Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0586697	12/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
San Luis Dermatology And Laser Clinic, Inc	1551 Bishop St Ste 410, San Luis Obispo, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the lack of a laboratory's policies and procedures manual and interviews with the office manager (OM) on December 18, 2025; the laboratory failed to provide a procedure manual for policies and procedures. The findings included: 1. It was the practice of the laboratory to perform Dermatopathology -Mohs processing in house with no policies and procedures approved, signed, and dated by the laboratory director available for: Mohs specimen processing, quality assurance, preventive maintenance, peer review, reagent use, reagent log, microscope use, retention of documents and slides, safety procedures etc. 2. All CLIA compliant protocols for histopathology practice were not available on the day of the survey. 3. The OM confirmed by interview on December 18, 2025, at approximately 2:45, that standard operation procedures and policies were not available, approved, signed, and dated by the laboratory director. 4. The laboratory's testing declaration form, signed by the laboratory director on December 16, 2025, stated that the laboratory performed approximately 2,648 histopathology tests annually with no CLIA compliant policies and procedures available to be followed by the testing personnel.
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, the lack of laboratory written procedures, and interview with the office manager (OM); the laboratory failed to have written requirements for specimen management, written procedures for managing laboratory records with regularly scheduled self-audits for quality assessment, and a process for documenting failures and noncompliance, appropriate corrective actions, and monitoring for recurrence. Findings included: 1. The laboratory failed to have written requirements for positive patient identification, patient preparation, specimen collection and labeling, storage, preservation, transportation and referral of Biopsy specimen, and criteria for specimen acceptability and rejection. 2. The laboratory failed to have written procedures for managing laboratory records, including receipt and retention of Histopathology reports and records relating to Mohs procedures. 3. The laboratory failed to have written policy and procedure for at least twice annually verifying the accuracy of tests performed onsite, including but not limited to Mohs to clear tumor and as applicable, Frozen Biopsy sections to identify pathology during Mohs procedures. 4. The laboratory failed to have a written policy and procedure for regularly scheduled self-audits of laboratory records to assess the quality of preanalytic, analytic, and postanalytic processes, apply remedial corrections as appropriate, and monitor for quality assurance and compliance. 5. The laboratory failed to have any other written policies and procedures pertinent to a Dermatopathology laboratory.
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 lack of laboratory policies and procedures manuals and an interview with the office manager on December 18, 2025, the laboratory director failed to provide Mohs testing and Sarcoptes scabbii (scabies) microscopic procedure manuals, as well as policies for the laboratory current practice. The findings included: 1. It was the practice of the laboratory to perform histopathology testing including Mohs

	Micrographic Surgery and detection of scabies in skin samples. 2. On December 18, 2025, at approximately 3:30 p.m., the OM confirmed that the laboratory director did not provide approved, signed, and dated policies and procedure manuals to reflect the current practice offered by the laboratory. 3. The laboratory's testing declaration form, signed by the laboratory director on December 16, 2025, stated that the laboratory performed approximately 1,654 dermatological test annually including Mohs and scabies testing without approved protocols and procedures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's instructions, laboratory temperature records, test volumes, and interview with the office manager (OM), the laboratory failed to state in the Mohs procedure log the cryostat temperature acceptable range. Findings included: 1. In direct observation on December 18, 202, none of the Mohs cryostat preventive maintenance logs stated the acceptable temperature range according to the manufacturer and Mohs procedure. 2. Review of the laboratory's temperature records for the cryostat and room temperature revealed no acceptable temperature range. 3. Based on interview, the OM confirmed that the temperature ranges were missing for the cryostat and room temperature in the preventive maintenance logs. 4. Review of the laboratory's test volume declaration by the laboratory director the annual histopathology test volume was 2,648 tests performed.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory's tour and interviews with the office manager (OM), the laboratory failed to provide a list of reagents used in the laboratory when processing samples for Mohs to indicate the received date, lot number, expiration date, opening date, and disposal date when such materials are used. The findings include: 1. Based on the surveyor's observation during the laboratory's tour on December 18,2025, at approximately 3:15 p.m. the OM failed to provide a log of the following reagents used when processing and staining samples for Mohs testing stating: received date, lot number, opening date, expiration date, and

	initials: Tissue dye markers Hematoxylin/Eosin Xylene 100% absolute alcohol Acetone Freezing oil and any other reagents used during the procedure. 2. The laboratory's OM affirmed by interview conducted on December 18, 2025, at approximately 3:15 p.m. that the reagents mentioned in statement #1 were not documented when in use. 4. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 2,648 samples for Mohs test procedure using reagents not documented as regulated.
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 lack of laboratory's policies and procedures, inspector's direct observation, review of patient test records, preventive maintenance documentation, and an interview with the laboratory office manager; the laboratory director is cited herein for failure to provide preanalytic, analytic, and postanalytic phases of testing oversight of the laboratory. The findings include: See D5401, D5403, D5407, D5413, and D5415.