

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2046630	(X3) Date Survey Completed 01/30/2025
Name of Provider or Supplier Maiden Lane Medical Pllcr	Street Address, City, State 90 Maiden Lane, Third Floor, 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
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 Quality Control (QC) and calibration data, as well as an interview with the testing personnel, the laboratory failed to remove from inventory expired reagents. Please note that this is a repeat citation from a prior survey performed on 01/13/2023. FINDINGS: 1. The surveyor's observations in the laboratory confirmed on January 30, 2025, at approximately 11:30 A.M. that 3 bottles of stain were not removed from inventory. Wright-Giesma Blue Lot# 9081 expiration date: 03/22/2021 Wright-Giesma Red Lot # 9079 expiration date: 03/20/2021 Fixative Lot #9080 expiration date: 03/21/2021 Centaur cleaning solution which had an expiration date of 12/31/2024. 2. The current, approved SOPs did not include instructions for removal of expired reagents and calibration materials from inventory. 3. The technical consultant and testing personnel confirmed the findings on January 30, 2025, at approximately 11:30 A.M.</p>
D6000	<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:</p>

D6000 Based on inventory and use of expired reagents, lack of SOPs, as well as interviews with the TC and TP, the Laboratory Director (LD) failed to provide overall management and direction of the laboratory services. Refer to D5417.