

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2259881	(X3) Date Survey Completed 05/16/2025
Name of Provider or Supplier William F Kivett Md Inc.	Street Address, City, State 1140 Sonoma Ave Ste 1a, Santa Rosa, 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	<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 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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's preventive maintenance (PM) documentation, patient records for Dermatopathology, and an interview with the laboratory director (LD), it was determined that the laboratory failed to ensure performed tests and function checks were documented properly prior to patient testing. The findings include: 1. The laboratory worked with a histology technologist (HT) from an external Mohs company to provide the technical component process. 2. During each Mohs surgery day, the HT was tasked with recording the room and cryostat's temperature, the PM activities performed on the cryostat, and the reagents utilized. However, on December 13, 2023, these records were not completed. Consequently, all five patients examined that day, including Patient 23-031, were impacted by this oversight. 3. The LD affirmed by interview on May 16, 2025, at approximately 10:45 a.m. that the three log sheets intended for recording the temperature, PM activities, and reagents used were overlooked by the HT. 4. According to the testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 40 patient tests for Dermatopathology, which included the timeframe when the HT failed to document information on the three log sheets mentioned in this deficiency. Thus, the accuracy and reliability of patient records cannot be assured.</p>

D5789

TEST RECORDS

CFR(s): 493.1283(b)

(b) Records of patient testing including, if applicable, instrument printouts, must be retained.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's policy/procedure, five (5) patient records, preventive maintenance log, and an interview with the laboratory director (LD); it was determined that the laboratory did not retained patient and test records after the cases had been closed. The findings include: 1. The laboratory's current practice involved scanning and uploading patient records into the electronic medical record (EMR) system. Once a case is closed, the original documents are subsequently destroyed. 2. Patient review for Dermatopathology showed discrepancies as follows: a. The Mohs surgery document detailing mapping and stages for Patient 24-021 on the day of examination could not be located. b. The quality control (QC) slide dated October 24, 2022, was missing. No other documentation provided information regarding the quality control assessment, which had a potential impact in the results for patients examined on that date. This included Patient 22-016, among the five patients reviewed was affected by the absence of the QC slide. 3. The LD affirmed by interview on May 16, 2025, at approximately 10:45 a.m., that no alternative methods to recover a destroyed document after it has been checked during the file upload process or to retrieve a missing QC slide from at least three years prior. 4. According to the testing declaration submitted at the time of survey, 40 Dermatopathology patient samples were processed and reported during the time when the records of patient was not retained properly. The quality and reliability of patient tests reported cannot be assured.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory policy/procedure, patient test records, preventive maintenance log sheets, and an interview with the laboratory director; it was determined that the laboratory director is cited for failure to provide oversight and management of the laboratory. The findings include: 1. Missing maintenance and function checks. See D5435. 2. Missing patient test records. See D5789.