Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1015242	08/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Steven E Hodgkin Md	415 Orange St, 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 the Mohs Tech CLS, (MT-CLS) the laboratory failed to establish safety procedures to ensure protection from physical, chemical, and biochemical materials. The findings include: 1. Based on the surveyor's review of policies and procedures on the day of the survey, August 28, 2025, at approximately 12:45 p.m. the laboratory failed to provide a written policy and procedures for laboratory safety. 2. Based on the surveyor's observations during the laboratory tour where processing of samples for Mohs procedure took place, it was found that the laboratory did not have either biological or chemical spill kits. 3. The MT-CLS affirmed by interviews August 28, 2025, at approximately 1:00 p.m. that the laboratory lacked safety procedures and spill kits in the sample processing and testing area as stated in #2. 4. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 07/16/2025 the laboratory processed and reported annually approximately 65 patients' test samples.
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 reflecting the current practice, and interview with the Mohs Tech- CLS (MT-CLS); the laboratory failed to have written requirements for specimen management, written procedures for quality assurance/assessment of laboratory records with regularly scheduled self-audits, and appropriate documentation of corrective actions. Findings included: 1. The laboratory failed to have written requirements for positive patient identification, patient preparation, specimen collection and labeling, storage, preservation. 2. The laboratory failed to have written procedures for document retention and storage of Pathology reports and records relating to Mohs procedures. 3. The laboratory failed to have a written policy and procedure for at least twice annually verifying the accuracy of tests performed onsite (peer review policy) including but not limited to Mohs to clear tumor and as applicable. 4. The laboratory failed to have any other written policies and procedures pertinent to a Dermatopathology laboratory. 5. The MT-CLS 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 policies and procedures, observation during the laboratory tour, and interview with the laboratory's Mohs Tech-Clinical Laboratory Scientist (MT-CLS) it was determined that the laboratory failed to have procedures and changes in procedures approved, signed, and dated by the current laboratory director before use. The findings included: 1. On the day of the survey August 28, 2025, at approximately 12:00 p.m. the Mohs surgery procedure and the Mohs staining protocol in place in the laboratory had not been approved, signed, and dated by the laboratory director. 2. The MT-CLS affirmed on August 28, 2025, that the laboratory protocols for the Mohs surgical procedure and staining failed to have approval date and signature of the laboratory director. 4. The laboratory's testing declaration form

	stated that the laboratory processes approximately 65 Mohs patients' samples annually for which the laboratory did not have a laboratory director approved and dated Mohs procedure in the laboratory.
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 Mohs procedure laboratory's tour and interviews with the Mohs Tech-Clinical Laboratory Scientist (MT-CLS), the laboratory failed to have a list of reagents used in the laboratory with received date, lot number, expiration date, and opening date. The findings include: 1. Based on the surveyor's observation during the Mohs laboratory tour on August 28, 2025, at approximately 12:45 p.m. no received date, opening date, and expiration date labels were used or documented for all the reagents used in the laboratory. 2. The laboratory's MT-CLS affirmed by interview conducted on August 28, 2025, at approximately 1:00 p.m. that the Mohs reagents used in the procedure were not labelled or documented as stated in #1. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 65 tests for Mohs using staining reagents not labeled or documented properly.
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 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, D5403, D5407, and D5415.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

	This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures, preventive maintenance documentation, randomly selected patient test records for Dermatopathology, and interview with the Mohs Tech-Clinical laboratory Scientist on August 28, 2025; it was determined that the laboratory director is herein cited for failure to ensure that established quality assessment programs were followed to assure the quality of services offered and identify problems as it occur. See D5403.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, survey findings and an interviews on August 28, 2025, the laboratory director is herein cited for failure to ensure that approved, signed, and dated, procedure manual that accurately reflects current laboratory practices is available for all personnel. See D5403.