Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0131868	05/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
West End Pediatrics	450 West End Avenue, New York, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of laboratory competency records and an interview with the laboratory testing person, the laboratory failed to follow their written policies and procedures to assess the competency of the laboratory testing personnel semi-annually for the first year of patient testing. Findings Include: It was confirmed by the laboratory testing person on May 30, 2019, at approximately 10:15 am, that the laboratory director acting as the technical consultant failed to have documentation of semi-annual competency for two of two new testing personnel who perform bacteriology and hematology testing.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of PT records from the API PT program and an interview with the testing person, the laboratory failed to successfully participate in a PT program

	approved by the Centers for Medicare and Medicaid Services (CMS) for the specialty of Bacteriology. The following scores were assigned: 2019 1st event: urine colony count = 50% 2018 1st event: urine colony count = 50% These results are all considered unsatisfactory PT performance.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the laboratory testing person, the laboratory failed to have a complete procedure manual. Findings Include: It was confirmed by the laboratory testing person on May 30, 2019, at approximately 10:20 am, that the laboratory failed to have procedures in place for 1) a lot to lot verification for new hematology controls; 2) performing urine colony counts and quality control for the urine colony counts.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of patient test reports, the A Taxo disk package insert and an interview with the laboratory testing person, the laboratory failed to follow the manufacturer's instructions for reporting patient test results. Finding Includes: It was confirmed by the laboratory testing person on May 30, 2019, at approximately 10:45 am, the manufacturer's package insert for the A Taxo disk states that patient test results for throat culture testing are to be reported as presumptive positive. The laboratory is reporting patient test results as "positive".

D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of calibration records and an interview with the testing person, the laboratory failed to calibrate the hematology analyzer every six months. Findings Include: It was confirmed by the testing person on May 30, 2019, at approximately 11:45 am that; 1. The Manufacturer requires calibration to be performed every six months; 2. Calibration was performed on July 17, 2017, then on May 21, 2018; 3. Calibration was due January 21, 2018; 4. The Coulter AcT Diff II was out of calibration from January 22, 2018, through May 21, 2018 (4 months). Approximately 340 patient specimens were tested and reported for hematology testing when calibration was not performed.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a lack of procedures and an interview with the laboratory testing person, the laboratory failed to have a Quality Control Plan (QCP) and Risk Assessment (RA) Plan as part of their Individualized Quality Control Plan (IQCP) for Urine (colony count) culture testing. Findings Include: It was confirmed by the laboratory testing person on May 30, 2019, at approximately 11:00 am, that the laboratory failed to have a QCP and RA (which includes: Specimen, Test system, Reagent, Environment, and Testing Personnel) as part of their IQCP for urine colony counts. This is a repeat deficiency from the survey of June 22, 2017.
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: 1) Based on a review of quality control procedures, lack of documentation and an interview with the laboratory testing person, the laboratory failed to perform quality control for the Strep Select agar (SSA) used to perform Throat cultures. Findings Include: It was confirmed by the testing person on May 30, 2019, at approximately 10: 30 am, that the laboratory failed to perform and document the physical characteristics of the SSA plates prior to patient from July 2017 through the date of this survey. Approximately 1592 patient specimens were tested for throat cultures during that time. 2) Based on a lack of procedures, documentation and an interview with the laboratory testing person, the laboratory failed to check each new batch or lot number of Uricult media for its ability to support and inhibit growth of specific organisms from July 2017 through the date of this survey. Approximately 180 patient specimens were tested for throat cultures during that time. This is a repeat deficiency from the survey of June 22, 2017.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of laboratory records and interview with the laboratory testing person, the laboratory director failed to provide overall management and direction for the laboratory and ensure that: 1. Plan of correction (POC) from the June 22, 2017 survey was implemented and maintained; 2. The QC procedures are maintained for hematology testing; Refer D6020 3. The QA policies are maintained and remediation performed for the less than 100% test scores; Refer to D6021 4. Training for new personnel was performed and documented; Refer to D6029 5. Semi-annual competency was performed; Refer to D6053
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on a review of QC records an interview the laboratory testing person, the laboratory director failed to ensure that the QC program for bacteriology and hematology testing was maintained to assure quality of laboratory services. Refer to: D5437, and D5477 This is a repeat deficiency from the survey of June 22, 2017.
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: 1) Based on a review of QA procedures, reviews and an interview with the laboratory testing person, the director failed to ensure that the laboratory's QA program for bacteriology and hematology was maintained for all phases of laboratory testing. Refer to: D5209, D5403, D5411 and D5445. This is a repeat deficiency from the survey of June 22, 2017. 2) Based on a review of PT results, and confirmed in an interview with the laboratory testing person on May 30, 2019, at approximately 12:45, the laboratory director failed to evaluate the non-regulated PT analyte test results to ensure that test results were accurate and reliable. Refer to D5215 Findings include: The laboratory scored 50% for urine colony counts for the 1st events in 2018 and 2019 and failed to perform remediation for both events.
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 a review of personnel records and an interview with the laboratory testing person, it was found on May 30, 2019, at approximately 10:20 am, that the laboratory director failed to ensure that appropriate training was documented for one of two new testing personnel who performs moderate complexity testing for hematology.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the laboratory testing person, the laboratory director, acting as the technical consultant, failed to perform the semi-annual evaluation for two of two testing personnel during the first year of patient testing in calendar year 2018. Refer to D5209.