Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1001250	07/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Linda Mak Md Inc	1073 Ross Ave, Ste A, El Centro, 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 surveyors' observation during the laboratory tour and interview with the laboratory's medical assistant (MA) it was determined that the laboratory failed to establish safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. The laboratory failed to provide a written procedure for laboratory safety. 2. On the day of the survey July 25, 2024, at approximately 11:00 a.m. the surveyors observed that the laboratory lacked an eyewash and biological & chemical spill kits in the area where tissue samples are processed. 3. The MA affirmed the lack of safety procedures, eyewash, and spill kits in the testing area. 4. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 07/25/2024, the laboratory processes and reports approximately 100 samples annually.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by:

	Based on review of patient testing records, patient final testing reports, and interviews with the medical assistant (MA) on July 25, 2024, at approximately 12:30 p.m. it was determined that for three (2) out of five (5) randomly selected patient Mohs testing records reviewed, the laboratory failed to follow written policies and procedures for specimen analytical phase testing, through completion of testing and reporting results. The findings included: 1. Review of Mohs documentation and patient's final test report found the following discrepancies: Patient 1 date of Mohs procedure performed on 6/17/2022; Mohs logs stated Stage VII as the final stage of SCC while the report indicated stage VII. Patient 2 date of Mohs procedure performed on 08/30/2023 stage II was missing one slide from storage. Records indicated four (4) slides were prepared labelled I A&B and II 1-2 and 2-2. Only three (3) were found at the time of the survey. 2. The MA affirmed that records were discrepant for two (2) patients an stated in #1 above 3. Based on the laboratory's annual test volume declaration signed by the LD on 7/25/2024 the laboratory performed and reported 100 Mohs procedures for which its accuracy cannot be affirmed.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 the lack of laboratory written policies and procedures for Mohs surgery and processing of samples performed in the laboratory and interviews with the laboratory's medical assistant (MA); it was determined that the laboratory failed to have available written policies and procedures at the time of the survey. The findings included: 1. On the day of the survey on July 25, 2024, at approximately 10:45 a.m., the laboratory failed to provide written policies and standard operating procedure (SOP) for Mohs test performed in the laboratory. 2. For five (5) out of (5) randomly selected patient test results reviewed for Mohs test performed in the lab, no CLIA compliant (SOP) was available at the time of the survey. 3. The MA confirmed on 07/25/2024 at approximately 12:00 p.m. that the laboratory did not have written policies and procedures available for testing performed.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)

	The laboratory director must 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 interviews with the medical assistant, lack the laboratory's policies and procedures, observations during the tour of the Mohs testing area, and review of five (5) randomly selected patient records on July 25, 2024, the laboratory director is herein cited for failure to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D3011, D5203, and D5403.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on interview with the medical assistant on the day of the survey (July 25, 2024), the laboratory director failed to ensure that an approved, signed, and dated, procedure manual reflecting the current practice is available to all personnel responsible for any aspect of the testing process. Findings include: D5403.