

**Lead Poisoning Prevention and Surveillance Branch (proposed)
LeadCare® Expanded Recall (Oct 2021)
Questions & Answers**

Q1. Can you clarify if non-recalled kits should be quarantined or can they be used?

- A. The [FDA Magellan Diagnostics Recall website](#) includes the sentence “Customers should discontinue use of all test kit lots identified as part of the recall and quarantine remaining inventory.” The term “quarantine” means that providers and labs should isolate any remaining “recalled” test kits. Non-recalled LeadCare® test kits can be used until they reach their expiration date.

Q2. Given that the recall has been expanded twice already, is there any indication or concern about using test kits not already recalled because the recall may be expanded yet again?

- A. Customers with questions about this recall should contact Magellan's LeadCare® Product Support Team at 1-800-275-0102 or by email at LeadCareSupport@magellandx.com.

Q3. During the first recall, Magellan reached out directly to those customers who had recently ordered kits from them. Is there similar outreach occurring from Magellan to providers directly as a result of this expanded recall?

- A. Customers with questions about this recall should contact Magellan's LeadCare® Product Support Team at 1-800-275-0102 or by email at LeadCareSupport@magellandx.com.

Q4. We have many health care providers that are still submitting test results from their LeadCare® analyzer. Have all LeadCare® tests been recalled or are there still test kits available that are not part of the recall?

- A. The [FDA Magellan Diagnostics Recall website](#) includes the sentence “Customers should discontinue use of all test kit lots identified as part of the recall and quarantine remaining inventory.” The term “quarantine” means that labs should isolate any remaining “recalled” test kits. Non-recalled LeadCare® test kits could be used until they reach their expiration date.

Q5. Is there any movement to establish alternative point-of-care (POC) options for blood lead screening?

- A. CDC is not aware of any alternative POC options for blood lead screening. We understand that the LeadCare® manufacturer is currently working to resolve issues with this product. Please refer to CDC’s Health Alert Network (HAN) Health Update for guidance on how to continue blood lead screening while LeadCare® testing kits are unavailable. Please contact Magellan's LeadCare® Product Support Team at 1-800-275-0102 or by email at LeadCareSupport@magellandx.com with specific questions about this recall. Additional information about this recall can also be found on [Magellan’s website](#).

Q6. Can filter paper be used as an alternative method for collecting a blood sample?

- A. Filter paper has multiple issues of possible contamination that are well documented (see the link below). Filter paper can have unequal blood distribution which can result in false positives or false negatives when the paper is punched for analysis. The contamination issue is based on the paper production itself and the possible contamination during the collection and drying of the blood spot on the filter paper. These issues become of greater significance with the lowering of the BLRV. Below is a link to a very recent review of blood lead filter paper issues at: [A critical review of the analysis of dried blood spots](#)

[for characterizing human exposure to inorganic targets using methods based on analytical atomic spectrometry - Journal of Analytical Atomic Spectrometry \(RSC Publishing\).](#)

Q7. Will additional method type entries be created (other than venous and capillary) for those advanced capillary analysis?

- A. CDC is unaware of studies that used additional sampling sites for children (e.g., ear lobes, heels, etc.) that have validated the alternate collection site for blood lead testing. Please reach out to the lab doing the testing.

Q8. Do capillary samples analyzed with ICP-MS or GFAAS require confirmatory testing with venous if above the Blood Lead Reference Value (BLRV)?

- A. Capillary screening results above the BLRV should be confirmed with blood drawn by venipuncture. This is because capillary samples may be contaminated during the collection process.

Q9. Do higher complexity measuring methods occur at referenced labs?

- A. Most high-capacity labs (private or public) have GFAAS or ICP-MS analytical methods for blood lead testing.

Q10. Through provider feedback we have learned of concerns over the required sample volume needed for capillary samples for national labs. Is CDC working with labs to decrease the required sample volume to only what is minimally necessary?

