Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0935360	07/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Edward M Kramer Md, Inc	27995 Greenfield Dr Ste C, Laguna Niguel, 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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy/procedure, preventive maintenance (PM) documentation, ten (10) patient records and interviews with the laboratory assistant (LA) and office manager (OM); it was determined that the laboratory failed to follow an established policy and procedure in place for the preventive maintenance (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 and cryostat used at the facility according to manufacturer's requirements, to be performed annually. 2. No corrective action report was available for review at the time of survey. Out of the ten patient records reviewed from 2023 to 2025, eight were impacted by the lack of PM. The quality and reliability of tests reported cannot be assured. 3. The LA and OM affirmed by interviews on July 10, 2025, at approximately 9:30 a.m., that the laboratory missed the PM for 2023 and 2024 for the microscope and cryostat used for patient testing. 4. According to the testing volume declaration submitted at the time of survey, the laboratory performed and reported approximately 2,289 tests annually for Histopathology during the time annual equipment PM for the microscope and cryostat were missed to be performed and documented.
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 policy /procedure, ten (10) Histopathology patient records, and interviews with the laboratory assistant (LA) and office manager (OM), it was determined that the laboratory failed to correctly document patient information upon its occurrence. The findings include: 1. The surveyor reviewed 10 Histopathology patient records dated from February 22, 2023, to March 28, 2025. It was found that one of the records was documented under an incorrect Mohs case number across all related documentation. Specifically, accession JL333-24 was noted on the patient log sheet, Mohs card/map, slides, and chart notes, when it should have been JL334-24. 2. The laboratory's protocol involved pre-filling records before patient testing. However, no corrective actions were available for review at the time of the survey for JL334-24. 3. The LA and OM affirmed by interview on July 10, 2025, at approximately 10:00 a.m., that discrepancies occurred were missed during quality assessment check. The accuracy and reliability of patient tests reported cannot be assured at this time. 4. According to the laboratory's testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 2,289 Histopathology tests, including the time when the discrepancies in the records occurred.
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 interviews with the office manager and laboratory assistant on July 10, 2025; the laboratory director is herein cited due to failure to ensure that several aspects of the pre-analytic, analytic and postanalytic phases of the laboratory testing were monitored. The findings include: 1. Missing preventive maintenance documentation. See D5429. 2. Discrepancy in documentation. See D5821.