Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0271787	12/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Gainesville Pediatric Associates	6440 W Newberry Rd Ste 402, Gainesville, FL	

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	At the time of the announced, on-site recertification survey, Gainesville Pediatric Associates was found to NOT be in compliance with the CLIA laboratory requirements of 42 CFR 493. .
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 record review and staff interview, the laboratory failed to perform quality control (QC) checks on media used for bacteriology testing for 2 of 2 years reviewed. (2019-2020) Findings include: A record review of quality control documentation was performed on 12/11/2020. The laboratory had no documentation of quality control being performed on the following media: Healthlink Tryptic Soy Agar- used for presumptive identification of Streptococcus A Uricult UTI Culture Paddles - used as a screening test for urinary tract infections (UTI) The interview with the Laboratory Director at 11:00am confirmed that no quality control had been performed on the media since the previous laboratory inspection.