

LAB NOTIFICATION FOR PROVIDERS

CDC alert about capillary blood lead test recall

Title: Capillary blood lead test CDC alert

Date: July 14, 2021

TO KNOW:

Allina Health Laboratory is aware of the July 6 CDC [alert](#) about capillary blood lead testing performed on the Magellan LeadCare test system. Magellan has recalled several lot numbers of reagents due to customer complaints about quality control (QC) failures and falsely low results with those test lots. Investigation by Magellan revealed a manufacturing defect that affected a small number of shipments from those lots.

Allina Health Laboratory was one of the customers that discovered the problem and reported it to Magellan. We stopped testing on April 15 due to quality control failures with new shipments of reagent. Before using any new lot of reagent, our laboratory runs QC and correlations with previously tested specimens to confirm accuracy before running any patient tests. Initial shipments of the recalled lots passed our QC process and were used for patient testing between December 16, 2020 and April 15, 2021. There were no QC or external proficiency test failures for reagents used for patient testing. Subsequently several shipments failed our QC process and were never used for patient testing. All patient results which were released over the time period out-lined in the CDC alert have been reviewed and there is no evidence of falsely low results. A number of patients also had follow-up venous testing by a different method at our reference lab which is not affected by the recall. In nearly every case, the Magellan result was higher than the venous result.

In summary, our analysis shows no evidence of falsely low capillary lead results from our laboratory due to this recall. Out of an abundance of caution, we are offering retesting for children < 6 years who had capillary lead results of 4-4.9, just below the screening cutoff. We will notify each of those providers by inbasket message.

TO DO:

1. As explained above, there is no evidence that falsely low capillary lead results reported by our laboratory.
2. Out of an abundance of caution, we will offer retesting for patients with capillary lead results just below the screening cutoff. If you have one of these patients, you will be contacted by inbasket message.
3. The reference laboratory uses a different method for lead testing and is not affected.

FEEDBACK OR QUESTIONS: Email to Lauren.Anthony@Allina.com