Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0104132	10/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Tenafly Pediatrics	301 Bridge Plaza North, Fort Lee, NJ	

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
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 review of the Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to verify that assayed QC material was within the acceptable range before it was put into use for all analytes ran on the Horiba ABX Micros 60 analyzer in September 2018 to the date of survey. The finding includes: 1. There were no QC verification records for Horiba Hematology controls Lot# MX413. 2. The LD confirmed on 10/18/18 at 1:00 pm that the laboratory did not verify QC material before use.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests

	and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the surveyor review of the Final Reports (FR) and interview with the Laboratory Director (LD), the laboratory failed to have a Reference Range (RR) for Hemoglobin parameters on FR from 10/31/16 to the date of the survey. The LD confirmed on 10/25/18 at 11:10 am that the above parameter did not have a RR on the FR.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the lack of a Quality Assessment (QA) program and interview with the Laboratory Director (LD), the LD failed to establish a QA program for laboratory testing from 10/31/14 to the date of survey. The findings include: 1)This deficiency was previously cited on 10/31/16. 2) The Plan Of Corrections (POC) stated "A QA program will be established to include evaluation of record keeping and transcription verification of medical records. Monthly evaluations will be put into effect" The LD confirmed on 10/25/18 at 10:50 AM that a QA program was not established.