



REFERENCES AND RESOURCES FOR SACRAMENTO COUNTY CHDP PROVIDERS

CHDP PROGRAM

- **CHDP Provider Manual:** https://files.medi-cal.ca.gov/pubsdoco/chdp_manual.aspx
- **Overview of EPSDT as it relates to CHDP Program:**
<https://www.commonwealthfund.org/publications/publication/2005/sep/epsdt-overview>
- **CHDP Program Consultation and Claims Processing, see California’s State Department of Health Care Services or DHCS:** <https://www.dhcs.ca.gov/>
- **DHCS Medi-Cal home page:** <https://www.medi-cal.ca.gov/>
- **Medi-Cal Provider manual:** https://files.medi-cal.ca.gov/pubsdoco/manuals_menu.aspx
- **Medi-Cal Telephone Service (TSC):** (800) 541-5555 for billing questions
- **Medi-Cal Subscription services:** <https://files.medi-cal.ca.gov/pubsdoco/mcss/mcss.aspx>
- **Information for CHDP Gateway:** <https://filesaccepttest.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/epsdtchdpgate.pdf>
- **Gateway Eligibility & POS Network/Internet Agreement form:** <https://files.medi-cal.ca.gov/pubsdoco/signup.aspx>
- **Gateway Guide:** https://files.medi-cal.ca.gov/pubsdoco/publications/Masters-Other/CHDP/userguide/gateway_guide.pdf
- **CHDP website home:** <https://dhs.saccounty.net/PUB/CHDP/Pages/CHDP-Home.aspx>
- **Gateway Post-Visit Flyer:** <https://dhs.saccounty.net/PUB/CHDP/Documents/FL-CHDPGatewayPostVisitParent.pdf>
- **Gateway Federal Income Guidelines:** https://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_30992.aspx

- **Bright Futures Periodicity Schedule:** https://www.aap.org/en-us/Documents/periodicity_schedule.pdf
- **CHDP Health Assessment Guidelines:** <https://www.dhcs.ca.gov/services/chdp/Pages/HAG.aspx>
- **Incorporating Recognition and Management of Perinatal and Postpartum Depression Into Pediatric Practice:** <http://pediatrics.aappublications.org/content/126/5/1032>
- **CHDP Care Coordination form:** <https://dhs.saccounty.net/PUB/CHDP/Documents/FM-CHDPCareCoordinationFollowUpRequest.pdf>
- **CHDP Foster Care Medical/Specialty Contact form:** <https://dhs.saccounty.net/PUB/CHDP/Documents/FM-CHDPFosterCareMedicalContactForm.pdf>
- **Sacramento County Public Health home page:** www.scph.com
- **Sacramento County CHDP Provider Relations Survey:** <https://fs11.formsite.com/HHS-ITS-Self-Services/rc17uoaae4/index.html>
- **Foster Care Medi-Cal Eligibility:** (916) 875-5770
- **Sacramento County CHDP Nurse Consultant: Teri Pond, P.H.N. ~ 9616 Micron Avenue, Suite 670, Sacramento, CA 95827 ~ (916) 875-6073**
- **Sacramento County CHDP Nurse Consultant: Jennifer Arcangel-Mata, P.H.N. ~ 9616 Micron Avenue, Suite 670, Sacramento, CA 95827 ~ (916) 875-4283**

ORAL HEALTH REFERENCES AND RESOURCES

- **Death of Deamonte Driver from a brain infection caused by tooth decay:** <https://www.mchoralhealth.org/milestones/2007.html>
- **AAP Oral Health Assessment Tool:** https://www.aap.org/en-us/Documents/oralhealth_RiskAssessmentTool.pdf
- **CDC Recommended Fluoride Supplement Schedule:** <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5014a1.htm>
- **Sacramento County's Fluoridation Map:** https://first5sacramento.saccounty.net/Programs/Documents/COS_Fluoridation_Map.pdf

- **California’s Drinking Water Fluoridation Tables:**
https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/fluoridation/Tables/data2016.pdf
- **Fluoride Varnish Research:** <http://www.astdd.org/www/docs/fl-varnish-research-brief.pdf>
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2257982/?tool=pubmed>
- **Efficacy of Fluoride Varnish:**
www.ncbi.nlm.nih.gov/pmc/articles/PMC2257982/?tool=pubmed
- **CDC’s Fluoride Recommendations:** https://www.cdc.gov/fluoridation/faqs/dental_fluorosis/
- **U.S. Public Health Service Research r/t Fluoride:**
<https://ilikemyteeth.org/fluoridation/dangers-of-fluoride/>
- **Medi-Cal Dental Benefits:** <https://smilecalifornia.org/>
- **Smiles for Life:** <http://www.youtube.com/watch?v=Hw99Aoti7ZE>
- **First Five Oral Health:** <http://www.youtube.com/watch?v=UF4Ra1ZgovI>
- **Sacramento County’s Oral Health/Fluoride Varnish Training:** 9616 Micron Avenue, Suite 670, Sacramento, CA 95827 ~ (916) 875-7151

