

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2300097	(X3) Date Survey Completed 05/28/2025
Name of Provider or Supplier Dermatology Spa Med, Inc	Street Address, City, State 120 N Miller St, Bldg C, Santa Maria, 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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy/procedure, five Dermatopathology patient test records, lack of preventive maintenance (PM) documentation, and interviews with the administration manager (AM) and office manager (OM), it was determined that the laboratory failed to follow a maintenance protocol for the reagent preventive maintenance prior to patient testing. The findings include: 1. The laboratory's protocol stated that at each day of testing, reagent PM is logged. 2. Three out of five Dermatopathology patient records reviewed were missing log entries for reagent PM. The dates included: a. 7-24-2024 for Patient 24-030. b. 10-25-2024 for Patient 24-053. c. 1-17-2025 for Patient 25-007. 3. The AM and OM affirmed by interviews on May 28, 2025, at approximately 11:20 a.m. that the laboratory failed to follow their established PM protocol for the reagents prior to patient testing. The reliability of patient tests reported cannot be assured. 4. According to the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 65 Dermatopathology samples during the time the missed PM entries occurred.</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</p>

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 policy /procedure, five (5) Dermatopathology patient records, and interviews with the administration manager (AM) and office manager (OM), it was determined that the laboratory failed to correctly document patient information upon its occurrence. The findings include: 1. Review of 5 Dermatopathology records revealed discrepancies for the following: a. Patient #1's date of birth (DOB) in the electronic chart is 9-19-1951. However, when cross-checked with the Mohs map and patient log sheet, the DOB recorded was 9-19-1957. b. Patient #3 was recorded until stage II in Mohs map, slides and patient log sheet, but only until stage I was recorded in the final assessment notes in the electronic chart. 2. No corrective action was available for review for any of the discrepancies mentioned in statement #1. 3. The AM and OM affirmed by interviews on May 28, 2025, at approximately 11:20 a.m., that discrepancies occurred were missed during quality assessment check resulting to findings in statements #1 and #2. 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 65 Dermatopathology tests, including the time when the discrepancies in the records occurred.

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, randomly selected Dermatopathology patient test records, lack of preventive maintenance records, and interviews with the administration manager and office manager on May 28, 2025, the laboratory director is herein cited due to failure to ensure that quality control and quality assessment programs established were followed to assure the quality of services offered and identify problems as it occur. The findings include: 1. Lack of preventive maintenance record. See D5433. 2. Discrepancies in test records. See D5821.