interChange Provider Important Message

Attention: All Providers

CDC Health Update: Expansion of Recall of LeadCare Blood Lead Tests Due to Risk of Falsely Low Results

The CDC has published an official CDC Health Update: Magellan Diagnostics, Inc. and the U.S. Food and Drug Administration (FDA) have issued notifications about the expansion of Magellan Diagnostics' recall of LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests, which were distributed from October 27, 2020, to August 19, 2021. Additional LeadCare II product lots, including lots previously reported to be unaffected, were recalled due to a significant risk of falsely low results. The use of these devices may cause serious injuries because they might underestimate blood lead levels. FDA has identified this as a Class I recall, the most serious type of recall.

The Centers for Disease Control and Prevention (CDC) is issuing a Health Alert Network (HAN) Health Update to notify healthcare providers and state and local health departments about the expansion of a recall notice and to recommend appropriate follow-up actions in the shortage of LeadCare Lead Tests. This HAN Health Update is an update to HAN Health Advisory 445: Recall of LeadCare Blood Lead Tests Due to Risk of Falsely Low Results that CDC issued on July 6, 2021.

View the following link for the full PDF version of the CDC HAN Health Update including recommendations and resources:
https://emergency.cdc.gov/han/2021/pdf/CDC_HAN_454.pdf

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