

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2041828	(X3) Date Survey Completed 10/30/2024
Name of Provider or Supplier Monica L Halem, Md Pc	Street Address, City, State 988 Fifth 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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 observations, review of the staining quality control log and the current, approved standard operating procedures (SOPs), as well as interview with the Laboratory Director (LD), the laboratory failed to remove from inventory expired reagents in the Mohs processing laboratory. FINDINGS: 1. The surveyor's observations in the Mohs processing laboratory confirmed on October 30, 2024, at approximately 11:30 A.M. the following reagents and processing materials were not removed from inventory: a. Tissue Marker Dye Yellow, lot: 148630, expiration: April 30, 2024. b. Tissue Marker Dye Black, lot: 151018, expiration: May 31, 2024. c. Tissue Marker Dye Green, lot: 151417, expiration: June 30, 2024. d. Gill 3 Hematoxylin Stain, lot: 144623, expiration: September 30, 2023. 2. LD informed the surveyor that the respective expired tissue marker dyes and Gill 3 Hematoxylin Stain were utilized for patient specimen processing. 3. Approximately two hundred patient specimens were processed utilizing the respective expired reagents. 4. The current, approved SOPs did not include instructions for removing expired reagents from inventory. 5. LD confirmed the findings on October 30, 2024, at 11:30 A.M.</p>