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

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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

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), (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 (tinyurl.com/CDC-LAB-821) when collecting a capillary blood sample (tinyurl.com/CDC-FSP-621) for lead testing.
  - Contact California Laboratory Field Services (tinyurl.com/DPH-LFS-CLIA) for a list of higher complexity laboratories.

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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 (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, 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 (tinyurl.com/CLPPB-MAG)

Information for Health Care Providers 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 (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.

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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 (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 (tinyurl.com/FDA-M21-928)

Retesting Recommendations

The US Centers for Disease Control and Prevention (CDC) recommends (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 (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, September 27, 2018 (tinyurl.com/FDA-M17-918)

CDC Retesting Recommendations (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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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. retiro 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 (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 (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 (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)

- 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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