DEVELOPMENTAL, SOCIO-EMOTIONAL/BEHAVIORAL SURVEILLANCE

REFERENCES AND RESOURCES

- **Bright Futures Developmental, Behavioral, Psychosocial, Screening and Assessment Forms**
<https://brightfutures.aap.org/materials-and-tools/tool-and-resource-kit/Pages/Developmental-Behavioral-Psychosocial-Screening-and-Assessment-Forms.aspx>
- **Autism Spectrum Disorder MCHAT form:** <https://mchatscreen.com>
- **American Academy of Pediatrics Policy Statement on Management of children with ASD:**
<https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Pages/autism-initiatives.aspx>
- **Adverse Childhood Experiences (ACE’s) Training:** <http://www.ACEsAware.org>
- **Adverse Childhood Experiences (ACE’s) Assessment, Treatment and Planning:**<https://www.acesaware.org/treat/clinical-assessment-treatment-planning/>
- **California Early Start /Early Intervention:** <https://www.dds.ca.gov/services/early-start/>

- **Sacramento ALTA California Regional Center:** <https://www.altaregional.org/>
(916) 978-6400
- **Help Me Grow Sacramento:** <https://www.helpmegrowsac.org/> ~ (916) 228-2506
- **Sacramento Office of Education (SCOE):** <https://www.scoe.net/> ~ (916) 228-2500
- **California Children's Services (CCS):** <https://www.saccounty.net/services/Pages/California-Children's-Services.aspx> ~ 9616 Micron Avenue, Suite 970, Sacramento, CA 95827 ~ (916) 875-9900

TUBERCULOSIS SCREENING AND TREATMENT REFERENCES AND RESOURCES

- **To file Confidential Morbidity Report (CMB):**
<https://dhs.saccounty.net/PUB/Pages/Confidential-Morbidity-Report-Forms.aspx>
- **Clinical care for Tuberculosis: Sacramento County Chest Clinic @ 4600 Broadway, Suite 1300, Sacramento, CA (916) 874-9823**

LEAD SCREENING REFERENCES AND RESOURCES

- **Lead in Jewelry:** <https://dtsc.ca.gov/toxics-in-products/lead-in-jewelry/>
- **CDC Guidelines on Lead Poisoning Prevention and Sources of Lead:**
<https://www.cdc.gov/nceh/lead/prevention/sources.htm>
- **Childhood Lead Poisoning Prevention Branch:**
<https://www.cdph.ca.gov/Programs/CCDCPHP/DEODC/CLPPB/Pages/prov.aspx>
- **Sacramento County's Childhood Lead Poisoning Prevention Program: 9616 Micron Avenue, Suite 670, Sacramento, CA 95827 ~ (916) 875-7151**

VISION SCREENING REFERENCES AND RESOURCES

- **Vision Care Provider Directory:**
<https://www.dhcs.ca.gov/provgovpart/pharmacy/Pages/Vision-Care-Provider-Directory.aspx>

SIDS REFERENCES AND RESOURCES

- **Sharing Parents of Sacramento** <http://sharingparents.org/> ~ P.O. Box 19538, Sacramento, CA 95819 ~ Email: hello@sharingparents.org ~ (916) 424-5150
- **California SIDS Program:** 3164 Gold Camp Drive, Suite 220, Rancho Cordova, CA 95670 ~ (800) 369-7437
- **Sacramento County's SIDS Coordinator:** Jackie Washington-Ansley, R.N., P.H.N. ~ (916) 876-7750 ~ 9616 Micron Avenue, Suite 670, Sacramento, CA 95827
- **Child Abuse and Prevention Center ~ Sacramento County Safe Sleep Baby Campaign**
<http://www.thecapcenter.org/what/child-safety/safesleepbaby>

CHILDHOOD LEAD POISONING PREVENTION BRANCH

Updated CDC Blood Lead Reference Value

The Centers for Disease Control and Prevention (CDC) announced a change in its blood lead reference value (BLRV) from 5 micrograms per deciliter (mcg/dL) to 3.5 mcg/dL on October 28, 2021. The CDC BLRV is used to identify children with higher levels of lead in their blood compared to most children.

