Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0995712	(X3) Date Survey Completed 05/03/2018
Name of Provider or Supplier West End Pediatrics Pc	**Street Address, City, State** 2 Fifth Avenue, Suite 8, 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
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 the surveyor's review of hematology calibration records and an interview with a testing person and the laboratory director, the laboratory failed to calibrate the Coulter AcT Diff hematology analyzer every six months as per manufacturer's requirement. Calibrations were performed on 10/14/16, 07/07/17, and 04/27/18. Findings Include: It was confirmed with a testing person and the laboratory director at approximately 11:00 AM on the date of survey that the Coulter AcT Diff hematology analyzer was out of calibration from April 14, 2017 until July 7, 2017, and from January 7, 2018 until April 27, 2018. Approximately 160 patient specimens were tested and reported for hematology testing during each of the three month periods when the Coulter AcT Diff analyzer was out of calibration.
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 the surveyor's review of the laboratory's Quality Control Plan (QCP) and Quality Assessment (QA) procedures and an interview with a testing person and the laboratory director, the laboratory failed to establish a Risk Assessment (RA) plan as part of the Individual Quality Control Plan (IQCP) for the urine colony count testing. Findings: The testing person and the laboratory director confirmed during the May 3, 2018 onsite survey that the laboratory director had failed to establish a Risk Assessment (RA) plan to identify and evaluate potential failures and sources of error in the urine colony count testing process, to include the five Risk Assessment Components: Specimen, Test System, Reagent, Environment, and Testing Personnel. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON 5/19/2016.
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 the surveyor's review of Quality Control (QC) records and confirmed, during this onsite survey, with a testing person and the laboratory director, the laboratory director failed to ensure that the QC program for bacteriology testing was maintained to assure quality of laboratory services. Refer to: D5445 PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON 5/19 /2016.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

	This STANDARD is not met as evidenced by: Based on the surveyor's review of hematology calibration records and confirmed in an interview with a testing person and the laboratory director, the laboratory director failed to ensure that remedial action was taken and documented when problems were identified. Refer to D5437.