Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 25D2139314	**(X3) Date Survey Completed** 10/02/2023
Name of Provider or Supplier East Lakeland Ob/Gyn Associates	**Street Address, City, State** 1020 River Oaks Dr Ste 320 Lab 1, Flowood, MS	
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**
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of verification of performance specifications for the Tosoh AIA-900 analyzer, patient accession log from 7/6/2023 through 10/2/2023, and interview with the laboratory director on 10/2/2023 at 3:30 p.m., the laboratory failed to verify the reportable range for Vitamin B12 testing before patient testing began on 7/6/2023. Findings include: 1. Review of verification of performance specifications for the Tosoh AIA-900 analyzer revealed no documentation of the verification of the reportable range for Vitamin B12 testing on the Tosoh AIA-900 analyzer. 2. In an interview at 3:30 p.m. on 10/2/2023, the laboratory director confirmed verification of reportable range for Vitamin B12 was not performed before patient Vitamin B12 testing began on 7/6/2023. 3. Review of the patient accession log for Vitamin B12 testing from 7/6/2023 through 10/2/2023 revealed 56 patient Vitamin B12 test results were reported during this time frame.