Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2109176	04/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Trinity Pediatric Medicine Of Fayetteville, Llc	719 W Lanier Ave, Fayetteville, 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 April 17, 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:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on operator guide reviews of the ABX Micros 60 and Piccolo Xpress and staff interview, the laboratory failed to monitor room temperature (RT) and relative humidity (RH) in the lab testing area per manufacturers requirements. Findings include: 1. Review of the ABX Micros 60 operators guide revealed the RT is required to be 18 - 32 degrees Celsius and the RH is required to be less than 80 %. 2. Review of the Piccolo Xpress operator's guide revealed the RT is required to be between 15 - 32 degrees Celsius and the RH is required to be between 8 - 80 %. 3. Interview with the lab director (CMS 209) on 4/17/19 at 11:50 AM in the lab area, confirmed the RT and RH were not monitored in the lab area.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

	(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview, the lab failed to monitor over time the accuracy and precision of test performance. Findings include: 1. Review of the Micros 60 hematology analyzer quality control records revealed no long term monitoring has been performed since August 2017. 2. Interview with the lab director (LD)(CMS 209) on 4/17/19 in the patient room across from the LD's office at approximately 12 Noon, confirmed the lack of long term QC monitoring.