Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0691718	05/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of The Bay Area	165 Lynch Creek Way, Petaluma, 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 observations during the tour, and an interview with medical assistant (MA); it was determined that the laboratory failed to follow safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. The laboratory failed to follow their safety policy and procedure to provide protection from physical, chemical, biochemical, and biohazardous materials as needed based on the laboratory's risk assessment. 2. Surveyor's observations during the tour and an interview with the MA include: a. No eye wash station or portable bottle found. b. All reagents and solutions used for Dermatopathology staining were observed to kept under the sink. No chemical safety storage cabinet found at the facility. c. The laboratory had no spill kit nor red biohazard bags used. All trash of any sort, even when stained with biohazardous materials were discarded on a regular black bag. d. The fire extinguisher was not serviced since February 22, 2018. e. No face shield nor goggles found. f. No clear ventilation observed in the laboratory area to direct flow of any chemical scents used during testing. 3. The MA affirmed by interview on May 8, 2025, at approximately 11:18 a..m., that the laboratory lacked and practiced all the findings mentioned in statement #2. 4. The safety of laboratory personnel and patients could not be assured at this time. 5. The annual testing declaration form submitted at the time of survey stated 1, 240 samples were processed and reported for Dermatopathology, Mycology and Parasitology during the time when safety concern for all personnel and patients could not be assured.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 surveyor's observation during the laboratory tour, examination of laboratory reagent material and solutions, and an interview with the medical assistant (MA); it was determined that the laboratory failed in using reagent materials and solutions when it had exceeded its expiration date. The findings include: 1. The laboratory performed Mohs and used multiple tissue marking dye (TMD) bottles beyond its expiration and were continuously used for patient testing. Some examples as follows: Reagent / Solution Lot # Expiry date a. Red TMD 21238 8-31-2023 b. Yellow TMD 120256 2-28-2023 c. Green TMD 120253 2-28-2023 d. Blue TMD 21235 8-31-2023 2. The Chlorazol Black E used for the Provider Performed Microscopy (PPM) testing with lot number 7282 had expired since October 9, 2019. It was the only bottle found at the facility during the tour and was currently in-use for patient testing. 3. The MA affirmed by interview on May 8, 2025 at approximately 11: 10 a.m. that the laboratory used the reagent materials and solutions beyond its expiration date for patient testing without noticing nor checking the label during their quality assessment checks. 4. Based on the testing declaration submitted at the time of survey, the laboratory tested and reported approximately 1,200 tests samples for Dermatopathology and 40 tests for PPM during the time when regaent material and solutions used were past its expiration date. Thus, the quality and accuracy of patient results cannot be assured.
D5819	TEST REPORT CFR(s): 493.1291(j) (j) All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, randomly selected patient records, preventive maintenance log, and interviews with the medical assistant (MA) and laboratory director (LD), it was determined that the laboratory failed to follow the established policies and procedures in maintaining reports or records for identification and timely accessibility. The findings include: 1. During patient review audit, patient M23-105 could not be located in the electronic medical records (EMR) system for the Mohs form detailing the stages and mapping. 2. The laboratory's standard practice is to scan and upload all documents into the EMR system immediately after the examination date is finalized. 3. During an interview on May 8, 2025, at approximately 10:30 a.m., the MA and LD affirmed that the missing electronic record might have been overlooked for processing on September 11, 2023. 4. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory reported approximately 1,200 patient tests for Dermatopathology during the time the document was missed to be uploaded.
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, observations during the tour of the facility, and an interview with the medical assistant (MA) on May 8, 2025, the laboratory director is herein cited due to failure to ensure that several aspects of the analytical and postanalytic phases of the laboratory testing were monitored. The findings include: 1. Improper storage of reagents and solutions. See D5417. 2. Missing patient record. See D5819.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) 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 during the tour and an interview with the medical assistant, the laboratory director is herein cited for the deficient practice in failure to provide and ensure a safe environment in which personnel and patients are protected from physical, chemical, biochemical, electrical hazards, and biohazardous materials. Findings include: See D3011.