

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0906328	(X3) Date Survey Completed 03/19/2025
Name of Provider or Supplier Women's Wellness Place Pc	Street Address, City, State 739 Irving Avenue Suite 530, Syracuse, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of current, approved standard operating procedures (SOPs), as well as interview with the Testing Person (TP), the laboratory failed to remove expired reagents from inventory. FINDINGS: 1. The surveyor's observations confirmed on March 19, 2025, at approximately 11:00 A.M., EDM3 Solutions Potassium Hydroxide 10%, lot: 1237, expiration: August 25, 2023, was stored in the upper cabinet in the laboratory. 2. The TP confirmed the expired Potassium Hydroxide 10% was utilized for patient specimen processing. Approximately thirteen patient specimens were processed utilizing the expired reagent. 3. This is contrary to instructions included in the current, approved SOPs. 4. The TP confirmed the findings on March 19, 2025, at approximately 3:00 P.M.</p>