Regional Medical Laboratory
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MEMORANDUM

To: All RML Clients
From: Ryan Hatley, MHA, C(ASCP), Manager of Chemistry and LCMS
Caitlin Schein, MD, Chief of Clinical Chemistry
Date: June 2, 2017
Subject: Blood Lead Testing

The U.S. Food & Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) issued a warning on May 17, 2017, of potentially inaccurate results from certain lead tests manufactured by Magellan Diagnostics. This warning is based upon currently available data indicating Magellan LeadCare tests may provide falsely low results on specimens collected by venipuncture.

Regional Medical Laboratory, Inc. (RML) utilizes the Magellan Diagnostics LeadCare platform for analysis of blood lead, and we have suspended testing in-house until further notice. Lead testing requested on or after May 17, 2017, will be referred to a reference lab and tested using an alternate methodology (Inductively Coupled Plasma/Mass Spectrometry or Atomic Spectroscopy).

The CDC is recommending healthcare providers consider retesting high risk patients, including:

- Patients younger than 6 years (72 months) of age at the time of the alert (May 17, 2017) who had a venous blood lead test result of less than 10 micrograms per deciliter (µg/dL) analyzed using a Magellan Diagnostics' LeadCare platform
- Patients who are currently pregnant or nursing who were tested while they were pregnant or nursing using a Magellan Diagnostics LeadCare platform

The alert **does not apply to the following**:

- Patients who had a capillary blood lead test collected by fingerstick or heelstick and analyzed using the Magellan Diagnostics' LeadCare platform
- Patients who had a venous blood lead test result of greater than 10 µg/dL analyzed using a Magellan Diagnostics LeadCare platform

For routine testing, please continue to order test code 3601650 – Lead, Whole Blood.

For retesting as a result of this notification, please order test code 3601659 – Retest – Lead, Whole Blood
(Availability of retesting will terminate December 31, 2017)

It is our understanding that CMS will pay the cost of retesting for patients covered by Medicare and Medicaid. For all others, as a convenience, RML will offer retesting at no charge.

Acceptable specimen types for lead testing are EDTA (lavender, tan or royal blue-top) and Sodium heparin (tan or royal blue-top). **Lithium heparin (green top) will no longer be acceptable.** Specimens should be refrigerated.

For more information, please reference the FDA and CDC communications at the following web addresses.
https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm
https://emergency.cdc.gov/han/han00403.asp

Please contact Ryan Hatley or Dr. Caitlin Schein at 918-744-2553 with questions regarding this update.