Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0934502	02/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Edward M Kramer, Md, Inc	3055 W Orange Ave Ste 207, Anaheim, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the review of the laboratory's quality assessment policies and procedures, personnel competency documentation, and an interview with the laboratory assistant (LA) on February 26, 2025, at approximately 10:35 a.m., as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform competency assessment for the laboratory personnel for the years 2022, 2023, and 2024. Findings include: 1. Based on the review of the laboratory's quality assessment policies and procedures and lack of the competency evaluation records, the laboratory is herein cited for the deficient practice for failure to perform competency assessment for the LA for the years 2022, 2023, and 2024. 2. The LA affirmed by interview on February 26, 2025, at approximately 10:35 a.m. that the laboratory had no records of any competency assessment for the years 2022, 2023, and 2024. 3. According to the laboratory's annual testing declaration submitted at the time of the survey, the laboratory reported and performed approximately 2,215 tests for Histopathology for which competency assessment of the testing personnel was not performed.
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 policies and procedures, observations during the tour of the facility, 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 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. Based on the surveyor's review of the laboratory's protocols, it was determined that the laboratory failed to follow an established policy and procedure for the equipment PM that included the calibration for the microscope and cryostat according to manufacturer's requirements, to be performed annually for the years 2023 and 2024. 2. Based on the surveyor's observations during the tour of the facility, the laboratory's only record of PM calibration was a sticker on the Olympus BH-2 microscope and the Leica CM1510S cryostat indicating that it was last calibrated in July 18, 2022. No service reports or any type of records were found to prove calibration were performed for the years 2023 and 2024. 3. The LA and OM affirmed by interviews on February 26, 2025, at approximately 1:05 p.m. that the laboratory only had PM log records reflecting the weekly cleaning or every time of use on both equipment, but no calibration was performed as mentioned in statement #2. 4. According to the testing volume declaration submitted at the time of survey, the laboratory performed and reported approximately 2,218 tests annually for Mycology and Histopathology during the time that annual equipment PM calibration was 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 and documentation, twenty-three (23) patient records and interviews with the laboratory assistant (LA) and office manager (OM), it was determined that the laboratory failed to correct errors upon its occurrence. The findings include: 1. Based on the surveyor's review of the quality assessment policy, procedure, and documentation, it was determined that the laboratory was performing monthly checks that covered the postanalytical phase of testing only. 2. The surveyor reviewed seven patient records for potassium hydroxide (KOH) tests in Mycology, covering the period from October 31, 2022, to April 22, 2024, and sixteen patient records for Histopathology, including Mohs tests, dated from August 16, 2022, to May 31, 2024. a. Based on the surveyor's review of 23 patient records, it was determined that three cases were found to have discrepancies in documentation: i. Patient MJ, examined on January 12, 2023, was recorded in the KOH patient log book as positive for the right knee; however, the patient chart notes indicated two sites: the left knee and ear/back as positive and negative respectively. ii. Patient DJ, examined on February 20, 2023, had a misspelling in the last name. The patient log book showed "Jaffe," while the slide, chart, and pathology report listed it as "Jeffe." iii. Patient ST, examined on

	August 16, 2022, was labeled under an incorrect case number. The Mohs patient log book and mapping recorded HA232-22, while all four slides were labeled under HA236-22. 3. On February 26, 2025, around 11:15 a.m., both the LA and OM confirmed in interviews that the discrepancies noted in statements #1 and #2 were neither recognized when they occurred nor detected during the monthly quality assessment checks. At the time of the survey, there were no records of corrective actions available. 4. According to the laboratory's testing declaration form submitted at the time of the survey, the laboratory performed and reported 2,218 patient tests for Mycology and Histopathology, including the time when the discrepancies in the reports 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 policies and procedures, randomly selected patient test records, observations during the tour of the facility, and interviews with the laboratory assistant and office manager on February 26, 2025, it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytical, and postanalytic phases of the laboratory testing were monitored. The findings include: 1. Missing records for preventive maintenance. See D5429. 2. Discrepancies in patient records. See D5821.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the interviews with the laboratory assistant and office manger, lack of documentation of testing personnel competency, and review of the laboratory's competency policies and procedures on February 26, 2025, the laboratory director is herein cited for failure to ensure that policies and procedures established for monitoring individuals who conduct preanalytical and analytical phases of testing are followed to assure that they are competent and maintain their competency to process specimens and perform test procedures promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. See D5209