For more information:

- CDC MMWR article: Update of the Blood Lead Reference value—United States, 2021
- CDC web page: Blood Lead Reference Value

Statement from CLPPB

CDPH plans to adopt the new CDC BLRV of 3.5 mcg/dL. CDPH is working to procure the required resources to implement CDC's new BLRV. CDPH will update California Management Guidelines and other required documents to reflect this change. CDPH will also be using the new BLRV to prioritize communities with the most need for primary prevention of exposure and evaluate the effectiveness of prevention efforts.

Information for California Health Care Providers

The new CDC BLRV at which healthcare providers are recommended to provide follow-up is 3.5 mcg/dL, and CDPH encourages healthcare providers to provide retesting and follow-up for blood lead levels \geq 3.5 mcg/dL.

For more information:

- Recommended Actions Based on Blood Lead Levels (CDC)

This page will be updated as implementation of CDC's new BLRV in California progresses.

CDC's New Blood Lead Reference Value FAQ

On October 28, 2021, the Centers for Disease Control and Prevention (CDC) announced a change in its blood lead reference value (BLRV) from ≥ 5 mcg/dL¹ to ≥ 3.5 mcg/dL². The California Childhood Lead Poisoning Prevention Branch has not yet updated the California Management Guidelines³ to match this change. The following are some frequently asked questions. Future updates or changes will be communicated as additional information becomes available.

1. Should CLPPPs begin outreach & education to children with BLL ≥ 3.5 mcg/dL?

Yes, as resources allow, CLPPP may provide outreach and education to these children.

2. Will children with BLLs between 3.5 to 4.4 mcg/dL be reported to CLPPPs via the Bi-Weekly Report?

Yes, CLPPB is working on redesigning the Bi-Weekly Report, which will include reports of children with BLLs of 3.5 mcg/dL and higher. We hope to have this project completed by early 2022.

3. Has CLPPB changed follow-up venous blood lead level (VBLL) value criteria for Standard Clinical Closure of full state cases and when to stop active monitoring for basic and potential case? Currently it is set at having at least one VBLL < 4.5 mcg/dL.

No, CLPPB has not changed the closure or VBLL monitoring criteria. The existing protocol remains in effect until CLPPPs are further notified of any related changes.

4. Is there additional funding to provide public health nurse (PHN) case management services for children with BLLs between 3.5 to 4.4 mcg/dL?

Currently, there is no additional funding to provide services for children with BLLs between 3.5 to 4.4 mcg/dL.

5. Are CLPPPs able to provide additional case management services including PHN home visits and Environmental Investigation (full or modified) for children with VBLLs ≥ 3.5 mcg/dL?

Yes, as resources allow, CLPPPs may provide additional services including a home visit and an Environmental Investigation.

6. What should we tell providers?

The new CDC BLRV at which healthcare providers are recommended to provide follow-up is 3.5 mcg/dL.⁴ CDPH encourages healthcare providers to provide retesting and follow-up for BLLs \geq 3.5 mcg/dL.

¹ CDC Response to Advisory Committee on Childhood Lead Poisoning Prevention Recommendations in "Low Level Lead Exposure Harms Children: A Renewed Call of Primary Prevention"

² CDC, Update of Blood Lead Reference Value – United States, 2021, MMWR / October 29, 2021 / Vol. 70 / No. 43

³ California Management Guidelines

⁴ CDC, Recommended Actions Based on Blood Lead Level, <https://www.cdc.gov/nceh/lead/advisory/acclpp/actions-blls.htm>

Recommended Actions Based on Blood Lead Level

Summary of Recommendations for Follow-up and Case Management of Children Based on Initial Screening Capillary and Confirmed* Venous Blood Lead Levels

Initial Screening Capillary Blood Lead Level (BLL) – if the initial screening test is done using a venous sample, proceed to the next section titled, “Confirmed Venous Blood Lead Level.”

≥3.5 µg/dL micrograms per deciliter

- Anticipatory guidance about common sources of lead exposure and how to prevent exposure
 - Common sources include paint in homes built prior to 1978, soil near sources of lead such as smelters, and take-home exposures related to adult occupations or hobbies. A full list of sources is available at [Sources of Lead Exposure](#).
 - Exposure can be reduced by frequent washing of hands, especially before meals, and washing toys. For children living in or frequenting homes or structures built before 1978, reduce potential lead-based paint dust by wet-wiping windows and windowsills and wet-mopping floors, avoiding renovations that may create lead-based paint dust, and covering chipping or peeling paint to make it inaccessible.
- Obtain a confirmatory venous sample for blood lead testing based on the schedule shown in Table 1, “Recommended Schedule for Obtaining a Confirmatory Venous Sample.”

