Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0113158	02/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Teaneck Pediatrics	197 Cedar Ln, Teaneck, 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 Laboratory Director (LD), the laboratory failed to review and evaluate coded PT results obtained from the College of American Pathologists (CAP) for UC Count Combo performed in the calendar year 2017 and 2018. The finding includes: 1. There was no evaluation documented when the laboratory received an exception code of 27 (no consensus) in event MC4 A 2017 and MC4 A 2018 for sample MC-02. 2. The LD confirmed on 2/14/19 at 1:30 pm that the laboratory did not review and evaluate coded PT results.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to evaluate results when the laboratory received an unacceptable score in PT for UC Count Combo performed with the College of American Pathologists (CAP) in 2018. The finding includes: 1. There was no review or evaluation documented when the laboratory received an

	unacceptable result for MC-10 in the MC4-B 2018 event. 2. The LD confirmed on 2 /14/19 at 1:20 pm that the laboratory did not perform and document an evaluation of unacceptable PT performance.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (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 check each lot number and shipment of Bacitracin Discs for negative reactivity from 3/1/17 to the date of the survey. The LD confirmed on 2/14/19 at 2:20 pm that the above QC was not performed.
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 surveyor review of the Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to check each new lot number and shipment of Urine Culture media for sterility, ability to support growth and select or inhibit organisms from 3/1/17 to the date of the survey. The LD confirmed on 2/14/19 at 2:30 pm the laboratory did not perform the above QC. Note: This deficiency was cited on the survey preformed on 3/1/17. The Plan of Correction (POC) stated "Each batch of urine culture media will be checked for sterility. Each batch will be tested to see they support growth properly."
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 the Personnel Files and interview with the Laboratory Director (LD), the LD failed to have education documented for two out of three Testing Personnel (TP) from 3/1/17 to the date of the survey. The LD confirmed on 2 /14/19 at 1:10 pm that all TP did not have education documented.