Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0586887	(X3) Date Survey Completed 06/25/2024
Name of Provider or Supplier San Luis Dermatology & Laser Clinic, Inc	**Street Address, City, State** 15 Santa Rosa St, 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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of patient testing records, patient final testing reports, and interviews with the laboratory's office manager (OM) on June 25, 2024, at approximately 11:30 a. m. it was determined that for three (2) out of five (5) randomly chosen patient Mohs testing records reviewed, the laboratory failed to follow written policies and procedures for specimen analytical phase testing, through completion of testing and reporting results. The findings included: 1. Review of Mohs documentation and patient's final test report it was found that patient slides were mislabeled for the date of testing and stage as follow: Patient 1 date of Mohs procedure 12/22/2021 slide labelled 12/23/2021. Patient 2 date of Mohs 4/26/2023 stage II mislabeled slides as A, B, C, and D 2. The OM affirmed that slides were mislabeled as stated in #1 above 3. Based on the laboratory's annual test volume declaration signed by the LD on 4/1 /2024 the laboratory performed and reported 2,595 Mohs procedures for which its accuracy cannot be affirmed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 laboratory written policies and procedures for potassium hydroxide (KOH) and preparations for the detection of Sarcoptes scabiei (scabies) and interviews with the office manager (OM): it was determined that the laboratory failed to have available and follow written procedures for mycology and parasitology test performed in the laboratory. The findings included: 1. On the day of the survey on June 25, 2024, at approximately 12:45 p.m. the laboratory failed to provide written policies and procedures for mycology and parasitology test performed in the laboratory. 2. For three (3) out of three (3) random patient test results reviewed from the KOH/scabies log, all the patients had mycology or/and parasitology test ordered, analyzed, and reported for which the laboratory had no written policies and procedures available. 3. The OM confirmed on 06/25/2024 at approximately 1:00 p.m. that the laboratory did not have written policies and procedures available for mycology and parasitology tests performed in the laboratory.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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 review of the laboratory's policies and procedures manual and interview with the laboratory's office manager (OM) it was determined that 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 June 25, 2024, at approximately 1:30 p.m. the procedure manual in place for the Mohs procedure had not been updated to reflect current Mohs procedure performed in the laboratory. 2. The OM affirmed on June 25, 2024, at approximately 2:00 p.m. that the laboratory failed to update protocols for the current testing performed in the laboratory and that the effective date and the laboratory director's signature were missing. 3. The laboratory's testing declaration form stated that the laboratory processes approximately 2,637 samples annually including the Mohs procedure.
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's reagent materials used for KOH preparations (Mycology) and Sarcoptes scabiei (Parasitology) and interview with the office manager (OM); it was determined that the laboratory failed to label various reagents to indicate date of use and expiration dates when such reagents are used in the

	laboratory. The findings included: 1. Based on the surveyor's observation no receive, opening, or expiration date labels were used or documented for KOH used the microscopic examination for the presence of yeast and fungal elements and saline used for identifying mites presence on tissues. 2. The laboratory's OM affirmed in an interview conducted 06/25/202411:30 a.m., that the reagents mentioned in statement 1 were not labeled with the receive, opening, preparation, and expiration dates or documented. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 42 mycology and parasitology test samples.
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 the surveyors' observation, examination of laboratory reagents, and interview with the office manager (OM) it was determined that the laboratory failed to not use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, June 25, 2024, at approximately 1:00 p.m. the surveyor found the following expired reagent: KOH (no lot number or expiration date), saline (no lot number or expiration date), Chlorazol Black E (Exp 10/29/2022), and Red Tissue Marking dye (Expired 01/31/2024) reagent used for microscopic examination for the presence of yeast and fungal elements, Sarcoptes scabiei, and Mohs tissue orientation respectively. 2. The OM affirmed on 06/25/2024 at approximately 1:30 p.m. that no new reagents beyond the expiration date were found in the laboratory. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 2,637 tests annually including Mycology, Parasitology and Mohs microscopic diagnostic tests.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's observation, review of the laboratory quality control (QC) records, logs of patients' Mohs procedure and results, lack of QC policy and procedure, and interview with the office manager (OM) it was determined that the laboratory failed to provide quality control records that monitor the accuracy and

	precision of the complete analytic process including the number, the type, and the frequency of the QC materials when performing Mohs procedure examinations. 1. On the day of the survey June 25, 2024, at approximately 1:15 p.m. the surveyor observed that QC documentation was unavailable for the period of 16 months (from 12/21/2021 to 04/06/2023. 2. For three (3) out of five (5) random patient test results reviewed for Mohs examinations performed, no QC documentation was available at the time of the survey. 3. The OM confirmed on June 25, 2024, that the laboratory lacked an established policy and procedure for QC and that no Mohs procedure QC documentation was available from 12/21/2021 to April 6, 2023.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must 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 surveyors' review of policies and procedures, five (5) randomly chosen patients' test results (KOH, scabies, and Mohs testing), and interviews with the laboratory 's office manager on June 25, 2024; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D5203, D5401, D5415, D5417, and D5441.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on interview with the laboratory office manager on the day of the survey (June 25, 2024), the laboratory director failed to ensure that an approved, signed, and dated, procedure manual reflecting the current practice is available to all personnel responsible for any aspect of the testing process. Findings include: D5401 and D5407.