Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2181294	02/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Thomas Dermatology	2350 Miracle Mile Ste 600, Bullhead City, AZ	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review for Mohs testing and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the sub-specialty of Histopathology at least twice annually during 2020, 2021 and 2022. Findings include: 1. No documentation was presented for review during the survey conducted on February 2, 2023 to indicate the laboratory verified the accuracy of the microscopic interpretation (reading/diagnosis) of histopathology specimens which are read during the Mohs procedure at least twice annually during 2020, 2021 and 2022. 2. The facility personnel interviewed on February 2, 2023 at 11:45am confirmed that the laboratory failed to verify the accuracy of histopathology testing at least twice annually during 2020, 2021 and 2022. 3. The laboratory's approximate annual test volume under the sub-specialty of Histopathology is 360.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by:

	Based on lack of established Quality Assessment (QA) policies and procedures for review and interview with the facility personnel, the laboratory failed to establish QA policies and procedures for the general laboratory systems, including but not limited to, policies and procedures related to the accuracy verification process for dermatopathology testing performed by the laboratory. Findings include: 1. The laboratory performs the microscopic interpretation (reading/diagnosis) of dermatopathology specimens which are read during the Mohs procedure. 2. No documenation was presented for review during the survey to indicate the laboratory established policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. 3. No documentation was presented for review during the survey to indicate the laboratory established policies and procedures related to the verification of accuracy process for Mohs testing, including but not limited to, information specific to the frequency of the review, number of cases reviewed, individual or laboratory performing the review and a remedial action plan in the event of a noted discrepancy. 4. The facilty personnel interviewed during the survey on February 2, 2023 at approximately 12:05pm confirmed that the laboratory failed establish a written policy and procedure specific to the verification of accuracy process for the microscopic interpretation of Mohs specimens and failed to establish policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. 5. The laboratory began patient testing on April 1, 2020. The laboratory's annual test volume is 360.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the severity and number of deficiencies cited for quality control practices identified during the survey conducted on February 2, 2023, it was determined that the laboratory failed to monitor the overall quality of the analytic systems and correct problems as specified in 493.1289 for patient testing performed by the laboratory in the sub-specialty of Histopathology. See D5403, D5407, D5413, D5473 and D5791 for findings.
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 review of the laboratory's test procedure for Mohs, Hematoxylin & Eosin (H&E) stain quality control (QC) records and interview with the facility personnel, the Mohs test procedure failed to include control procedures for the H&E stain performed on patient specimens. Findings include: 1. The laboratory began reading and diagnosing patient specimens during the Mohs procedure in the sub-specialty of Histopathology on April 1, 2020, with a reported annual test volume of 360. Each patient specimen is stained with the H&E stain prior to the microscopic interpretation. 2. The Mohs test procedure reviewed during the survey conducted on February 2, 2023 failed to include control procedures for the H&E stain, including but not limited to, the number and frequency of testing controls, criteria to determine acceptable control results, and remedial action to take if the control results are unacceptable. 3. The facility personnel interviewed on February 2, 2023 at 11:55am confirmed that the Mohs test procedure reviewed during the survey lacked information regarding control procedures as indicated above.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's test procedure for Mohs and interview with the facility personnel, the laboratory director failed to approve, sign and date the Mohs test procedure before use. Findings include: 1. The laboratory began patient testing in conjunction with the Mohs procedure in the sub-specialty of Histopathology on April 1, 2020, with a reported annual test volume of 360. 2. The Mohs test procedure presented for review during the survey conducted on February 2, 2023 failed to include the approval, signature and date of the current laboratory director. 3. The facility personnel interviewed on February 2, 2023 at 11:15am acknowledged that the Mohs test procedure was not signed and dated by the current laboratory director at the time of the survey.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and

