Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1021321	03/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Tenafly Pediatrics-Paramus Facility	26 Park Place, Paramus, 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
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 review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to evaluate a score of 20% for Hematocrit % (Hct%) and 80% for Red Blood Cell (RBS) Count results obtained in FH2-A 2016 Hematology Auto Differentials event with the College of American Pathologists (CAP). The findings include: 1. The laboratory did not evaluate unacceptable results for Hct% for specimens FH2-01, FH2-03 through 05 in FH2-A-2016 event. 2. The laboratory did not evaluate unacceptable results for RBC for specimen FH2-02 in FH2-A- 2016 event. 3. The GS confirmed on 11/28/17 at 2:30 pm that the laboratory failed to evaluate coded results for PT events in 2017 and 2016.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on the lack of Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to check QC on each batch of Urine Culture Media (UCM) from 11/13/15 to the date of the survey. The findings include: 1. The laboratory did not check UCM for: a. Ability to support or inhibit specific organisms b Sterility of media. c. visual check 2. The LD confirmed on 3/23/18 at 1:00 pm that the laboratory did not perform the above-mentioned QC checks.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of Personnel Files (PF) and interview with the General Supervisor (GS), the Laboratory Director failed to have education records for four out of five Testing Personnel from 11/13/15 to the date of the survey. The GS confirmed on 2/23/18 at 9:40 am that there were no education records for four out of five TP.