May 26, 2017

To: Chiefs of Service, Attending Physicians, Housestaff, Nurses and Other Concerned Personnel

From: Alan Wu, Ph.D. and Kara Lynch, Ph.D.
Core Laboratory Co-Division Chiefs

cc: Barbara L. Haller, MD, PhD
Director, Clinical Laboratory

Re: Blood Lead Testing at ZSFG Hospital

On May 17, 2017, the FDA sent a notice warning clinical laboratories using Magellan Diagnostics LeadCare Testing Systems for lead testing on venous blood that this assay may produce values that are falsely low. The FDA recommended that clinical laboratories discontinue use of this instrument until corrections are made by the manufacturer to the satisfaction of the FDA.

Effective May 17, 2017, the ZSFG Clinical Laboratory has discontinued use of this instrument. Until further notice, all requests for blood lead (venous and capillary collections) will be sent to our reference laboratory, ARUP, where lead levels are determined by ICP-mass spectrometry. Note that the FDA does not believe erroneous results are produced by this mass spectrometry method.

The FDA further recommends that patients under the age of 6 years (as of May 17, 2017) who had a previous venous blood lead test result of less than 10 μg/dL on the LeadCare analyzer have a fresh sample collected and retested by the clinical laboratory.

The ZSFG Clinical Laboratory has completed an evaluation of our LeadCare test results dating back several years. Using fresh samples and proficiency testing samples, we have compared our LeadCare results against results from other laboratories using this device, and against labs that use the ICP-mass spectrometry instrument. We have not observed any significant low bias of lead results, as described in the FDA notice. Therefore, we believe that our LeadCare results are accurate and retesting is unnecessary.

Nevertheless, if you wish to have a patient retested, please indicate that a retest is being requested on the requisition slip. There will be no charge to the patient for this repeat testing, which will be performed using the mass spectrometry method. If “retest” is not clearly indicated on the requisition, the patient will be charged.

If you have any further questions, please contact Dr. Alan Wu at 415-206-3540, or Dr. Kara Lynch at 415-206-5477. Thank you.