

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2150673	(X3) Date Survey Completed 08/27/2025
Name of Provider or Supplier Redwood Empire Dermatology	Street Address, City, State 301 East St, Healdsburg, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, proficiency testing (PT) records, patient record documentation, and interviews with the practice manager (PM) and testing personnel (TP); it was determined that the laboratory failed to verify the accuracy of any test or procedure performed at least twice annually for the year 2023. The findings include: 1. The laboratory's policy and procedure for proficiency testing stated that it will be performed bi-annually through the use of the American Proficiency Institute or an in-house PT program. Records for each provider was performed for the years 2024 and 2025 but was missed to be performed in 2023 for the potassium hydroxide (KOH) test for the subspecialty of Mycology. 2. The 2023 records reviewed by the surveyor indicated that the laboratory combined the PT and patient examination records on the same log sheet. There were no available records of bi-annual PT review for any providers performing the KOH test in 2023. 3. The PM and TP affirmed by interviews on August 27, 2025, at approximately 11:10 a. m., that the laboratory missed the 2023 PT assessment as mentioned in statements #1 and #2. 4. The laboratory's testing declaration form submitted at the time of the survey stated that 50 tests for KOH for the subspecialty of Mycology were performed and reported annually, including the time when PT for the year 2023 was missed. The reliability and accuracy of patient tests reported cannot be assured.</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</p>

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 quality assessment (QA) policy /procedure, randomly chosen patient test records, and an interview with the practice manager (PM), it was determined that the laboratory failed to correctly document patient information upon its occurrence. The findings include: 1. The surveyor reviewed five patient test records for Dermatopathology from August 28, 2023 to July 28, 2025. One out of five records contained discrepancies, specifically: a. Patient 24-035, examined on February 26, 2024, was recorded in the patient log, Mohs map, and slides to be until stage 3, while on the final report, it was recorded until stage 4. 2. Review of the QA policy/procedure and documentation had no corrective action for the discrepancy found as mentioned in statement #1. 3. The PM affirmed by interview on August 27, 2025, at approximately 11:00 a.m., that the discrepancies found for patient 24-035 was missed during the quality assessment check. The accuracy and reliability of patient tests reported cannot be assured. 4. According to the laboratory's testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 1000 Dermatopathology tests, including the time when the discrepancies in the records occurred.

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 and procedures, proficiency testing documentation, patient test records and interviews with the practice manager and testing personnel on August 27, 2025, the laboratory director is herein cited for failure to perform verification of test accuracy at least twice annually for the year 2023 for all testing personnel. See D5217.

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 policy/procedure, preventive maintenance documentation, selected patient test records for Dermatopathology, and an interview with the practice manager on August 27, 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 D5821.