Confirmed Venous Blood Lead Level (BLL) – an initial screening test using a venous sample or an initial screening capillary test followed by a venous blood sample.

< 3.5 µg/dL micrograms per deciliter

- Anticipatory guidance about common sources of lead exposure and how to prevent exposure
- Routine assessment of developmental milestones and nutritional status with a focus on iron and calcium intake
- Follow-up blood lead testing at recommended intervals based on child’s age
 - All Medicaid-enrolled children are required to be tested at ages 12 and 24 months, or at age 24–72 months if they have not previously been screened.
 - For children not enrolled in Medicaid, CDC recommends targeted screening efforts to focus on high-risk neighborhoods and children based on age of housing and sociodemographic risk factors. Public health and clinical professionals should collaborate to develop screening plans responsive to local conditions using local data. In the absence of such plans, universal blood lead testing is appropriate.

3.5–19 µg/dL micrograms per deciliter

- Follow recommendations for BLL < 3.5 µg/dL as described above.
- Report test result to state or local health department.
- Environmental exposure history to identify potential sources of lead
- Environmental investigation of the home to identify potential sources of lead, as required**
- Ensure iron sufficiency via testing and treatment per [AAP guidelines](#) [↗](#).
- Nutritional counseling related to calcium and iron intake and refer to supportive services, as needed (e.g., Special Supplemental Nutrition Program for Women, Infants and Children (WIC), etc.)
- Assess development per [AAP guidelines](#) [↗](#) and refer to supportive services, as needed (e.g., developmental subspecialists. Early Intervention Program (EIP), etc.)

- Follow-up blood lead monitoring at recommended intervals according to the schedule shown in Table 2, "Schedule for Follow-Up Blood Lead Testing"

20–44 µg/dL micrograms per deciliter

- Follow recommendations for BLL 3.5-19 µg/dL as described above.
- Complete history and physical exam assessing for signs and symptoms related to lead
- Environmental investigation of the home and lead hazard reduction
- Consider obtaining an abdominal X-ray to evaluate for lead-based paint chips and other radiopaque foreign bodies, especially in children in whom pica or mouthing of lead-contaminated surfaces is a concern; initiate bowel decontamination if indicated.
- Contact a Pediatric Environmental Health Specialty Unit (PEHSU) or poison control center for guidance.

≥45 µg/dL micrograms per deciliter

- Follow recommendations for BLL 20-44 µg/dL as described above.
- Complete history and physical exam including detailed neurological exam
- Obtain abdominal X-ray and initiate bowel decontamination if indicated.
- If the patient exhibits signs or symptoms of lead poisoning, emergently admit them to a hospital.
- If a lead-safe environment cannot be assured or if chelation therapy is being considered in consultation with a PEHSU or poison control center, admit the patient to a hospital.
- Contact a Pediatric Environmental Health Specialty Unit (PEHSU) or poison control center for assistance.

µg/dL: micrograms per deciliter

***Confirmed BLL:** capillary screening results equal to or greater than the BLRV should be confirmed with blood drawn by venipuncture (see Table 1 below, "Recommended Schedule for Obtaining a Confirmatory Venous Sample"). Confirmatory testing is not required when an initial screening test is performed using a venous sample.

**** Environmental investigations** at BLLs 3.5–19 µg/dL vary based on jurisdictional requirements and available resources.

Table 1: Recommended Schedule for Obtaining a Confirmatory Venous Sample

Blood Lead Level (µg/dL)	Time to Confirmation Testing
≥3.5-9	Within 3 months*
10-19	Within 1 month*
20-44	Within 2 weeks*
≥45	Within 48 hours*

*The higher the BLL on the initial screening capillary test, the more urgent the need for confirmatory testing using a venous sample.

Table 2: Schedule for Follow-Up Blood Lead Testing^a



Venous Blood lead Levels (µg/dL)	Early follow up testing (2-4 tests after identification)	Later follow up testing after BLL declining
≥3.5-9	3 months*	6-9 months

Venous Blood lead Levels (µg/dL)	Early follow up testing (2-4 tests after identification)	Later follow up testing after BLL declining
10-19	1-3 months*	3-6 months
20-44	2 weeks-1 month	1-3 months
≥45	As soon as possible	As soon as possible

^aSeasonal variation of BLLs exists and may be more apparent in colder climate areas. Greater exposure in the summer months may necessitate more frequent follow ups.

