Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2177603	08/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Kathryn Kent, Md	3443 Villa Lane Ste 10, Napa, 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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (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/procedure, preventive maintenance (PM) documentation, six patient records and an interview with the medical assistant (MA); it was determined that the laboratory failed to follow an established policy and procedure in place for the 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.The laboratory failed to provide PM documentation for the years 2023 and 2024 for the microscope used at the facility according to manufacturer's requirements, to be performed annually. 2. The surveyor reviewed six Mohs patient records from January 13, 2023 to August 15, 2025. Two out of six (23-013 and 25-013) were missing entries for the cryostat PM. 3. No corrective action reports were available for review at the time of the survey. 3. The MA affirmed by an interview on August 28, 2025, at approximately 10:30 a.m., that the laboratory missed the PM as mentioned in statements #1 and #2. 4. According to the testing volume declaration submitted at the time of survey, the laboratory performed and reported approximately 160 tests annually for Histopathology during the time the microscope and cryostat PM were missed to be performed and documented.
D5603	HISTOPATHOLOGY

	CFR(s): 493.1273(b)(f) (b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (f), or (g). This STANDARD is not met as evidenced by: Based on the surveyor's review of laboratory quality control and patient testing records, and an interview with the medical assistant, the laboratory failed to retain the quality control slides for the hematoxylin and eosin stains that was used to interpret the results of patient slides. The findings include: 1. The laboratory performed Mohs on March 15, 2024, wherein, the quality control slide was not found affecting one out of six selected patients for review. 2. Upon further review of the patient log sheet, ten patients were scheduled for Mohs surgery on March 15, 2024. 3. The MA affirmed by interview on August 28, 2025 at approximately 10:30 a.m., that the quality control slide was missing for March 15, 2024. Thus, the quality and reliability of patient tests reported cannot be assured. 4. According to the laboratory declaration form submitted at the time of survey, the laboratory performed and reported 160 patient cases for Mohs including the date with the missing quality control slide.
D5821	TEST REPORT CFR(s): 493.1291(k) (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 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 (QA) policy /procedure, randomly chosen patient test records, and an interview with the medical assistant (MA), it was determined that the laboratory failed to correctly document patient information upon its occurrence. The findings include: 1. The surveyor reviewed six patient test records for Histopathology from January 13, 2023 to August 15, 2025. Two out of six records contained discrepancies, specifically: a. Patient 24-022, examined on March 15, 2024, recorded different anatomical locations acorss all records (Mohs map, log sheet, chart, and slides). b. Patient 25-013, examined on February 14, 2025, had missed to record entries on the cryostat temperature and preventive maintenance log sheets. 2. A review of the QA policy and documentation indicated that no corrective action for the identified discrepancies was available for review. 3. The MA affirmed by interview on August 28, 2025, at approximately 10:30 a.m., that the discrepancies found for patient 24-035 and 25-0313 were missed during the QA check. 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 160 Histopathology 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 patient test records, preventive maintenance documentation, and an interview with the medical assistant on August 28, 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. Maintenance and function check. See D5435. 2. Missing quality control slide. See D5603. 3. Errors in test report. See D5821.