persons with elevated blood lead levels not receiving appropriate follow-up care. Therefore, CDC recommended: (1) children less than 6 years of with a venous blood lead test of less than 10 μg/dL analyzed using a LeadCare instrument at an onsite (e.g., healthcare facility) or at an offsite laboratory; and (2) currently pregnant or lactating women who had a venous blood lead test performed using a LeadCare instrument be retested.[15] Although the root cause of the most recent negative bias identified, i.e. when LeadCare Testing Systems are used with venous blood, is still under investigation by FDA, it is possible that the use of certain blood collection tubes (BD Vacutainer® plastic tubes with K2EDTA anticoagulant, Becton Dickinson (BD) & Company, Franklin Lakes, NJ) may be involved due to significant changes to the formulation of the rubber stoppers.[31]

The simultaneous U.S. FDA LeadCare Testing Systems Recall and CDC Health Alert and subsequent response by state and local health departments highlights both strengths and weaknesses of the current public health and laboratory testing systems to identify and respond to those, particularly children, with lead exposure in need of follow-up services and

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coordinated care. Federal agencies such as the CDC and the FDA are at the forefront of providing timely and relevant information to public health agencies during times of emergency, as well as to inform their day-to-day activities. The CDC CLPPP is committed to serving local, state, and tribal CLPPPs who implement actions to protect the health and well-being of the nation from lead exposures and resulting adverse health outcomes.

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Implications for Policy and Practice

- A well-functioning surveillance system is at the core of lead poisoning prevention program activities and not only enables public health agencies to perform their daily activities, but is essential to their ability to respond to extraordinary or emergency events in a timely and efficient manner. In order to improve surveillance capabilities, healthcare providers and laboratories could improve surveillance by documenting and reporting details related to type of specimen obtained and laboratory methods used for analysis as well as provide information on analytic methods such as precision, limits of detection, and rules used for rounding or truncating results.
- It may be helpful for public health agencies to know the key relationships in the continuum of care that are necessary to identify and follow up on lead-exposed children. Understanding the role of each entity, i.e., healthcare provider, clinic, hospital laboratory, and/or independent laboratory, and having up-to-date contact information for key staff in each organization may help programs improve their ability to respond to an emergency or other serious event.
- Federal, state, and local partners may benefit from working together to develop, communicate, and reinforce consistent messages aimed at providing important and necessary information to target audiences during emergency or other serious events.
- While POC instruments have increased the ability to reach high-risk populations, ACCLPP recommended that these instruments be used for screening purposes only. Current ACCLPP-recommendations suggest using a CLIA-categorized high complexity test for confirmatory blood lead testing.

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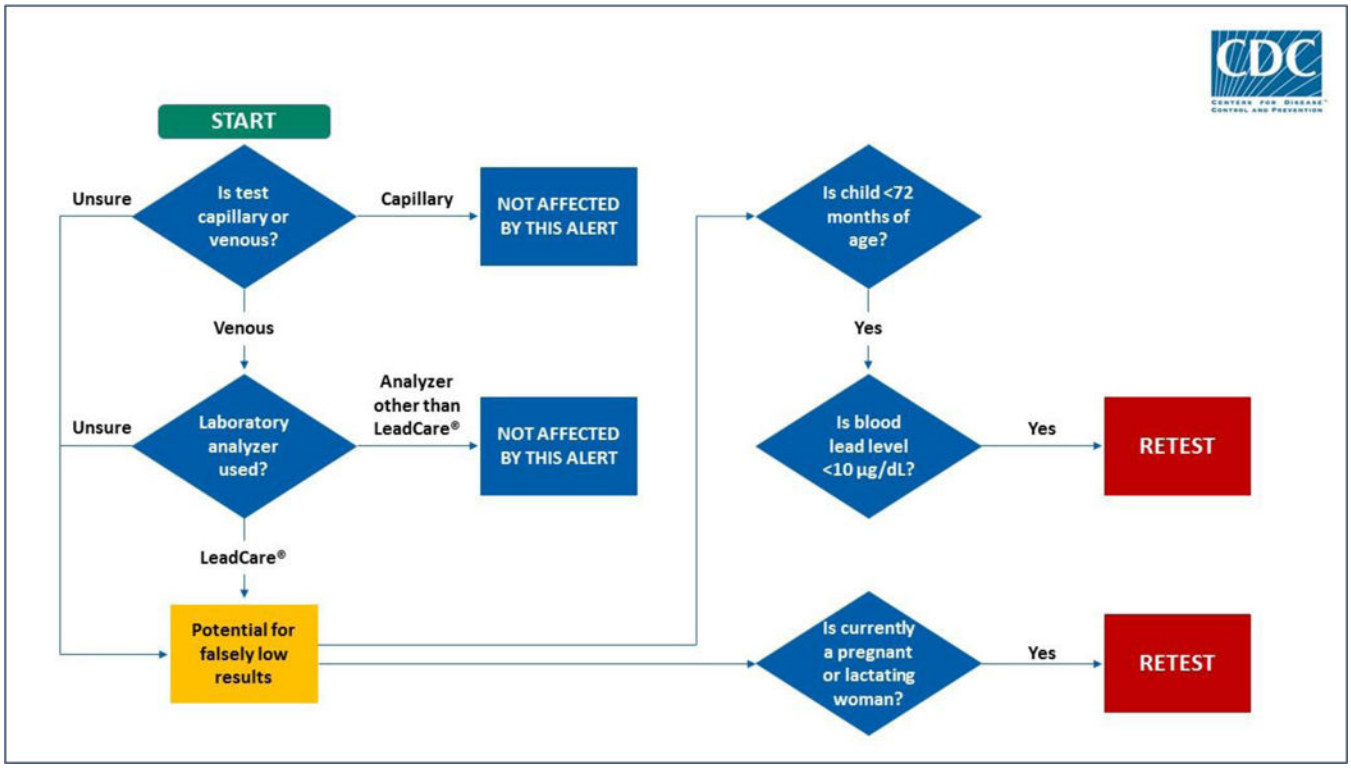

Figure 1.
CDC Flow Diagram for Determining Potentially Affected Blood Lead Tests and the Need for Retesting