

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0995712	(X3) Date Survey Completed 08/23/2022
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>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 2:00 PM.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's "Specimen & Handling" procedure, surveyor'</p>

	<p>direct observation of the hematology tube & microtainer 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 with a first name only on the counter next to Coulter DXH 520 Hematology analyzer at 2:20 PM. a.. The practice manager confirmed at 2:30 P 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.</p>
<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>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</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>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. Testing personnel had appropriated education & training prior to patient testing, Refer to D6029, 2. Performed initial training and six-month competency evaluation for four of the two testing personnel, Refer to D6053.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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.</p>

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

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.