

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D1078752	<b>(X3) Date Survey Completed</b>  10/15/2025
<b>Name of Provider or Supplier</b>  Solano Dermatology Associates	<b>Street Address, City, State</b>  600 Nut Tree Rd, Ste 260, Vacaville, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour, examination of laboratory reagent materials and solutions, and an interview with the office manager (OM); it was determined that the laboratory failed in using reagent materials and solutions when it had exceeded its expiration date. The findings include: 1. The laboratory performed Mohs and used reagent materials and solutions beyond its expiration and were continuously used for patient testing. Specific examples include: a. Tissue marking dye (TMD) Reagent / Solution Lot # Expiry date i. Green TMD 23187 7-31-2025 ii. Yellow TMD 23193 7-31-2025 iii. Red TMD 23209 7-31-2025 iv. Blue TMD 23188 7-31-2025 b. OCT compound (Embedding medium) Lot number Expiry date Bottle count i. 5079-00 9/30/2025 11 ii. 4393-00 2/28/2025 1 2. The OM affirmed by interview on October 15, 2025 at approximately 3:30 p.m. that the laboratory used the reagent materials and solutions beyond its expiration date for patient testing without noticing nor checking the label during their quality assessment checks. 3 According to the testing declaration submitted at the time of survey, the laboratory tested and reported approximately 250 patient samples for Dermatopathology during the time when reagent materials and solutions used were past its expiration date. Thus, the quality and accuracy of patient results cannot be assured.</p>
<b>D5435</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p>

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's policy and procedure, preventive maintenance (PM) documentation, five (5) patient records for Dermatopathology, and an interview with the office manager (OM), it was determined that the laboratory failed to ensure performed tests and function checks were documented or maintained prior to patient testing. The findings include: 1. The surveyor reviewed the policy for PM documentation, which indicated that all PM performed on the cryostat should be recorded prior to patient testing. However, this protocol was not followed on October 18, 2024, wherein the temperature of the cryostat was missed to be recorded impacting a total of five patients examined by the provider that day. 2. Five Dermatopathology patient records were reviewed by the surveyor and found one with a recorded out-of-range temperature on November 8, 2023. Further review revealed that there were two other patients that were examined that day. Thus, quality and reliability of patient tests reported cannot be assured. 3. The OM affirmed by an interview on October 15, 2025, at approximately 2:35 p.m. that the PM entries were overlooked during the daily quality assessment check. 4. According to the testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 250 Dermatopathology cases, which included the period when errors in the cryostat temperature occurred as mentioned in this deficiency.

**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 and procedure, randomly selected patient test records, preventive maintenance documentation, and an interview with the medical assistant on October 15, 2025; the laboratory director is herein cited due to failure to ensure that several aspects of the preanalytical and postanalytic phases of the laboratory testing were monitored. The findings include: 1. Use of expired reagent materials and solutions. See D5417 2. Preventive maintenance errors. See D5435.