Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0573825	08/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology & Laser Center Of Redlands	255 Terracina Blvd Ste 206, Redlands, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour, review of the laboratory's policy and procedure, and interviews with Mohs Tech-office manager (MT-OM); the laboratory failed to establish safety procedures to ensure protection from physical, chemical, and biochemical materials. The findings include: 1. Based on the survey on August 28, 2025, at approximately 4:00 p.m. the laboratory failed to provide a written policy and procedures for laboratory safety. 2. Based on the observations during the laboratory tour where the Mohs processing and staining of samples took place, it was found that the laboratory lacked an eye wash. 3. The MT-OM affirmed by interviews August 28, 2025, at approximately 4:15 p.m. that the laboratory lacked safety procedures and eyewash in the Mohs processing area. 4. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 8/26/2025, the laboratory processed and reported annually approximately 1,500 Mohs patients' test samples without an established and approved laboratory safety plan and eyewash in the Mohs procedure testing area.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on the lack of a Quality Assurance plan (QA), review of the laboratory's policies and procedures, and interview with the laboratory's staff; the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. The findings include: 1. Based on the day survey on August 28, 2025, at approximately 2:30 p.m., no documentation could be retrieved by the laboratory to show that a written QA plan was in place for the years 2023, 2024, and 2025. 2. Laboratory staff reviewed and documented two (2) times per year one (1) patient tracer. The laboratory staff randomly selected 2 patients annually and reviewed the requisition, final report, test results, QC, and preventive maintenance. However, no written QA plan was found at the time of the survey. 3. The laboratory staff confirmed by interview on August 28, 2025, at approximately 2:45 p.m., that the laboratory did not establish a QA plan to follow written policies and procedures reflecting the current practice for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. 4. According to the testing declaration signed by the laboratory director on August 26, 2025, the laboratory performed annually 1,500 Mohs tests and diagnosis without an established written, signed and dated QA plan.
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 review of laboratory records, direct observation, lack of laboratory written procedures and procedures reflecting the current practice, and interview with the Mohs Tech-Office Manager (MTOM); the laboratory failed to have written procedures for quality assurance/assessment of laboratory records, a laboratory Safety Plan, and retention of documents and storage policy. Findings included: 1. The laboratory failed to have written procedures for quality assessment including scheduled and frequency of self-audits and peer review. 2. The laboratory failed to have written procedures for document retention and storage of Histopathology reports

	and records relating to Mohs procedures . 3. The laboratory failed to have a safety plan for the laboratory. 5. The MT-OM affirmed on the day of the inspection 8/28 /2025 the lack of policies and procedure reflecting the current practice.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures and interviews with the Mohs-Tech-Office Manager (MT-OM) the laboratory failed to update protocols in place when changes in the practice occurred in the laboratory and the effective date and signature of approval by the laboratory director of such changes. The findings included: 1. On the day of the survey August 28, 2025, at approximately 3:00 p.m. the policies and procedure for Mohs testing in place had not been reviewed by the current LD to reflect current practice and testing, neither had it been approved, signed, and dated by the laboratory director. 2. The laboratory director failed to have a written delegation of responsibilities signed and dated. 3. The MT-OM affirmed on August 28, 2025, that the laboratory failed to update protocols for the current test performed in the laboratory, did not have a written delegation of responsibilities letter, and that the effective date and the laboratory director's signature were missing. 4. The laboratory's testing declaration form stated that the laboratory processes approximately 1,500 patients' samples test annually where written policies and procedures were not approved, signed, and dated by the laboratory director.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures, randomly selected patient test records, preventive maintenance documentation, and an interview with the Mohs Tech - Office Manager on August 28, 2025, the laboratory director is herein cited due to failure to ensure that several aspects of the preanalytical, analytic and postanalytic phases of the laboratory testing were monitored. The findings include See D3011, D5291, D5403, and D5407.