Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1075013	03/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology	230 Newport Center Dr Ste 200, Newport Beach, CA	

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
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory policies and procedures, laboratory records, and interviews, the laboratory failed to monitor and evaluate the overall quality of the preanalytic systems and failed to correct identified problems. The findings included: 1. The laboratory failed to refer specimen grossing to a CLIA-certified laboratory. See D5315. 2. The laboratory failed to have updated written procedure manuals including all necessary criteria relevant to the laboratory operations. See 5403
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as

	established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 a review of the laboratory's procedures and policies, the prior inspection conducted on October 16, 2025, and an interview with the Laboratory Director (LD) on March 24, 2026, it was determined that the laboratory failed to maintain updated written procedure manuals and evidence of compliance including all necessary criteria relevant to the laboratory operations. The findings included: 1. It was the practice of the laboratory to perform histopathology testing. The recertification survey was conducted on October 16, 2025. On October 31, 2025, the laboratory director was notified by a letter and form CMS-2567 for deficient practices related to the procedure manuals. (D5401) 2. The survey team requested and reviewed updated policies and procedures on March 24, 2026, at 11:30, Findings identified the laboratory procedure manuals failed to contain updated written procedures that clearly addressed criteria specific to laboratory operations. a. The laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for specimen processing. b. The laboratory failed to provide detailed step-by-step procedures for grossing and slide preparation. c. The laboratory failed to provide detailed step-by-step procedures for referring specimens to reference laboratories and specimen transportation tracking for accountability. d. The laboratory failed to provide detailed procedures for conducting microscopic examinations, especially regarding the identification and verification of inadequately prepared slides. e. The laboratory failed to provide control procedures defining the specific criteria for slide acceptability and rejection. f. The laboratory failed to describe quality assessment practices to verify slide acceptability, ensure accuracy in slide interpretation, and verify correct recording of patient information and results.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on severity of the deficiencies cited herein, the Condition for Laboratories performing high complexity testing, specifically regarding the laboratory director's responsibilities, was not met. The laboratory director failed to provide overall management and direction in accordance with 493.1445 of this subpart. See 6079
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the review of the laboratory policies and procedures, specimen referral and an interview with the Laboratory Director (LD) on March 24, 2026, it was determined that the Laboratory Director (LD) failed to provide comprehensive management and direction as required under 493.1445 of this subpart. The findings included: 1. The laboratory director failed to ensure that the reference laboratory for specimen grossing maintains a current CLIA certificate. See 5315 2. The laboratory director failed to ensure that the laboratory maintains a comprehensive written procedure manual and evidence of compliance including all necessary criteria relevant to the laboratory operations. See 5403