Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0131868	03/05/2025
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
D2128	HEMATOLOGY CFR(s): 493.851(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting System (CASPER 0155D) and American Proficiency Institute (API) PT summary reports as well as interviews with the Practice Manager (PM) and Testing Personnel (TP), the laboratory failed to perform, document, and retain remedial action for unacceptable specialty and analyte testing event scores. FINDINGS: a. A review of the CASPER 0155 report revealed the following unsatisfactory scores: 1. Hematology Specialty: 2024 First Event = 64% 2. Red Blood Cell (RBC) Test Analyte: 2024 First Event = 60% 3. Hematocrit (HCT) (Non-Waived) Test Analyte: 2024 First Event = 60% 4. Hemoglobin (HGB) (Non-Waived) Test Analyte: 2024 First Event = 60% 5. White Blood Cell (WBC) Count Test Analyte: 2024 First Event = 60% 6. Platelets Test Analyte: 2024 First Event = 60% b. A review of the proficiency testing scores from API (2024) confirmed the above findings. c. There was no documentation of plan of correction for the respective specialty and test analyte unsatisfactory scores. d. The PM and TP confirmed the findings on March 5, 2025, at approximately 3:00 P.M.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b)

	(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 review of the Standard Operating Procedures (SOPs), lack of thermometer calibration records, as well as interviews with the PM and TP, the laboratory failed to draft and approve procedures for thermometer calibration. FINDINGS: 1. There was no calibration certificate documentation for the thermometers utilized in the refrigerator, freezer, and laboratory area room where reagent storage occurred. 2. The current, approved SOPs did not include instructions for thermometer calibration and calibration certificate retention. 3. The PM and TP confirmed the findings on March 05, 2025, at approximately 3:00 P.M.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on reviews of the SOPs, Medonic M series instrument manual, as well as interviews with the PM and TP, the laboratory failed to document approval and date of approval by the current LD. FINDINGS: 1. There was no documentation of LD approval and date of approval for the current, approved SOPs. 2. There was no documentation of LD approval and date of approval for the current Medonic M series instrument manual. 3. The PM and TP confirmed the findings on March 05, 2025, at approximately 3:00 P.M.