- A. High complexity blood lab tests by ICP-MS and GFAAS are lab-developed tests specific to the laboratories that performed the testing. CDC provides resources to labs, such as our detailed laboratory methodologies that are published in peer-reviewed journals (Jones, D., et al. (2017). "Analysis of whole human blood for Pb, Cd, Hg, Se, and Mn by ICP-DRC-MS for biomonitoring and acute exposures." *Talanta* (Oxford) 162: 114-122). The information is also posted with each cycle of the National Health and Nutrition Examination Survey (NHANES) that is published on the [National Center for Health Statistics \(NCHS\) website](#).

Q11. Can you provide resources that emphasize the importance of washing child's hands with soap and water to remove ambient lead particles-- prior to alcohol swabs -- when collecting capillary samples as office and labs are moving to BD microtainers/scoop vials?

- A. CDC's fingerstick blood collection [poster](#) and [video](#) describes hand washing with soap and water.

Q12. Will the Centers for Medicare & Medicaid Services (CMS) pay for all re-testing costs?

- A. CMS is prepared to cover re-testing costs for Medicaid-eligible children because blood lead screening tests are mandatory services. If issues arise, please contact your state Medicaid office.

Q13. Will providers get penalized by Medicaid for not reporting a lead result if patient's families do not adhere to follow up?

- A. Questions about Medicaid policies and procedures should be directed to the state Medicaid office.

Q14. Can state and local public health departments as well as territories, use CDC Childhood Lead Poisoning Prevention Program (CLPPP) Notice of Funding Opportunity (NOFO) funds to cover re-testing cost? If so, are there limitations on how the funds can be used, i.e., can funds be used only for supply purchase or also for lab analysis fees?

A. CMS is prepared to cover re-testing and primary testing costs for Medicaid-eligible children in the CMS network. For children on private insurance, this should be determined by the provider in consultation with the patient's insurance. Recipients may also use CLPPP funds on a limited basis to cover the cost of blood lead retesting due to the recall where no other form of payment exists. Programs must work with project officers on any redirection requests.

Q15. What information will CDC project officers be asking recipients to provide when they call weekly?

A. Your Project Officer will be contacting you on a weekly basis to better understand the impacts in your jurisdiction related to the LeadCare® recall so that CDC can offer additional advice or technical support. We ask that you help by monitoring screening rates to identify where extra support is needed.

Q16. Will CDC share what they learn from weekly contact with programs to facilitate the sharing of successful outreach methods?

A. CDC project officers will share information they learn about successful outreach methods from other programs upon request from NOFO recipients as it becomes available.

Q17. In the future, can Project Officers directly send lead relevant Health Alert Network (HAN) Health Updates to funded programs?

A. Yes. Additionally, recipients are encouraged to register to receive alerts from CDC's HAN Health Update. Sign up to receive email updates at: <https://emergency.cdc.gov/han/updates.asp>

Q18. Can CDC develop questions that all programs can share with local healthcare providers to learn more about the barriers to lead testing in lieu of the LeadCare® recall?

A. Yes. CDC is developing questions that your project officer will share with you in order to capture information to better understand the impacts in your jurisdiction related to the LeadCare® recall. This will enable CDC to offer additional support. We ask that you help by monitoring screening rates to identify where extra support is needed.

Q19. Can CDC send out communication in a timely manner to help support state health departments through the recall?

A. CDC continues to monitor the situation and will provide updates as more information becomes available.

Q20. What information can recipients give to health care providers to help them explain the recall to parents and caregivers?

A. The following CDC resources may provide helpful information for parents:

- Health Alert Network (HAN) Health Update
[CDC HAN 454.pdf](#)
- Blood Lead Levels in Children
<https://www.cdc.gov/nceh/lead/prevention/blood-lead-levels.htm>

- Health Effects of Lead Exposure
<https://www.cdc.gov/nceh/lead/prevention/health-effects.htm>
- 5 Things You Can Do
<https://www.cdc.gov/nceh/lead/docs/5things-508.pdf>
- Information for You – Parent and Caregivers
<https://www.cdc.gov/nceh/lead/audience/parents.html>

Q21. Does CDC fully understand the impact of having no point-of-care (POC) Blood Lead Level (BLL) testing devices?

