

## Safety Communication to Customers of All LeadCare® Blood Lead Testing Systems



- 1) If your site uses only capillary samples (fingersticks) to perform blood lead testing with any LeadCare Blood Lead Testing System this notification does not impact your LeadCare testing. Capillary results are not impacted, and you should proceed with testing as usual. Please **complete Part I and sign** the form on the next page and return it by fax.



- 2) If your site uses **venous samples** (collected from a vein, in a blood collection tube), please discontinue the use of any LeadCare Blood Lead Testing System with venous blood samples. Please read the information below carefully as it supersedes information in the package insert. Please **complete Parts I, II and sign** the form on the next page and return it by fax.

### Mandatory Customer Action

This notification is to advise your facility regarding a performance issue with blood samples collected in evacuated venous collection tubes when used with all LeadCare Blood Lead Testing Systems.

**Please follow these instructions:**

- Do NOT use venous blood samples with LeadCare Testing Systems.
- Capillary samples are permitted, for example:
  - Capillary tubes shipped in LeadCare II test kits
  - RAM Scientific SAFE-T-FILL capillary collection tubes
- Contact Product Support at 800-275-0102 with any questions.
- Share this information with your staff.
- Retain a copy of this letter in your files as a record of the notification.

**Issue Description and Result Impact**

Following the FDA's Safety Notice, published May 17, 2017 this notification is to advise your facility regarding a change to existing LeadCare product usage and labeling. Prior instructions for use included capillary and venous blood samples. However, because the LeadCare Testing Systems may underestimate blood lead levels and give inaccurate results when processing venous blood samples, the FDA recommends discontinuing the use of any LeadCare Blood Lead Testing System (LeadCare, LeadCare II, LeadCare Ultra, LeadCare Plus) with venous blood samples.

At this time, the FDA noted that all LeadCare Blood Lead Testing Systems can be used with capillary blood samples.

If your facility uses venous blood collection tubes please use an alternative method for blood lead testing until further notice.

Magellan will continue to work closely with the FDA to address the concerns identified with venous samples as quickly as possible. For more information, see the FDA's safety notice at:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm558769.htm>

**The vast majority of tests performed on LeadCare Systems use capillary samples and are performed at the point of care, in physician offices and clinics.** The LeadCare II System was designed to help ensure broad-based blood lead screening is available by providing a quick, easy and accurate way to identify children, pregnant women and adults at risk for lead exposure. We remain committed to the importance of providing results at the point of care, as this creates the best opportunity to facilitate patient education and intervention.

We sincerely apologize for this interruption in your venous blood lead testing.

Sincerely,

Reba Daoust  
Director of Quality & Regulatory Affairs

## Safety Communication to Customers

### FAX FORM RECORD: Notification on LeadCare® Systems

.....  
**This Fax Form Record is intended to verify that you have read and understood the Safety Communication to Customers on page 1 and is being tracked for regulatory purposes.**

**Please complete this form acknowledging receipt of the notification and fax the signed copy to the indicated fax number.**

**Please return via fax to 978-600-1480 or in the event of a transmission problem fax 888-789-8040.**  
.....

#### Part I: Site information for ALL responses

My site uses **only capillary samples** on LeadCare Systems – Complete Part 1 and sign this form.

My site uses **venous samples** on LeadCare Systems – Fill out this entire form and sign.

Key Contact Name & Title \_\_\_\_\_

Email \_\_\_\_\_ Phone Number \_\_\_\_\_

Institution Name \_\_\_\_\_

Instrument & Serial #(s): (i.e., LeadCare II, WLC#####) \_\_\_\_\_

Street Address \_\_\_\_\_

City \_\_\_\_\_ State/Province \_\_\_\_\_ Zip/Postal Code/Country \_\_\_\_\_

Are you actively using the system?  Yes  No, we stopped testing  Not yet installed

Populations being tested?  12 mo.  24 mo.  Pregnant/lactating women  Other: \_\_\_\_\_  
.....

#### Part II: Safety Communication to customers using venous blood samples

Please verify with a check (√) that the following actions were taken by your facility:

We read, understood and reviewed the Safety Communication with our staff:

- **Discontinue the use of venous blood samples on LeadCare Systems.**

Please describe your blood sample collection methods for blood lead testing.

% Venous \_\_\_\_\_ Primary tube type and brand? \_\_\_\_\_

% Capillary \_\_\_\_\_ Primary collection device and brand? \_\_\_\_\_  
.....

#### Signature for ALL responses

Name (please print) \_\_\_\_\_ Title \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

*Contact Magellan Diagnostics with any questions: 800-275-0102*  
.....

**Please fax this record back to:**

**Attention: Reba Daoust, Quality Assurance**

Phone No.: 978-856-2345 (for transmission problems only)

**Fax: 978-600-1480 or 888-789-8040**