

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1036234	(X3) Date Survey Completed 10/17/2025
Name of Provider or Supplier Sonoma Dermatology	Street Address, City, State 461 7th St W Ste 3, Sonoma, 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	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's observations during the laboratory tour, review of the policy and procedure, and an interview with the office manager (OM); 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 surveyor observed during the laboratory tour that two bottles of eye wash mounted near the testing area had expired since 2018 and no other bottle or station was available. 2. The OM affirmed by an interview on October 17, 2025, at approximately 10:40 a.m. that the laboratory had failed to replace the expired eye wash bottles during quality assessment check. 3. The safety of laboratory personnel cannot be assured at this time. 4. The annual testing declaration form (Lab-144) submitted at the time of the survey stated 976 Dermatopathology samples were processed and reported, including the time when the laboratory failed to follow safety procedures.</p>
D5821	<p>TEST REPORT CFR(s): 493.1291(k)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:
 Based on the surveyor's review of the laboratory's quality assessment (QA) policy and procedure, randomly chosen patient test records, and an interview with the office manager (OM); it was determined that the laboratory failed to transcribe the correct test result information prior to finalizing reports. The findings include: 1. The surveyor reviewed fourteen randomly selected patient test records for Dermatopathology dated from September 9, 2022, to October 2, 2025 and found the following discrepancies: a. Patient 22-095, examined on October 3, 2022 was recorded for the right lateral cheek in the patient log and slides, but were reported at right mid jawline in the Mohs map and assessment notes. b. Patient SOD23-318 had a date mismatch for the collection date between the patient log, pathology report, and slide. c. Patient 24-034, examined on April 15, 2024 was misspelled on the patient's last name in the log book and the slide date of service was labeled 4/15/23. 2. It was the practice of the laboratory to conduct patient record review at every patient testing day. 3. The surveyor reviewed the QA policy and related documentation and determined that there was no corrective action report available for the discrepancies identified during the patient review. 4. The OM affirmed by an interview on October 17, 2025, at approximately 10:10 a.m., that the laboratory failed to catch the discrepancies found. The accuracy and reliability of patient tests reported cannot be assured. 5. According to the laboratory's testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 976 Dermatopathology tests, including the time when the patient record was missing.

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 lack of corrective action reports for the errors found during patient review and an interview with the office manager, the laboratory director is herein cited for failure to provide quality laboratory services for all aspects of testing especially in the postanalytic phase of testing. See D5821.

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 review of the laboratory's policy and procedure, observations during the tour of the facility, and an interview with the office manager on October 17, 2025; the laboratory director is herein cited due to failure to provide a safe environment in which both employees and patients are protected from physical, chemical, and biological hazards. See D3011.