Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0161740	05/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Troy Pediatrics, Llp	258 Hoosick Street, Suite 106, Troy, NY	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on the surveyor's review of the American Proficiency Institute (API) Proficiency Testing (PT) records and confirmed in an interview with the laboratory director on May 23, 2019 at 10:00 AM, the laboratory failed to retain copies of the signed attestation forms for the third events of 2017 and 2018 and the first event of 2019.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor's review of American Proficiency Institute (API) Proficiency

	Testing (PT) records and confirmed in an interview with the laboratory director, the laboratory failed to evaluate and document the review of the laboratory's scored PT results. FINDINGS: On the date of survey, at approximately 10:15 AM, the laboratory director confirmed that there was no evidence of PT review of the scored results for the second events of 2017 and 2018, the third events of 2017 and 2018, and the first event of 2019.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Quality Control (QC) records for hematology and confirmed in an interview with the laboratory director, the laboratory failed to perform a lot to lot comparison of assayed hematology controls used with the Coulter AcT Diff analyzer prior to use. FINDINGS: The laboratory director confirmed at approximately 9:30 AM on May 23, 2019 that the laboratory does not test new lots of controls against the current lot before using the new lot as primary QC.