Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1045698	07/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of Cny Pllc	4110 Medical Center Drive, Suite 110, Fayetteville, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on direct observations, review of the Safety Data Sheets (SDS), reagent manufacturer's storage requirements, approved standard operating procedures (SOPs), as well as interview with the Testing Person (TP), the laboratory failed to properly store flammable reagents in the Mohs processing laboratory and Storage Closet as required by the SDS and reagent manufacturer's storage requirements. FINDINGS: 1. The surveyors' observations in the Mohs processing laboratory and Storage Closet confirmed on July 31, 2024, at approximately 11:30 A.M. the following reagents and processing materials were not properly stored in the flammable materials storage cabinet as required by the SDS and the reagent manufacturer's storage requirements: a. Avantik Gill3 Hematoxylin lot: 178237 expiration: January 31, 2025, was retained in a lower cabinet in the Mohs processing laboratory and Storage Closet. Lot: 193125 expiration: September 30, 2025, was retained in the Storage Closet. b. Avantik Eosin Working Solution lot: 43050631 expiration: May 22, 2025, was stored in a lower cabinet in the Mohs processing laboratory. Lot: 44010010 expiration: January 29, 2026, was retained in the Storage Closet. c. Avantik Xylene lot: KMH22XYL was stored in a lower cabinet in the Mohs processing laboratory. d. EKI SafeClear Xylene Substitute lot: 2405176 was retained in in a lower cabinet in the Mohs processing laboratory and Storage Closet. e. Avantik 95% Reagent Alcohol lot: 2329612 expiration: October 25, 2026, was retained in a lower cabinet in the Mohs processing laboratory and Storage Closet. Lot: 2316716 expiration: June 19, 2026, was retained

	in the Storage Closet. f. Avantik 100% Reagent Alcohol lot: 2327242 expiration: October 3, 2026, was retained in a lower cabinet in the Mohs processing laboratory and Storage Closet. Lot: 2410303 expiration: April 16, 2027, and lot: 2415111 expiration: June 4, 2027, were retained in the Storage Closet. g. CareMount2 lot: 196904 expiration: April 30, 2026, was stored in an overhead cabinet in the Mohs processing laboratory. 2. The current, approved 4.3 "Storage, Use and Handling" SOP did not include such instructions. 3. The TP confirmed the findings on July 31, 2024, at approximately 1:30 P.M.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observations, review of SDS and approved SOPs, lack of room temperature records, as well as interview with the TP, the laboratory failed to monitor and document ambient room temperatures in the areas where on-site laboratory testing was performed and reagents, processing materials were stored. FINDINGS: 1. There was no documentation of ambient room temperatures in the Mohs processing laboratory and Storage Closet where on-site laboratory testing was performed and reagent and processing materials were stored. 2. This is contrary to instructions included in the current, approved "Temps" section 4.3.2 SOP. 3. The Avantik Gill3 Hematoxylin, Eosin Working Solution, 95% Reagent Alcohol, and 100% Reagent Alcohol SDS included instructions for reagent storage in a "cool, well-ventilated place". 4. The TP confirmed the findings on July 31, 2024, at approximately 1:30 P. M.