U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

August 3, 2017

The Honorable Edward J. Markey
United States Senate
Washington, DC 20510

Dear Senator Markey:

Thank you for your letter to Dr. Scott Gottlieb, Commissioner of the U.S. Food and Drug Administration (FDA), and me regarding your concerns about the accuracy of certain tests manufactured by Magellan Diagnostics for blood lead levels. This response is on behalf of CDC. The FDA will respond separately.

CDC provides national expertise in lead poisoning prevention. We work with states to monitor childhood blood lead levels and serve as a technical resource for other federal, state, and local agencies. CDC also maintains laboratory reference methods and offers voluntary quality assurance programs to improve the accuracy and precision of blood lead measurements.

On April 14, 2017, the FDA and the Center for Devices and Radiological Health (CDRH) contacted CDC to request assistance in assessing the potential public health risk of a negative bias associated with Magellan's lead testing systems. CDC responded on April 17, 2017, and a call to discuss potential risks took place on April 24, 2017. CDC worked with the FDA/CDRH as they developed a safety communication warning about the use of Magellan Diagnostics' LeadCare® analyzers (LeadCare, LeadCare II, LeadCare Ultra, and LeadCare Plus) with venous blood samples. At the same time, CDC developed and disseminated recommendations for retesting based on the FDA's warning. CDC and the FDA continue to work together on this matter.

Enclosed with this response are CDC's answers to the questions directed to CDC.

Again, thank you for your letter and your interest in this important public health issue. We hope this information is helpful to you. A copy of this response is being sent to the cosigners of your letter.

Sincerely,

Anne Schuchat, MD
(RADM, U.S. Public Health Service)
Principal Deputy Director, CDC

Enclosure

Enclosure

The Centers for Disease Control and Prevention's (CDC) Response to Senators Edward J. Markey, Patty Murray, Debbie Stabenow, Jack Reed, Gary C. Peters, Tammy Baldwin, Sherrod Brown, Elizabeth Warren, Cory A. Booker, Robert Menendez, Richard Blumenthal, and Dianne Feinstein regarding a Recent Announcement from the Food and Drug Administration (FDA) and CDC about Lead Detection Tests

1. Generally, capillary tests are the first blood lead level screening tests administered, and venous tests are often sent to a lab to confirm the initial diagnosis. Magellan's LeadCare II test, however, is designed for in-office diagnostics, and can use either a capillary sample or blood from a vein.

a. What guidelines, if any, does CDC put in place to ensure that the appropriate test is approved and/or used for the applicable sample type?

CDC does not produce regulatory guidelines for blood lead tests. Blood lead testing practices vary greatly according to local practice guidelines and individual healthcare provider preferences. CDC serves in an advisory capacity by providing technical assistance to state childhood lead poisoning prevention programs (CLPPP), maintaining a reference quality test for blood lead, and operating the Lead and Multi-element Proficiency program, a voluntary laboratory standardization program that helps more than 100 laboratories improve the precision and accuracy of blood lead and other measurements.

b. What guidance does the CDC provide on the suitable use of in-office lead testing for venous blood samples?

CDC does not produce general, regulatory guidance for in-office, venous blood lead testing. However, since May 17, 2017, based on the FDA safety alert, CDC has recommended that healthcare providers re-test patients who:

1) are younger than 6 years (72 months) of age at the time of the alert (May 17, 2017), and
2) had a venous blood lead test result of less than 10 micrograms per deciliter (µg/dL) analyzed using a Magellan Diagnostics LeadCare® analyzer at an onsite (e.g., healthcare facility) or offsite laboratory.

CDC also recommends that healthcare providers re-test currently pregnant or lactating women who had a venous blood lead test performed using a Magellan Diagnostics LeadCare analyzer.

CDC recommends parents discuss re-testing with their healthcare provider or health department to determine if their child's blood should be re-tested.

If re-testing indicates blood lead levels in excess of the CDC reference level (www.cdc.gov/nceh/lead/acclpp/blood_lead_levels.htm) or the state or local action level, the healthcare provider or public health official should refer to CDC and/or local guidelines for appropriate follow-up action (www.cdc.gov/nceh/lead/acclpp/actions_blls.html).

Re-tests are not recommended if the provider is certain that analyzers other than those described in the health advisory distributed by the CDC Health Alert Network (www.emergency.cdc.gov/han/index.asp) were used to analyze the venous blood samples.

2. When the FDA notices safety, efficacy, accuracy, or reliability issues upon reviewing product malfunction reports or updates to device labels, to what extent has FDA worked with CDC to gain an understanding of the prevalence of malfunctions for high-risk users? Specifically, has CDC identified how many of these tests were administered in areas with a high risk of lead poisoning, like Flint, Michigan; Cleveland, Ohio; or Boston, Massachusetts?

CDC estimates that less than 1 percent of blood lead tests conducted in the Flint, Michigan, area in the first quarter of 2016 were affected by inaccurate test results. The Michigan CLPPP simultaneously and independently confirmed this estimate for all Flint follow-up samples. However, CDC does not collect information necessary to assess all possibly affected tests ("prevalence of malfunction") nationwide. CDC collaborates with state partners to establish a set of core data variables collected from every child at the time of blood lead testing. These include the blood sample type (capillary or venous blood) but do not include detailed information on the type of blood collection tube, time between blood collection and analysis, or the laboratory method and instrumentation.

a. Has CDC or Magellan provided additional assistance or information to product users in high-risk areas?

Yes, CDC has taken several steps to assist clinicians and healthcare providers across the country. In addition to issuing a CDC health advisory with its recommendations for re-testing, CDC held an informational call with funded state and local CLPPPs. CDC also organized a clinical outreach call to healthcare providers and regularly responds to requests for information on an individual basis.

3. What additional authorities or resources would help CDC to intervene in these types of situations sooner, or to help rectify such situations as soon as possible to ensure patients receive accurate testing results? Please detail what these resources and authorities would be.

CDC's CLPPP currently funds 35 programs in states and cities to support appropriate data systems and personnel that are essential to ensure screening, surveillance, and case follow-up efforts. A nationwide program would provide additional infrastructure to monitor blood lead test results in near real-time, including technical personnel, upgraded information technology, and data systems at the national, state, and local levels.