Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2004723	03/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Of Nj Pc	700 Paramus Park, Paramus, NJ	

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 surveyor review of the Procedure Manual (PM), and interview with the Regional Manager (RM), the laboratory failed to have all applicable procedures for Histopathology tests in the PM from 10/20/22 to 3/5/24. The findings include: 1. The laboratory failed to have a procedure in the PM for the preparation of Toluidine Blue Solution used in Histopathology testing. 2. The RM confirmed on 3/5/24 at 10:45 am that the PM did not have a procedure for the preparation of Toluidine Blue Solution.
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 surveyor observation of the laboratory cabinet, stains used in Histopathology testing, surveyor review of the Procedure Manual (PM) and interview with the Regional Manager (RM), the laboratory failed to appropriately label Toluidine Blue Solution used for Histopathology tests from 10/20/22 to 3/5/24. The findings include: 1. The PM states "all reagents are to be labeled with the following information: Reagent, dilution, date prepared, technician, temperature for storage if not room temperature." 2. A container only labeled as "T-Blue" was observed with no other pertinent information required for proper use on the label. 3. The RM confirmed on 3/5/24 at 10:35 am that the Toluidine Blue solution was not labeled correctly. Note: This deficiency was previously cited on the survey performed on 10/20/22
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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. This STANDARD is not met as evidenced by: Based on surveyor observation of the Tissue Marking Dyes and Reagents, surveyor review of the Procedure Manual (PM) and interview with the Regional Manager (RM), the laboratory used and failed to discard expired Tissue Marking Dye used for Histopathology testing from 3/31/23 to 3/5/24. The findings include: 1. The PM states " Do not use reagent after expiration date." 2. One Blue Tissue Marking Dye Lot# 116716 was observed to be on expired 3/31/23. 3. The laboratory performs approximately 200 Histopathology tests annually. 4. The RM confirmed on 3/5/24 at 10:55 am that the laboratory used and failed to discard expired dye used in Histopathology testing.