Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0689641	12/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology, Pc	175 Iu Willets Road Suite 2, Albertson, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the current, approved standard operating procedures (SOPs) and interview with the office manager (OM), the laboratory failed to draft and approve written instructions for removal of expired reagents from inventory. FINDINGS: 1. The OM confirmed on December 19, 2023, at approximately 11:00 A.M. that current, approved SOPs did not include written instructions for performing such activities.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation of the Tissue Tek Embedding O.C.T. Rapid Differential, Toluidine Blue 1% Aqueous for Frozen Section, and Acid Alcohol 0.5% bottles as well as interview with the OM, the laboratory failed to ensure that expired stains and embedding reagents were not utilized for Mohs slide processing. FINDINGS: 1. Toluidine Blue 1% Aqueous for Frozen Section (32oz), Lot #130621, Expiration Date: September 15, 2023. 2. Eyewash (16oz), Lot # 19NP0058, Expiration Date: January 2023. 3. Tissue Tek Embedding O.C.T. Medium, Lot #2231-00, Expiration Date: May 31, 2023, for three of the four ounce bottle inventory. 4. Acid Alcohol 0.5% (1GL), Lot#002936, Expiration Date: January 30, 2021. 5. Confirmed findings by interview with OM on December 19, 2023, at approximately 11:00 A.M. 6. Approximately one hundred patient samples were processed.