*Some case managers or healthcare providers may choose to repeat blood lead tests on all new patients within a month to ensure that their BLL level is not rising more quickly than anticipated.

References:

- Pediatric Environmental Health Specialty Units. Recommendations on Management of Childhood Lead Exposure: A Resource for Clinicians. Last Updated Sep 2021. Accessed 15 Oct 2021. [PEHSU_Fact_Sheet_Lead_Management_Health_Professionals_9_2021.pdf](#) [PDF - 232 KB] 
- American Academy of Pediatrics Council on Environmental Health. Chapter 32: Lead. In: Etzel RA, ed. Pediatric Environmental Health, 4th Edition; Itasca, IL: American Academy of Pediatrics; 2019:557-584.
- Hauptman M, Bruccoleri R, Woolf AD. An Update on Childhood Lead Poisoning. Clin Pediatr Emerg Med. 2017 September; 18(3): 181-192.
- Advisory Committee for Childhood Lead Poisoning Prevention, 2012. [Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention pdf icon](#) [PDF - 922 KB]
- The Clinical & Laboratory Standards Institute (CLSI) Guidelines #C40: Measurement Procedures for the Determination of Lead Concentrations in Blood and Urine, 2nd Edition (October 2013). <https://clsi.org/standards/products/clinical-chemistry-and-toxicology/documents/c40/> 

The following actions are NOT recommended at any BLL:

- Searching for gingival lead lines
- Testing of neurophysiologic function
- Evaluation of renal function (except during chelation with EDTA)
- Testing of hair, teeth, or fingernails for lead
- Radiographic imaging of long bones
- X-ray fluorescence of long bones

Page last reviewed: October 27, 2021



MICHELLE BAASS
DIRECTOR

State of California—Health and Human Services Agency
Department of Health Care Services



GAVIN NEWSOM
GOVERNOR

DATE: January 18, 2022

CHDP Provider Notice: 22-01

TO: All Child Health and Disability Prevention Program Directors, Deputy Directors, Child Health and Disability Prevention Program Providers, and Med-Cal Managed Care Plans

SUBJECT: Class I Recall - Magellan LeadCare® Blood Lead Test Kits Due to Significant Risk of Falsely Low Results

The purpose of this CHDP Provider Information Notice is to inform CHDP providers and Medi-Cal managed health care plans about recommendations and resources for providers and patient families regarding the Magellan LeadCare® recall.

The California Department of Public Health, Childhood Lead Poisoning Prevention Branch, has developed the following resources:

1. A [Magellan LeadCare web page](#) with links to fact sheets and communications.
2. A [fact sheet for healthcare providers](#).
3. Two fact sheets (in English and Spanish) for healthcare providers to share with the families of affected patients.
 - a. [Why Retesting is Necessary](#)
 - b. [Additional Information for Interested Families](#)

We hope that this updated information will assist you in providing quality care in your practice. If you have questions, please contact your [local CHDP Program](#).

Sincerely,

ORIGINAL SIGNED BY RICHARD NELSON

Richard Nelson, Chief
Integrated Systems of Care Division

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Attachments:

1. Important Recall of Several Magellan LeadCare Test Kits and CDC Recommendations for Healthcare Providers
2. Magellan LeadCare Recall: Why You Need to Have Your Child Retested for Lead (English and Spanish)
3. Additional Information About Risk of Falsely Low Results from Certain Magellan LeadCare Tests

Attachments

Important Recall of Several Magellan LeadCare® Test Kits and CDC Recommendations for Healthcare Providers

On August 31, 2021, Magellan Diagnostics, Inc. began customer notification of an expansion of its May 2021 recall of its LeadCare® Blood Lead Test Kits due to a significant risk of falsely low results, which may lead to health risks especially in special populations such as young children and pregnant and lactating individuals. The recall now includes the majority of all test kits distributed since October 27, 2020. The US Food and Drug Administration (FDA) has identified this as a Class I recall, the most serious type of recall. Obtaining falsely low results may lead to patient harm.

[FDA Magellan recall](#), updated September 28, 2021 (tinyurl.com/FDA-M21-928)

Customers should discontinue use of all LeadCare® Test Kits lots identified as part of the recall and quarantine remaining inventory.

