Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0600489	(X3) Date Survey Completed 08/19/2025
Name of Provider or Supplier Solano Dermatology Associates	**Street Address, City, State** 1030 Main Street, Suite 200, Saint Helena, 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
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, review of the laboratory's preventive maintenance protocol, 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. Blue TMD 23028 2-28-2025 b. Green TMD 23158 6-30-2025 c. Red TMD 23040 2-28-2025 d. OCT medium 4398-00 2-28-2025 2. The PM affirmed by interview on August 19, 2025 at approximately 11:45 a. 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. Based on the testing declaration submitted at the time of survey, the laboratory tested and reported approximately 625 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.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (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. 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, preventive maintenance documentation, observations during the tour, and an interview with the practice manager (PM), it was determined that the laboratory failed to follow an established maintenance protocol for the cryostat preventive maintenance prior to patient testing. The findings include: 1. The laboratory's protocol stated that at each day of testing, reagent preventive maintenance is logged. The in-use cryostat temperature range was between -18 to -28 degree Celsius. 2. The surveyor reviewed five patient records for Dermatopathology wherein one out of five (MO-309) was operated under an out-of-range temperature of -24 degree Celsius on 7/21/2025. Further review on the same date revealed that a total of 13 patients were documented as having undergone Mohs surgery. 3. Observations by the surveyor during the laboratory tour revealed that the timer used when staining slides had no record of calibration for 2023, 2024, and 2025. 4. The PM affirmed by interview on August 19, 2025, at approximately 11:00 a.m. that the laboratory failed to follow their established temperature range for the cryostat prior to patient testing and that no calibration was performed for the timer. The reliability of patient tests reported cannnot be assured. 5. According to the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 625 Dermatopathology samples during the time the cryostat was operated on an out-of-range temperature in addition to the use the timer without any calibration record.
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 policy/procedure, randomly selected patient test records, preventive maintenance documentation, and an interview with the practice manager on August 19, 2025, the laboratory director is herein cited due to failure to ensure that several aspects of the preanalytical, analytic and postanalytic phases of the laboratory testing were monitored. The findings include: 1. Use of expired reagents and solutions. See. D5417. 2. Maintenance and function check. See D5433.