Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2135677	06/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Of Pennsylvania	107 Gamma Drive, Ste 120, Pittsburgh, PA	

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
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 observation of the laboratory and interview with the Office Manager (OM), the laboratory failed to ensure 5 of 5 bottles of tissue marking inks for dermopathology were labeled to indicate their received and expiration dates at the day of survey. Findings Include: 1. On the day of survey, 06/07/2022, observations of the laboratory revealed, the laboratory did not label the received and expiration dates of the following 5 of 5 tissue marking ink bottles: - Green: Lot A801608 exp 5-26-2026 - Blue: Lot A806348 exp 1-10-2026 - Yellow: Lot A806355 exp 1-10-2026 - Black: Lot A806357 exp 1-10-2026 2. The OM confirmed the finding above on 06/07/2022 at 12:40 p.m.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of quality control records and interview with the Office Manager (OM), the laboratory failed to document Quality control (QC) each day of patient testing for Potassium Hydroxide KOH and Scabies microscopic examinations in 2021. Findings include: 1. On the day of survey, 06/07/2022, review of KOH and scabies QC records revealed, that physicians performing KOH and scabies examination were not documenting QC each day of patient testing in 2021. 2. The laboratory performed 16 KOH and 2 scabies microscopic examinations in 2021 3. The OM confirmed the finding above on 06/07/2022 around 14:45 pm.