Recalled Test Kit Lot Codes:

- **LeadCare II:** 2013M, 2014M, 2015M, 2016M, 2017M, 2101M, 2103M, 2105M, *Expansion:* 2012M Sublots: -08, -09, -10, -11, -12, -13, and -14, 2018M, 2102M, 2106M, 2107M, 2109M, 2110M, 2111M, 2112M, 2113M, 2114M, 2115M and 7114M
- **LeadCare Plus and LeadCare Ultra:** 2011MU, *Expansion:* 2104MU, 2108MU

US Centers for Disease Control (CDC) Recommendations

- **Retesting** (tinyurl.com/CDC-HAN-457)
 - Retest children who were:
 - Tested with the recalled LeadCare® test kits whose results were less than the current [CDC blood lead reference value \(BLRV\)](https://tinyurl.com/CDC-BLRV-21) (tinyurl.com/CDC-BLRV-21)
 - Previously tested with a LeadCare® test kit if the lot number of the initial test kit is unknown and the test was done after October 27, 2020.
 - Retesting should be done with a venous or capillary blood sample analyzed with high complexity testing:
 - Inductively coupled plasma mass spectrometry (ICP-MS)
 - Graphite furnace atomic absorption spectroscopy (GFAAS).
 - Capillary screening results above the BLRV should be confirmed with a venous blood draw.
 - Priority for retesting should be given to:
 - Children where there is clinical concern that symptoms or developmental problems may be related to lead exposure.
 - Populations at higher risk of elevated blood lead levels, such as children tested due to Medi-Cal-required screening or due to other state or local requirements.
 - Individuals who are pregnant or breastfeeding.
 - Children who are immigrants, refugees, or recently adopted from outside of the United States.
 - Discuss the recall and retesting recommendations with the parents or guardians of children who meet the retesting criteria.
- **Test Kit Shortages for Blood Lead Screening** (tinyurl.com/CDC-M21-KITS)
 - If LeadCare® test kits are unavailable, CDC strongly recommends clinicians continue to schedule and perform required blood lead tests for patients.
 - Blood lead tests can be done with either a venous or capillary blood sample, submitted to a laboratory for analysis with higher complexity methods. Contact your lab for acceptable minimum sample size and recommended blood collection supplies.
 - Follow [best practices](https://tinyurl.com/CDC-LAB-821) (tinyurl.com/CDC-LAB-821) when [collecting a capillary blood sample](https://tinyurl.com/CDC-FSP-621) (tinyurl.com/CDC-FSP-621) for lead testing.
 - Contact [California Laboratory Field Services](https://tinyurl.com/DPH-LFS-CLIA) (tinyurl.com/DPH-LFS-CLIA) for a list of higher complexity laboratories.

2017 FDA Warning about Magellan LeadCare® Analyzers Producing Falsely Low Results with Venous Blood Samples

Some children have not received appropriate venous retesting related to this 2017 FDA warning. These children should be retested with a venous sample analyzed using a high complexity device.

On May 17 2017, FDA issued a [safety communication warning](http://tinyurl.com/FDA-M17-517) (tinyurl.com/FDA-M17-517) about the use of Magellan Diagnostics, Inc.'s LeadCare® analyzers (LeadCare, LeadCare II, LeadCare Ultra and LeadCare Plus) with venous blood samples because they might result in falsely low test results. FDA advised that Magellan's LeadCare® analyzers should no longer be used with venous blood samples.

- This safety alert applied to venous blood lead tests conducted using Magellan's LeadCare® analyzers whether the patient was a child or an adult.
- The safety alert did not apply to capillary blood lead test results from samples collected by fingerstick or heelstick and analyzed using Magellan's LeadCare® analyzers.
- Further [FDA safety issue report](http://tinyurl.com/FDA-M17-918), September 27, 2018. (tinyurl.com/FDA-M17-918)

CDC HAN notification (tinyurl.com/CDC-HAN-403) **recommended:**

- Healthcare providers retest:
 - Children who were younger than 6 years (72 months) of age at the time of the alert (May 17, 2017) AND
 - Had a venous blood lead test result of less than 10 mcg/dL analyzed using a Magellan LeadCare® analyzer at an onsite (e.g., healthcare facility) or at an offsite laboratory.
 - Pregnant or lactating individuals who had a venous blood lead test performed using a Magellan LeadCare® analyzer.
- Providers should send venous samples to laboratories using ICP-MS or GFAAS (also known as electrothermal atomic absorption spectrometry [ETAAS]) instruments.

If you have questions, contact Magellan's LeadCare® Product Support Team at 1-800-275-0102 or email: LeadCareSupport@magellandx.com.

