

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2150064	<b>(X3) Date Survey Completed</b>  08/19/2025
<b>Name of Provider or Supplier</b>  Solano Dermatology Associates	<b>Street Address, City, State</b>  1700 Second St Ste 220, Napa, 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 tour, review of the laboratory's policy /procedure, and an interview with the practice manager (PM); 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 multiple tissue marking dye (TMD) bottles and OCT medium beyond its expiration date for patient testing. Some examples as follows: Reagent / Solution Lot # Expiry date a. Black TMD 7255 9/2019 b. Blue TMD 21293 10/31/2023 c. Yellow TMD 21288 10/31/2023 d. Green TMD 21259 9/30/2023 e. Red TMD 21292 10/31/2023 f. OCT medium 3722-00 7/31/2024 2. The PM affirmed by interview on August 19, 2025 at approximately 3:35 p.m. that the laboratory used the reagent materials and solutions beyond its expiration date prior to patient testing. 3. Based on the testing declaration submitted at the time of survey, the laboratory tested and reported approximately 427 tests for Mohs during the time when reagent material 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> <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</p>

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/procedure, preventive maintenance documentation, five patient records for Mohs, and an interview with the practice manager (PM), 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 five Mohs patient records and found the following discrepancies: a. Patient #4 (MO-002), examined on January 16, 2025, was missing an entry for the cryostat temperature. b. Patient #5 (MO-383), examined on August 7, 2025, was performed at an out-of-range cryostat temperature. 2. In addition, observations by the surveyor during the laboratory tour revealed that the timer used for manual staining for Mohs quality control and patient slides was not calibrated. No preventive maintenance documentation was available for review at the time of survey. 3. The PM affirmed by interview on August 19, 2025, at approximately 3:37 p.m. that the discrepancies found and mentioned on statements #1 and #2 occurred and were missed during quality assessment check. The quality and reliability of patient tests reported cannot be assured. 4. According to the testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 427 Mohs cases, which included the period when the discrepancies 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, preventive maintenance documentation, selected patient test records for Mohs, and an interview with the practice manager on August 19, 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. The findings include: 1. Use of reagent materials and solutions beyond its expiration date See D5417. 2. Maintenance and function check. See D5435.