

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1005661	(X3) Date Survey Completed 02/19/2025
Name of Provider or Supplier Redwood Family Dermatology	Street Address, City, State 2725 Mendocino Ave, Santa Rosa, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour, review of the laboratory's policies and procedure, six (6) randomly selected patient records, and interviews with laboratory supervisor (LS) and testing personnel (TP); it was determined that the laboratory failed to perform and document preventive maintenance (PM) and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for small equipment used in the laboratory for sample testing. The findings included: 1. At the time of survey on 2/19/2025, based on the surveyors' observation during the laboratory tour and review of records documentation at approximately 3:30 p.m., it was determined that the laboratory failed to perform PM and calibration on the microtomes, the tissue Tek embedding instrument, and small equipment used in the laboratory for sample processing: hot bath, thermometers, and timers for the years 2023 and 2024. 2. The TS and TP affirmed on February 19, 2025, at approximately 4:00 p.m. that maintenance and calibration was missed for the equipment mentioned in #1 for the years 2023 and 2024. 3. According to the laboratory's testing declaration submitted and signed by the laboratory director; the laboratory performed approximately 8,000 histopathology samples annually for which no preventive maintenance of microtomes, tissue Tek embedding equipment, hot bath, thermometers, and timers for the years 2023 and 2024 for sample processing was performed.</p>
D5893	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c)</p>

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assurance/assessment plan, incident reports, and interview with the laboratory supervisor (LS) on February 19, 2025, the laboratory failed to include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, discussion of postanalytic systems quality assessment reviews with appropriate staff, and documentation of all postanalytic systems quality assurance /assessment activities. Findings include: 1. The laboratory had a policy for quality assurance and assessment, however; the laboratory failed to follow the policy for quality assessment and documentation of review of accuracy of patient reports for the years 2023 and 2024. 2. Although the laboratory had documentation of incident reports, the reports did not include corrective actions taken to resolve the problems or revision of policy or procedures to prevent recurrence of problems. 3. The LS affirmed by interview on February 19, 2025, at approximately 2:45 p.m. that quality assurance/assessment of all postanalytic systems was not performed and review of the effectiveness of corrective actions was not documented for the years 2023 and 2024. 4. The laboratory reported performing approximately 8,100 laboratory test including Histopathology, Mycology and Parasitology for which quality assurance/assessment was not performed and incident reports review was not documented.

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 interview with the laboratory supervisor on February 19, 2025; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytical, and postanalytic phases of the laboratory testing were monitored. The findings include: 1. No documentation for quality assurance /assessment activities. See D5893. 2. No preventive maintenance of small equipment used during specimens processing for histopathology. See D5429.