Additional Information and Resources

[Childhood Lead Poisoning Prevention Branch Magellan LeadCare® Recall Information](http://tinyurl.com/CLPPB-MAG)
(tinyurl.com/CLPPB-MAG)

[Information for Health Care Providers](http://tinyurl.com/CLPPB-Prov) on the CLPPB web site (tinyurl.com/CLPPB-Prov)

December 2021

Childhood Lead Poisoning Prevention Branch
850 Marina Bay Parkway, Building P, Third Floor
Richmond CA 94804
PHONE 510-620-5600 FAX 510-620-5656
www.cdph.ca.gov/programs/clppb



Magellan LeadCare® Recall: Why You Need to Have Your Child Retested for Lead



Lead is a metal that can be found in many places inside and outside your home. Lead can hurt your child. Lead poisoning can make it hard for children to learn, pay attention and behave. But most children who have lead poisoning do not look or act sick.

Your child had a Magellan LeadCare® test to see if there was lead in their blood. The test may have given a falsely low result. Falsely low blood lead level results may lead to your child not receiving the care they need. [More information about problems with some Magellan tests](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/More-information-about-problems-with-some-Magellan-tests.aspx) (tinyurl.com/MAG-INFO).

It is very important to know how much lead is in your child's body. This is why we are asking that you have your child tested for lead again. This should be a venous blood test. For more information, ask your doctor.

We want be sure that your child is safe and healthy.

December 2021

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Retiro del mercado de Magellan LeadCare®:

Por qué necesita que su hijo vuelva a realizar la prueba de detección de plomo



El plomo es un metal que se puede encontrar en muchos lugares dentro y fuera de su hogar. El plomo puede dañar a su hijo. El envenenamiento por plomo puede dificultar el aprendizaje, la atención y el comportamiento de los niños. Pero la mayoría de los niños que tienen intoxicación por plomo no parecen ni actúan como si estuvieran enfermos.

A su hijo le hicieron una prueba Magellan LeadCare® para ver si había plomo en la sangre. La prueba puede haber dado un resultado falsamente bajo. Los resultados de niveles de plomo en sangre falsamente bajos pueden hacer que su hijo no reciba la atención que necesita. [Más información sobre problemas con algunas pruebas de Magellan](http://tinyurl.com/MAG-INFO) (tinyurl.com/MAG-INFO).

Es muy importante saber cuánto plomo hay en el cuerpo de su hijo. Es por eso que le pedimos que vuelva a realizar la prueba de plomo a su hijo. Debe ser un análisis de sangre venosa. Para obtener más información, consulte con su médico.

Queremos estar seguros de que su hijo esté sano y salvo.

diciembre 2021

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Additional Information About Risk of Falsely Low Results from Certain Magellan LeadCare® Tests

There were problems with certain Magellan LeadCare® tests in 2021 and 2017, described below. Talk to your doctor if you have questions.

Recall of Magellan LeadCare® Test Kits - May 2021, Expanded September 2021 Class I recall of LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Test Kits

Magellan Diagnostics, Inc. recalled certain blood lead test kits due to a risk of falsely low results. Obtaining falsely low results may lead to health risks, especially in young children and individuals who are pregnant or breastfeeding. The US Food and Drug Administration (FDA) has identified this as a Class I recall, the most serious type of recall.

[FDA Magellan recall](https://www.fda.gov/oc/press/2021/s051121) ([tinyurl.com/FDA-M21-928](https://www.tinyurl.com/FDA-M21-928))

Retesting Recommendations

The US Centers for Disease Control and Prevention (CDC) [recommends](https://www.tinyurl.com/CDC-HAN-457) ([tinyurl.com/CDC-HAN-457](https://www.tinyurl.com/CDC-HAN-457)) retesting children and individuals who are pregnant or breastfeeding:

- Who were tested with the recalled LeadCare® test kits, and whose results were less than 3.5 micrograms per deciliter (mcg/dL)
- Who were tested with a LeadCare® test kit if the lot number of the initial test kit is unknown and the test was done after October 27, 2020.

2017 FDA Warning about Magellan LeadCare® Analyzers - May 2017 Safety warning for LeadCare II, LeadCare Plus, and LeadCare Ultra

On May 17 2017, FDA issued a [safety communication](https://www.fda.gov/oc/press/2017/s051717) ([tinyurl.com/FDA-M17-517](https://www.tinyurl.com/FDA-M17-517)) about the use of Magellan Diagnostics, Inc.'s LeadCare® analyzers with venous blood samples because they might result in falsely low test results. FDA advised that Magellan's LeadCare® analyzers should no longer be used with venous blood samples.

