

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2033588	(X3) Date Survey Completed 02/18/2025
Name of Provider or Supplier Norcal Dermatology & Cosmetic	Street Address, City, State 196 Wikiup Dr, 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
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 observation during the laboratory tour, review of the laboratory's policy and procedure, and interviews with testing personnel (TP) it was determined that the laboratory failed to establish safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. Based on the survey on February 18, 2025, at approximately 3:30 p.m. the laboratory failed to provide a written policy and procedure for laboratory safety. 2. Based on the observations during the laboratory tour where the Mohs processing and staining of samples took place, it was found that: a. the laboratory lacked an eye wash b. no chemical spill kit was available 3. The TP affirmed by interviews February 18, 2025, at approximately 3:40 p.m. that the laboratory lacked safety procedures, eyewash, and a chemical spill kit in the Mohs processing area. 4. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 02/04/2025, the laboratory processed and reported approximately 260 Dermatopathology patients' test samples.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent</p>

information required for proper use.

This STANDARD is not met as evidenced by:

Based on the surveyor's observation of the reagent used for the Mohs procedure in the laboratory during the facility's tour and interview with the laboratory's testing personnel (TP), it was determined that the laboratory failed to label reagents and dyes used in the laboratory. The findings include: 1. Based on the surveyor's observation during the laboratory tour on February 18, 2025, at approximately 3:00 pm.; labelling of various reagents, stains, and dyes with name of reagent, lot number, expiration date, opening date, and expiration date used during the preparation of Mohs slides were missing. 2. The TP affirmed by interview on February 18, 2025, at approximately 3:15 pm that reagents, stains, and dyes used when processing specimens for Mohs slides observed during the laboratory tour were not labeled correctly as mentioned in statement #1. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 260 Histopathology- Mohs test samples during the time various reagents and solutions had no labelling.

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 reagents, and interviews with the laboratory's testing personnel (TP); it was determined that the laboratory failed in not using reagents when they have exceeded their expiration date. The findings include: 1. Based on the surveyor's observations during the laboratory tour, the laboratory stored one (1) only one available of KOH reagent Lot # 1264 Expiration Date 09/21/2023. 2. The TP affirmed on February 18, 2025, at approximately 3:00 p.m. that the laboratory only had one bottle of expired KOH reagent for yeast and fungal microscopic KOH mounts as stated in #1 above. 3. Based on the laboratory's submitted testing declaration test volume, the laboratory tested and reported approximately 5 KOH analysis annually where expired KOH reagent may have been used.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

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 procedures, and interviews with the laboratory testing personnel (TP); it was determined that the laboratory failed to have and follow an established policy and procedure in place for preventive maintenance (PM) as defined by the manufacturer, with at least the frequency recommended for the laboratory's

equipment prior to patient testing. The findings include: 1. Based on the surveyor's observations during the tour of the laboratory on February 18, 2025, at approximately 3:15 p.m., the Leica cryostat did not have any record of calibration and service reports for the years 2023 and 2024. 2. Based on the surveyor's review of the laboratory's policies and procedures, it was determined that the laboratory failed to have and follow an established policy and procedure for the equipment PM including the cryostat according to manufacturer's requirements to be performed annually. 3. The TP affirmed by interviews on February 18, 2025, at approximately 3:20 p.m., that the laboratory only had PM log records reflecting the weekly cleaning or every time the cryostat was, but no calibration was performed as mentioned in statement #2 above. 4. According to the testing volume declaration submitted at the time of survey, the laboratory performed and reported approximately 260 Histopathology during the time that annual equipment PM calibration of the cryostat for the years 2023 and 2024 was missed to be performed and 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 interviews with the laboratory's testing personnel on February 18, 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. Correct labeling of reagents, stains, and dyes used in Mohs procedures. See D5415 2. Storage and possible use of expired reagents. See D5417 3. Missing records for preventive maintenance. See D5429.

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 lack of safety policies and procedures, the laboratory director is herein cited for the deficient practice in failure to provide and overall administration of the laboratory to ensure a safe environment in which personnel are protected from physical, chemical, biochemical, electrical hazards, and biohazardous materials. Findings include See D3011.