

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0859137	(X3) Date Survey Completed 01/23/2019
Name of Provider or Supplier Galen Medical Group Laboratory Pc	Street Address, City, State 4976 Alpha Lane, Hixson, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A revisit survey was conducted on Galen Medical Laboratory for all previous deficiencies cited on January 23, 2019. All deficiencies have been corrected, and no new noncompliance was found. The facility is in compliance with all regulations surveyed.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of 2018 precision results and an interview with the laboratory supervisor, the laboratory failed to confirm the precision for Vitamin B 12, Prolactin, and Human Chorionic Gonadotrophin (HCG) testing. Findings include: 1. A review of Vitamin B 12, Prolactin and HCG precision testing for 2018 yielded an "imprecise" response from the testing company preparing the results for Linearity 8 A and Linearity 8 B. 2. An interview with the laboratory supervisor at 1:30 PM on January 23, 2019 confirmed Vitamin B 12, Prolactin and HCG precision testing for 2018 yielded an "imprecise" response from the testing company preparing the results for Linearity 8 A and Linearity 8 B.</p>