Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0131868	08/23/2022
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 surveyor's review of laboratory personnel records and an interview with the practice manager, the laboratory failed to follow their establish written competency policy that included the six required components that assess testing person's competency,twice annually during the first year of testing and annually thereafter. Refer to D6029 and D6053. FINDINGS: The laboratory failed to perform the training and six month competency evaluation for the two new testing personnel , who perform moderate complexity testing. a. Confirmed by the practice manager on 8-22-22 at approximately 11:00 AM. This is a repeat deficiency from the survey conducted on May 30, 2019.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's "Specimen & Handling" procedure, surveyor' direct observation of the hematology tube & microctainer in the laboratory and an interview with practice manager, the laboratory personnel failed to follow the established laboratory's procedure for labeling patient specimens. FINDINGS: 1. The laboratory's establish written procedure requires the patient's full name, and/or date of birth (DOB) or medical records number (MR), date of collection on the specimen container. 2. Surveyor observed a EDTA tube in a cup and a EDTA microctainer on the counter next to Coulter DXH 520 Hematology analyzer at 10:30 AM were unlabeled. 3. Surveyor observed a hematology report sequence # 48187 on the DXH 520 screen but could not determine which sample it was used to report the Complete Blood count (CBC) results. a.. The practice manager confirmed at 11:47 that the laboratory staff failed to follow the established "Specimen & Handling Procedure. b. All laboratory manuals are in the laboratory, for personnel to access the material when needed.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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 review of the Coulter DXH 520 operations manual at the time of survey and interview with the practice manager, the current laboratory director failed to approve (sign and date) the manufacturer's operations manual for automated CBC testing. Refer to D6031
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor's observation of the Select Strep Agar (SSA), patient sample in the incubator and an interview with the practice manager, the laboratory failed to discontinue the use of the expired SSA. Refer to D6020. FINDINGS: 1. The surveyor observed a throat culture in the incubator labeled with DOB 1/9/06 and date of service 8/22/22, initials HAJ at approximately 11:30 AM with an expired SSA media on 8/18 /22 lot# 145058P. a. Observed 3 SSA plates in the refrigerator same lot # and expiration date b. Observed 5 vials of 0.04 bacitracin disc lot # 9182592 expiration date 7/31/22 2. A new lot of 0.04 bacitracin disc Lot # 145480P expiration date 4/30 /23 was opened and used on the patient SSA plate. 3. Confirmed by practice manager at 11:30 AM
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 the review of the laboratory's Quality Control (QC) records for the bacitracin disc and an interview with the practice manager, the laboratory failed to check the new lot number of 0.04 bacitracin disk for positive and negative reactivity. Refer to D6020 FINDINGS: 1. The laboratory failed to check new lot # 1297972 expiration date 4/30/22 of 0.04 bacitracin disks for positive and negative reactivity. a. One disc was used for a patient throat culture plate labeled HAJ, DOB 1/9/06 and date of service 8/22/22.. b. Confirmed by the practice manager at 11:30 AM.
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 review of Horiba operations manual, laboratory records and direct observation and an interview with the laboratory testing person, the laboratory director failed to provide overall management of the laboratory. FINDINGS: The laboratory director failed to ensure that the laboratory: 1. Implemented and maintained the plan of correction from the survey conducted on May 15, 2019 2. Established & maintained a QC program, Refer to D6020, 3.Testing personnel had appropriated education & training prior to patient testing, Refer to D6029, 4. Performed initial training and six-month competency evaluation for four of the two testing personnel, 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 surveyor's review of hematology QC records and an interview with the laboratory testing person, at the time of this survey, the laboratory director failed to ensure that the QC program for hematology was maintained to assure the quality of laboratory services. Refer to D5417and D5471 This is a repeat deficiency from the survey conducted on May 30, 2019.

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 the lack of training records for the two of the five testing personnel and an interview with the practice manager and confirmed at the time of this survey, the laboratory director failed to ensure that two new testing personnel had appropriated education and training was documented for the perform moderate complexity bacteriology and hematology testing. Refer to D5209 This is a repeat deficiency from the survey conducted on May 30, 2019.
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 lack of the training & competency evaluation records for the two new testing personnel and confirmed in an interview with the practice manager, the laboratory director, failed to perform the six month competency evaluation for the two new testing personnel during the first year of patient testing. Refer to D5209. This is a repeat deficiency from the survey conducted on May 30, 2019.