Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0672521	05/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lawrenceville Pediatrics Pc	980 Highway 29 South, Lawrenceville, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 1, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency test (PT) report review and staff interview, the laboratory failed to evaluate and verify all unsatisfactory scores and the corrective action taken. The findings include: 1. American Proficiency Institute (API) PT review revealed the laboratory failed to perform corrective action for the following PT scores of less than 100 percent: 2017 Hematology second event and 2018 Hematology second event both scored 80 percent. 2. An interview with Staff #2 (CMS 209) in an office area at approximately 5:00 p.m. on 5/1/19 confirmed the lack of corrective action for the aforementioned PT scores.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by:

	Based on hematology quality control (QC) document review and staff interview, the laboratory failed to follow the laboratory policy and procedure for performing corrective action as required. Findings include: 1. Micros 60 Minitrol 16 hematology control document review revealed the laboratory failed to follow the established policy and procedure for corrective action for the following QC results: March, 2018 -- QC was out of acceptable range 2 of 24 days; May, 2018 -- QC was out of range 1 of 22 days. 2. An interview with Staff #2 (CMS 209) in an office area on 5/1/2019 at approximately 5:00 p.m. confirmed the failure to follow the laboratory policy and procedure for corrective action when hematology controls were out of range..
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on calibration document review and staff interview, the laboratory failed to perform and document instrument calibration procedures every six months as required. Findings include: 1. ABX Micros 60 calibration document review revealed the laboratory failed to perform required instrument calibration between 2/8/18 and 11 /11/18. 2. An interview with Staff #2 (CMS 209) in an office area at approximately 5: 00 p.m. on 5/1/19 confirmed the aforementioned gap in calibration in 2018.