

**F.D.A. & CDC Register
Concerns Over Magellan Diagnostics LeadCare System Test**

Blast Communication!

Last week the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) warned that certain lead tests manufactured by Magellan Diagnostics may provide inaccurately low results. A summary of the CDC is recommendations note that only VENOUS samples run on portable analyzers by Magellan (e.g. LeadCare, LeadCare II, LeadCare Plus, and LeadCare Ultra) are in question. Additionally, if a child under age six had a venous-drawn sample analyzed using the LeadCare, and received a result of less than 10 micrograms per deciliter ($\mu\text{g}/\text{dL}$), the CDC recommends a venous retest using lab analysis.

Our Georgia, Medicaid EPSDT program recommends blood lead level screening at the 12 and 24 month visits and at either 36 months and 72 months if a blood lead level test has not been performed previously. Here are some reminders from Georgia EPSDT program which allows providers to utilize the Lead Care II Analyzer to perform blood lead tests:

- Venous samples are considered confirmatory testing therefore, all venous samples should be laboratory analyzed by a properly accredited laboratory.
- A blood test is the preferred method for lead screening.
- Finger stick capillary blood tests can be done as the initial screening.
- If a child's capillary Blood Lead Test comes back elevated ($\geq 10\mu\text{g}/\text{dL}$ reported by a certified lab or $\geq 6\mu\text{g}/\text{dL}$ using the Lead Care II analyzer), then a confirmatory test must be performed. The confirmatory diagnostic test should be lab analyzed
- Providers who utilize the Lead Care II Analyzer to perform blood lead tests should report the Lead Care II Analyzer generated results to the GHHLPPP by doing weekly uploads of their tests to the to the State Electronic Notifiable Disease Surveillance System (SendSS). SendSS recommends providers keep track of their Lead Care II

For questions, contact Fozia Khan Eskew at the Chapter office, feskew@gaaap.org or at 404-881-5074. Thank you.

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The Ritz-Carlton, Amelia Island, Fla.
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