Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2075709	05/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Southern Marin Dermatology Inc	2330 Marinship Way Ste 370, Sausalito, 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 review of the laboratory's policies and procedures, lack of safety procedure, and an interview with office manager (OM); the laboratory failed to establish safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. The laboratory failed to provide a written safety policy and procedure that accurately reflects the existing systems. 2. The OM affirmed by interview on May 14, 2025, at approximately 4:25p.m., that the laboratory lacked a written safety policy and procedures based on the laboratory's risk assessment. 3. According to the laboratory's testing volume declaration submitted at the time of survey, 106 test samples were processed and reported for Mycology, Parasitology, and Dermatopathology.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, proficiency testing records, eight (8) randomly selected patient records for Mycology and Parasitology, and an interview with the office manager (OM); it was determined that

	the laboratory failed to verify the accuracy of any test or procedure performed at least twice annually for the years 2021, 2022, 2023, and 2024. The findings include: 1. The laboratory's policy and procedure for proficiency testing was limited to only performing peer review for Dermatopathology. Thus, the regulation requirement for proficiency testing for Mycology and Parasitology was not met for all providers for the years 2021, 2022, 2023, and 2024. 2. All 8 patient records reviewed, covering from October 18, 2021 to October 17, 2024 were performed by various providers affiliated with the laboratory and had no records of any proficiency testing. 3. The OM affirmed by interview on May 14, 2025, at approximately 3:00 p.m., that the laboratory only performed proficiency testing for Dermatopathology as mentioned in statement #1. 4. The laboratory's testing declaration form submitted at the time of the survey stated that 6 tests for Mycology and Parasitology were performed and reported during the time when proficiency testing was missed to be performed for all the providers. The reliability and accuracy of patient reporting cannot be assured.
D5821	TEST REPORT CFR(s): 493.1291(k) (k)When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, six (6) Dermatopathology patient records, preventive maintenance (PM) logs, and an interview with the office manager (OM), it was determined that the laboratory failed to correctly document patient information upon its occurrence. The findings include: 1. One out of 6 patient records reviewed for Dermatopathology was initially recorded in the patient log sheet under March 27, 2022. All logs for cryostat PM, temperature, stain PM, visit note, Mohs surgery note, and patient slides were recorded under March 21, 2022. 2. Patient slides are labeled by the histology technologist (HT) for identifiers that included case number, patient's name, site/location of sample, date of service/examination, and stage-block number. However, for Patient 23-027, examined on March 27, 2022, there were inconsistent labeling, making identification difficult. 3. The OM checked the schedule and affirmed by interview on May 14, 2025 at approximately, 4:10 p.m., that the Mohs surgery date of schedule was under March 27, 2022 and none were examined on March 21, 2022. No corrective action was available for review. 4. According to the laboratory's testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 100 Dermatopathology tests, including the time when the discrepancy in the records occurred. Thus, the accuracy of patient records cannot be assured.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory

	director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory policy/procedure, patient test records, preventive maintenance log sheets, and an interview with the office manager; the laboratory director is herein cited for failure to provide overall operation and administration of the laboratory. See D5821.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies & procedures, proficiency testing records, six patient test records and an interview with the office manager on May 14, 2025.; the laboratory director is herein cited for failure to perform verification of test accuracy at least twice annually. See D5217.
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 interview with the office manager on May 14, 2025 and a review of policy/procedure, the laboratory director failed to ensure that an approved, signed, and dated, procedure manual that accurately reflects current laboratory safety practices for all personnel are available. Findings include: D3011.