Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0978114	04/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Michael P Tabibian Md Inc	30300 Agoura Rd, Ste 200, Agoura Hills, 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, lack of safety policies and procedures, and interviews with the nursing supervisor (NS) and office manager (OM); it was determined that the laboratory lacked an eyewash station in the testing area as well as an evacuation route. The laboratory failed to observe safety procedures to ensure protection from physical, chemical, and biohazardous materials. The findings included: 1. During the laboratory tour conducted on April 26, 2024, at approximately 1:30 p.m. the surveyors observed that the laboratory's hand shower spray hose on the sink does not satisfy the requirement for an eyewash station in the area where histopathology samples are prepared. 2. Upon review of the policies and procedures manual of the laboratory, it was observed that no safety policies and procedures were found at the time of the survey. 3. The NS affirmed there was no other eyewash station in the laboratory aside from the hand shower spray hose in the processing area and is unaware of any policies and procedures for safety. 4. Both NS and OM affirmed that there was no evacuation route posted anywhere in the laboratory. 5. Based on the laboratory's annual testing volume declaration signed by the laboratory director on April 25, 2024, the laboratory processed and reported approximately 2,000 samples for dermatopathology and Mohs collectively.
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the

	date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on the written policies and procedures manual for retention and storage applicable to histopathology and Mohs, review of ten (10) randomly chosen dermatopathology test records, and interview with the nursing supervisor (NS); the laboratory failed to have a written policy for Mohs and dermatopathology documentation and slide retention. The findings included: 1. Based on the day of survey conducted on April 26, 2024, at approximately 12:00 p.m., a written policy for retention of documents for two years was found but lacked the information for retention period for slides. 2. The NS affirmed by interview on April 26, 2024, at approximately 12:00 p.m. that the laboratory had an incomplete policy for documents retention for Mohs and histopathology slides. 3. The laboratory declared on April 26, 2024, that 2,000 tests are performed annually for Mohs and dermatopathology.
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 the surveyors' review of ten (10) randomly selected patient records for Mohs and histopathology, interviews with the nursing supervisor (NS) and office manager (OM) on April 26, 2024 at approximately 12:30 p. m., the laboratory failed to correctly match the document of their slide accession number / Mohs case number to the final report. The findings included: 1. The surveyors reviewed a total of ten (10) randomly selected patient records that consisted of five (5) records for Mohs and five (5) for histopathology records from June 7, 2022 to February 9, 2024. One (1) out of five (5) records for Mohs was discrepant as Mohs case number was missing on the slide presented at the time of survey. 2. Four (4) out of five (5) Mohs patient records were discrepant as Mohs case number assigned to the patients were different from the assessment notes and final report recorded in the patient's chart. 3. No Quality Control staining slide was found for five (5) out (5) histopathology patient records reviewed at the time of the survey. 4. Based on an e-mail response from the OM, she affirmed that the discrepancy in statements 1 and 2 above were due to the automatic assignment of the Electronic Health Record (EHR) without their knowledge. No corrective action was available at the time of the survey. 5. The laboratory reported approximately 2,000 Mohs and histopathology cases performed annually.
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 review of the laboratory's written policies and procedures and interviews with the office manager (OM) and nursing supervisor (NS), it was determined that the laboratory had an incomplete and outdated written procedure manual at the time of the survey. The findings included: 1. On the day of the survey on April 26, 2024, at approximately 12:00 p.m., the laboratory failed to provide a complete and updated written policies and procedures manual for all the tests performed in the laboratory including the quality assessment and equipment quality control. 2. Based on further review of the laboratory's documents, it was observed that there was no policies and procedures for safety, staining, and cross-contamination prevention. 3. For ten (10) out of (10) randomly selected test results for Mohs and dermatopathology performed in the laboratory, the policies and procedures manual found were not reviewed since 2019. 4. The NS affirmed on 4/26/2024 at approximately 12:00 p.m. that the laboratory did not have written policies and procedures manual available for safety, staining, and cross-contamination prevention performed for dermatopathology and Mohs. 5. Based on the laboratory's testing declaration signed and submitted on April 26, 2024 at approximately, 11:00 a.m., the laboratory performs 2,000 tests annually for dermatopathology and Mohs.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (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. (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. This STANDARD is not met as evidenced by: Based on the review of written policies and procedure manual for equipment quality control, interview with the nursing supervisor (NS), and ten (10) randomly selected patient test results for dermatopathology and Mohs, it was determined that the

	laboratory is ensuring that the microscope is serviced yearly but no record of documentation for preventive maintenance (PM) was found after 2019. The findings included: 1. Based on the survey conducted on April 26, 2024, at approximately 1:30 p.m. and review of laboratory's policies and procedures manual, the surveyors observed that written policies and procedures for Equipment Quality Control for the microscope had no documentation for PM that was found after 10/15/2019. 2. The NS affirmed that no documentation for PM was performed for the microscope as mentioned on statement #1. 3. Based on the laboratory's testing declaration submitted on 04/26/2024 at approximately 11:00 a.m., and review of ten (10) randomly selected patient test records for dermatopathology and Mohs, the laboratory performs 2,000 tests annually without documentation for PM.
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 surveyors' review of the laboratory's records, policies and procedures, patients' test results records, and interviews with the laboratory's nursing supervisor (NS) and office manager (OM) on April 26, 2024; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D3011, D3043, D5203, D5403, and D5435.