Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1010935	08/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
San Diego Dermatology And	320 Santa Fe Dr, Ste 303, Encinitas, 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 laboratory's office manager (OM) and medical assistant (MA), it was determined that the laboratory failed to establish safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. Based on the survey on August 9, 2024 at approximately 11:20 a.m., the laboratory failed to provide a written policy and procedure for laboratory safety. 2. Based on the observations during the laboratory tour, it was found that the laboratory lacked an eye wash in each exam room with sink and at the staining area used by Mohs Tek. It was also found that the annual checking of the fire extinguisher was missed inside of the facility (last checked: 12/1/2022). 3. The OM and MA affirmed by interviews on August 9, 2024 at approximately 11:20 a.m. that the laboratory lacked in safety procedures, eyewash, and missed to update the fire extinguisher in the testing area. 4. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 07 /31/2024, the laboratory processed and reported approximately 1,000 Dermatopathology patient test samples.
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The

	laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures manual, a review of six (6) randomly chosen Dermatopathology patient test records, and interviews with the office manager (OM) and medical assistant (MA), it was determined that the laboratory failed to have an approved written policy and procedure for documentation and slide retention and storage. The findings include: 1. Based on the review of the laboratory's policies and procedure manual at approximately 10:30 a.m. on August 9, 2024, no written and approved policy and procedure was found for the retention and storage of documents and slides. 2. The deficient practice was affirmed by interviews with the OM and MA on August 9, 2024, at approximately 10:30 a.m. as mentioned on statement #1. 3. According to the laboratory's testing declaration form submitted at the time of the survey and a review of 6 randomly chosen patient test records covering the period of March 17, 2022 to June 20, 2024, the laboratory performed 1,000 tests annually for Dermatopathology during the time the laboratory had no written and approved retention and storage policy and procedure for documentation and slides.
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 a review of the laboratory's policies and procedures and interview with the office manager (OM), it was determined that the laboratory failed to follow the 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 survey on August 9, 2024, at approximately 10:30 a.m., no documentation could be retrieved by the laboratory to show that quality assessment and assurance were performed for the years 2022, 2023, and 2024. 2. The OM affirmed by interview on August 9, 2024, at approximately 10:30 a.m., that the laboratory did not have any documentation that followed the plan and written policies and procedures reflecting the current practice for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. 3. According to the testing declaration submitted on August 9, 2024, signed and dated by the laboratory director, the laboratory performed 1,000 tests for Dermatopathology annually.
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 interviews with the office manager and medical assistant, lack the quality assessment records, review of policies and procedures, observations during the laboratory tour, and review of eight randomly selected patient records on August 9, 2024, the laboratory director is herein cited for failure to ensure that several aspects of the analytic, and postanalytic phases of the laboratory testing were monitored. 1. No retention and storage policy and procedure. See D 3043 2. Lack of quality assessment records. See D5291
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on the surveyor's findings, the laboratory director is herein cited for deficient practice in failure to provide and overall administration of the laboratory to ensure a safe environment in which personnel are protected from physical, chemical, biochemical, and biohazardous materials. Findings include: See D3011.