- A. CDC is aware of the impact of this recall on blood lead testing. This issue is extremely important to CDC, and we understand that this may cause challenges for your programs. CDC is engaging in several activities to support your programs so that comprehensive blood lead screening continues and to provide additional laboratory capacity support. We understand that the LeadCare® manufacturer is currently working to resolve this issue, and we are hopeful that the situation will be resolved soon. It is critical that we work together to ensure that children continue to be tested using the resources that are available. At this time, it is crucial that we focus our efforts on increasing blood lead screening levels, particularly for children in low-income communities and communities of color. CDC is committed to preventing childhood lead exposure and will continue to support you by providing technical assistance, providing funding flexibility and sharing information and updates.

Q22. What is the starting time period recipients can use when evaluating the impact of the recall on screening rates?

- A. The affected lots were distributed from October 27, 2020, through August 19, 2021. Programs should compare screening rates two to three months before these lots were distributed with screening rates observed after August 19, 2021.

Q23. Since most results reported to states do not include information such as test lot number, are states expected to follow up with all their providers to obtain this information for quarterly reporting?

- A. No, there is no way to report the lot number in the blood lead reports submitted to CDC. CDC is not expecting this information.

Q24. Should recipients omit the test results from known recalled test kits in quarterly data submissions and Childhood Lead Poisoning Prevention Program (CLPPP) databases?

- A. Generally, test results conducted using the recalled test kits should be reported as usual with quarterly data submissions. Multiple lab test records can be submitted for the same patient within a reporting quarter if the specimen collection dates are different. If the samples were drawn on the same date, then refer to the Childhood Blood Lead Surveillance (CBLS) data protocol for selecting the proper test to report. If possible, programs should omit invalid test records (e.g., false positives, duplicates, lab errors, etc.) from inclusion within their quarterly data submissions. If programs are aware of previously submitted invalid or duplicate records they can be corrected with corresponding “delete” records in the next data submission cycle. Tests performed on a LeadCare® instrument using one of the recalled lots should still be reported taking into account the qualifiers noted above. Because state surveillance programs may not know whether the test was performed with one of the recalled kits, or if the result was invalid, both the initial and repeat test should be reported to CDC following the standard CBLS quarterly data protocols unless it is clearly an invalid result.

Q25. Due to the recall, are there any specific strategies recommended for how public health departments should work with providers to improve testing and focus efforts to ensure children receive required blood lead tests?

A. The following CDC resources may provide helpful information:

- Health Alert Network (HAN) Health Update
[CDC_HAN_454.pdf](#)
- Blood Lead Levels in Children
<https://www.cdc.gov/nceh/lead/prevention/blood-lead-levels.htm>
- Health Effects of Lead Exposure
<https://www.cdc.gov/nceh/lead/prevention/health-effects.htm>
- 5 Things You Can Do
<https://www.cdc.gov/nceh/lead/docs/5things-508.pdf>
- Information for You – Parent and Caregivers
<https://www.cdc.gov/nceh/lead/audience/parents.html>

Q26. How do recipients work with providers to ensure parents who face logistical challenges receive venous testing for their children?

A. If providers do not have the capacity to do a venous draw, but the provider is confident the family will go to the lab and comply with an external laboratory visit, then the normal referral should take place. However, if the provider is concerned that the parent will face logistical challenges getting the child to the lab then the provider should consider collecting capillary blood samples according to the CDC guidance, then send the specimen to a CLIA compliant laboratory.

Q27. Can CDC collaborate or provide technical assistance to Meridian Bioscience to rapidly, efficiently, and thoroughly resolve the issue with containment in the plastic supply chain that is impacting the LeadCare® II testing material supplies and the test results?

A. FDA is currently working with Meridian. CDC continues to monitor the situation and will provide updates as more information becomes available.