

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0995712	(X3) Date Survey Completed 11/18/2024
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory testing logs, American Proficiency Institute (API) Proficiency Test (PT) reports, as well as interviews with the Testing Personnel (TP) and Practice Manager (PM), the laboratory failed to test PT samples by TP who routinely perform patient testing. FINDINGS: 1. Laboratory testing logs indicated eight TP who routinely perform hematology and bacteriology patient testing yet 2022, 2023, and 2024 API PT reports documented only one TP performing hematology and bacteriology PT. 2. Confirmed findings by interview with the TP and PM on November 18, 2024, at approximately 2:00 P.M.</p>
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 review of personnel competency records, standard operating procedures (SOPs), as well as interview with the PM, the laboratory failed to perform and document TP six-month competency evaluations. FINDINGS: 1. There was no documentation of TP six-month competency performance. 2. The current, approved</p>

SOPs did not include instructions for performing such activity. 3. Confirmed findings by interview with the PM on November 18, 2024, at approximately 2:00 P.M.

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 direct observations, review of SOPs, as well as interview with the Testing Personnel (TP), the laboratory failed to remove from inventory expired reagents in the patient specimen processing laboratory. FINDINGS: 1. The surveyor's observations in the patient specimen processing laboratory confirmed on November 18, 2024, at approximately 2:00 P.M. that two bottles of Hemocult developer, lot number: 75009H, expiration: September 2023 were not removed from inventory. 2. The current, approved SOPs did not include instructions for removal of expired reagents and calibration materials from inventory. 3. The TP confirmed that the respective reagents were not utilized for patient specimen testing. 4. The TP confirmed the findings on November 18, 2024, at approximately 2:00 P.M.