Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1042330	06/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Keith Mark Gross Md Inc	1113 Alta Ave, Ste 200, Upland, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the surveyor's observations during the laboratory tour, review of the laboratory's policies and procedures, and interviews with the office manager (OM); the laboratory failed to have and follow written and approved laboratory safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. The laboratory failed to have a written Safety plan and procedures based on the laboratory's risk assessment to provide protection from physical, chemical, biochemical, and biohazardous materials as needed. 2. Surveyor observed during the laboratory tour that no eye wash station or eye wash portable bottle kit was found in the testing area. The fire extinguisher was located in a different room, not accesible to the laboratory. 3. The laboratory did not have a biological or chemical spill kit in the laboratory area where the Mohs procedure is performed. 4. The OM by interview on June 16, 2026, at approximately 12:00 p.m. affirmed that the laboratory did not have a written and laboratory director approved, signed, and dated Safety Plan and lacked an eye washing station and a chemical spill kit in the laboratory area. 5. The safety of laboratory testing personnel could not be assured at this time. 6. The annual testing declaration form submitted at the time of the survey stated 85 samples were processed and reported for Dermatopathology during the time when safety concern for all testing personnel could not be assured.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, six (6) randomly selected patient test results for Mohs and Histopathology, and interviews with the laboratory's office manager (OM) and laboratory staff (LS) on June 16 2026; the laboratory failed to have CLIA compliant written procedures manuals for all tests, assays, and examinations performed by the laboratory available and followed by laboratory personnel. The findings included: 1. The laboratory lacked CLIA compliant written and LD approved, dated, and signed policies and procedures for: Mohs testing, microscope preventive maintenance, document retention, storage of slides, and laboratory safety policies. 2. Reliability of the laboratory tests' performance based on complete laboratory procedures to follow by testing personnel to ensure compliance with federal CLIA regulations could not be assured during this survey. 3. The OM and LS affirmed by an interview on June 16 , 2026, at approximately 11:45 a.m. that the laboratory failed to provide LD signed, dated, and approved laboratory policies and procedures for all the current tests and examinations performed in the laboratory. 4. According to the testing declaration form (CMS-116) submitted at the time of survey, the laboratory processed, tested, and reported approximately a total of 85 patient tests annually for Mohs and Histopathology, when the laboratory lacked written and approved policies and procedures manuals.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory records, the lack of laboratory CLIA compliant written procedures, and interview with the office manager (OM) and laboratory staff (LS); the

	laboratory failed to have written requirements for specimen management, written procedures for managing laboratory records with regularly scheduled self-audits for quality assessment, and a process for documenting failures and noncompliance, appropriate corrective actions, and monitoring for recurrence. The findings included: 1. The laboratory failed to have written requirements for positive patient identification, patient preparation, specimen collection and labeling, storage, preservation, transportation and referral of Biopsy specimens, and criteria for specimen acceptability and rejection. 2. The laboratory failed to have written procedures for managing laboratory records, including receipt and retention of Histopathology reports and Mohs procedures. 3. The laboratory failed to have a written policy and procedure for regularly scheduled self-audits of laboratory records to assess the quality of preanalytic, analytic, and postanalytic processes, apply remedial corrections as appropriate, and monitor for quality assurance and compliance. 4. The laboratory failed to have any other written policies and procedures pertinent to a Dermatopathology laboratory such as a comprehensive Laboratory Safey Plan. 7. The OM and LS affirmed by interview at the time of the survey the lack of CLIA compliant procedures.
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 surveyors' observation, lack of a reagent list/documentation of the chemicals used for the processing and staining of Mohs samples, and interviews with the laboratory's office manager (OM) and laboratory staff (LS); the laboratory failed to have proof of using reagents when they have not exceeded their expiration date, have deteriorated, or are of substandard quality. The findings included: 1. On the day of inspection, 06/16/2026, at approximately 12:45 p.m., the examiner found lack of a list/record of the reagents used for the Mohs procedure that include: date received, manufacturer, lot number, expiration date, date opened, date discarded, and technician initials for the years 2024, 2025, and 2026. 2. The OM and LS affirmed on 06/16, 2026 at approximately 1:00 p.m. the lack of documentation on the reagents used for the Mohs procedure as stated in 1. above. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 85 Mohs tests annually for which the laboratory could not demonstrate using reagents when they have not exceeded their expiration date, have deteriorated, or are of substandard quality.
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 direct observation during the laboratory tour, review of the laboratory's policies and procedures, preventive maintenance (PM) documentation, six

	(6) randomly selected patient records, and interviews with the laboratory's office manager (OM) and laboratory staff (LS); the laboratory failed to establish and follow a policy and procedure in place for preventive maintenance as defined by the manufacturer, with at least the frequency recommended for the laboratory's equipment prior to patient testing. The findings included: 1.The laboratory failed to provide PM documentation for the years 2024, 2025, and 2026 for the cryostat used to process samples for the Mohs procedure. 2. No corrective action report for preventive maintenance was available for review at the time of the survey. 3. The OM and LS affirmed by interviews on June 16, 2025, at approximately 12:45 p.m., that the laboratory missed the PM for the years 2024,2025, and 2026 for the cryostat used in the laboratory for patients' Mohs samples procedure. 4. According to the testing volume declaration submitted at the time of the survey, the laboratory performed and reported approximately 85 Mohs tests annually during the time annual equipment PM for the cryostat equipment was missing.
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 lack of a written Laboratory Safety Plan (D3011), lack of established CLIA compliant policies and procedures (D5401 and D5403), lack of documentation of the reagents used for the Mohs procedure (D5417), and no records of preventive maintenance for the cryostat (D5429); the laboratory director is cited herein for failure to ensure that testing systems developed and used for each of the Mohs 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.