- This applied to venous blood lead tests conducted using Magellan's LeadCare® analyzers.
- This did not apply to capillary blood lead test results from samples collected by fingerstick or heelstick, and analyzed using Magellan's LeadCare® analyzers.
- [FDA safety issue report](https://www.fda.gov/oc/press/2018/s092718), September 27, 2018 ([tinyurl.com/FDA-M17-918](https://www.tinyurl.com/FDA-M17-918))

[CDC Retesting Recommendations](https://www.tinyurl.com/CDC-HAN-403) ([tinyurl.com/CDC-HAN-403](https://www.tinyurl.com/CDC-HAN-403))

- Children who were younger than 6 years (72 months) of age at the time of the alert (May 17, 2017) AND
- Had a venous blood lead test result of less than 10 mcg/dL analyzed using a Magellan LeadCare® analyzer.
- Pregnant or breastfeeding individuals who had a venous blood lead test performed using a Magellan LeadCare® analyzer.

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1

Información Adicional Acerca Riesgo de Resultados Falsamente Bajos de Ciertas Pruebas Magellan LeadCare®

Hubo problemas con ciertas pruebas de Magellan LeadCare® en 2021 y 2017, que se describen a continuación. Hable con su médico si tiene preguntas.

Retiro de prueba Magellan LeadCare® - mayo 2021, Expandido septiembre 2021 Retiro Clase I de LeadCare II, LeadCare Plus, y LeadCare Ultra prueba de sangre

Magellan Diagnostics, Inc. retiró ciertos kits de análisis de sangre debido al riesgo de resultados falsamente bajos. Obtener resultados falsamente bajos puede conllevar riesgos para la salud, especialmente en niños pequeños y personas que están embarazadas o amamantando. La Administración de Drogas y Alimentos de los EE. UU. (FDA) ha identificado esto como un retiro de clase I, el tipo de retiro más grave.

[Retiro del mercado de Magellan por la FDA](https://www.fda.gov/oc/announcements/fda-withdraws-certain-magellan-leadcare-test-kits) ([tinyurl.com/FDA-M21-928](https://www.tinyurl.com/FDA-M21-928))

Recomendaciones para repetir la prueba

Los Centros para el Control y la Prevención de Enfermedades (CDC) de EE. UU. [recomienda](https://www.cdc.gov/han/457) ([tinyurl.com/CDC-HAN-457](https://www.tinyurl.com/CDC-HAN-457)) reevaluar a niños e individuos que están embarazadas o amamantando:

- Quiénes fueron evaluados con la prueba retirada LeadCare®, y cuyos resultados fueron inferiores a 3,5 microgramos por decilitro (mcg/dL)
- Quiénes fueron evaluados con la prueba LeadCare® si se desconoce el número de lote del kit de prueba inicial y la prueba se realizó después del 27 de octubre de 2020.

2017 FDA Advertencia sobre Analizadores LeadCare® de Magellan - mayo 2017 Advertencia de seguridad para LeadCare II, LeadCare Plus, y LeadCare Ultra

El 17 de mayo de 2017, la FDA emitió una [comunicación de seguridad](https://www.fda.gov/oc/announcements/fda-issues-safety-alert-certain-magellan-leadcare-test-kits) ([tinyurl.com/FDA-M17-517](https://www.tinyurl.com/FDA-M17-517)) sobre el uso de analizadores LeadCare® de Magellan con muestras de sangre venosa porque pueden dar resultados de prueba infaliblemente bajos. La FDA recomendó que los analizadores LeadCare® de Magellan ya no se utilicen con muestras de sangre venosa.

- Esto se aplica a las pruebas de plomo en sangre venosa realizadas con los analizadores LeadCare® de Magellan.
- Esto no se aplica a los resultados de la prueba de plomo en sangre capilar de muestras recolectadas por punción digital o talón y analizados con los analizadores LeadCare® de Magellan.

Recomendaciones de los CDC para reevaluación ([tinyurl.com/CDC-HAN-403](https://www.tinyurl.com/CDC-HAN-403))

- Niños que tenían menos de 6 años (72 meses) de edad en el momento de la alerta (17 de mayo de 2017) Y
- Se analizó un resultado de prueba de plomo en sangre venosa de menos de 10 mcg/dL con un analizador Magellan LeadCare®.
- Personas embarazadas o en período de lactancia a quienes se les realizó una prueba de plomo en sangre venosa con un analizador Magellan LeadCare®.

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2