	test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature logs and interview with the facility personnel, the laboratory failed to define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. Findings include: 1. The laboratory began reading and diagnosing patient specimens during the Mohs procedure in the sub-specialty of Histopathology on April 1, 2020, with a reported annual test volume of 360. 2. Each day of patient testing, the laboratory documented the room temperature where staining reagents are utilized for Mohs slide processing. 3. Each day of patient testing, the laboratory documented the temperature of the cryostat used in the processing of Mohs specimens. 4. No documenation was presented for review during the survey conducted on February 2, 2023 to indicate the laboratory defined the criteria for the room temperature and cryostat that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. 5. The facility personnel interviewed on February 2, 2023 at 11:48am confirmed that the laboratory had not defined the criteria for the room temperature and cryostat as indicated above.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to document the acceptability of Hematoxylin & Eosin staining materials each day of use for intended reactivity to ensure predictable staining characteristics. Findings include: 1. The laboratory began reading and diagnosing patient specimens during the Mohs procedure in the sub-specialty of Histopathology on April 1, 2020, with a reported annual test volume of 360. Each Mohs specimen is stained with the H&E stain prior to the microscopic interpretation. 2. No documentation of the Hematoxylin & Eosin (H & E) stain acceptability was presented for review for testing that occurred on the following dates: - 5/31/22 (12 Mohs cases performed); 6/14/22 (25 Mohs cases performed); 6/28/22 (22 Mohs cases performed); 7/12/22 (21 Mohs cases performed); 7/26/22 (15 Mohs cases performed); 8/09/22 (15 Mohs cases performed); 8/23/22 (11 Mohs cases performed); 9/27/22 (17 Mohs cases performed); 10/11/22 (19 Mohs cases performed); 10/25/22 (17 Mohs cases performed); 11/01/22 (15 Mohs cases performed); 11/15/22 (17 Mohs cases performed); 11/29/22 (11 Mohs cases performed); 12/13/22 (11 Mohs cases performed); 12/27/22 (15 Mohs cases performed); and 01/10/23 (13 Mohs cases

	performed). 3. A total of 256 Mohs cases were performed on the dates indicated above. 4. The facility personnel interviewed on February 2, 2023 at 11:50am confirmed the laboratory failed to document the H&E stain acceptability on the testing dates indicated above for intended reactivity to ensure predictable staining characteristics. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of established quality assessment (QA) policies and procedures for review and interview with the facility personnel, the laboratory failed to establish QA policies and procedures to monitor, assess and correct errors found in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. The laboratory began reading and diagnosing patient specimens during the Mohs procedure in the sub-specialty of Histopathology on April 1, 2020, with a reported annual test volume of 360. 2. No QA documentation was presented for review during the survey to indicate the laboratory established policies and procedures to monitor, assess and correct issues found in the analytic systems specified in 493.1251 through 493.1283. 3. The laboratory failed to identify and correct errors associated with quality control performance, specifically the failure to perform and document Hematoxylin & Eosin (H&E) stain acceptability each day of patient testing. See D5473 for specific findings. 4. The facility personnel interviewed on February 2, 2023 at 12:05pm confirmed that the laboratory failed to establish QA policies and procedures to monitor, assess and correct errors identified in the analytic systems specified in 493.1251 through 493.1283.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) documentation, review of post-analytic QA policies, review of electronic test records and interview with the facility personnel, the laboratory failed to follow established policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings include: 1. The laboratory began Mohs testing in the sub-specialty of Histopathology on April 1, 2020, with an approximate annual test volume of 360. It is the practice of the laboratory to scan the Mohs map into the patient's Electronic Medical Record (EMR). 2. The laboratory's established policy reviewed during the survey titled, "Mohs Audit", states, "At the end of each Mohs, there will be an audit performed by the office manager. The office manager will be responsible for verifying the Mohs Map card, patient case number, Mohs

	technician log, pathology report and slides. This is to ensure that the information that is input on all these records is correct and true....Mohs Map cards need to be scanned in color and scanned into the patient chart after Mohs audit. If there are any discrepancies in any of the above named patient information, there will be corrective action taken by the office manager who is auditing the patient information". 3. During the survey, review of patients' Mohs maps maintained in the EMR revealed the laboratory failed to scan one out of four Mohs maps into the patient's EMR (case# B22-373 from 12/27/22), as indicated by laboratory policy. 4. No corrective action documentation was provided for review during the survey to indicate the laboratory identified the error referenced above and followed their established postanalytic QA policy and procedure indicated above to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. 5. The facility personnel interviewed on February 2, 2023 at 12:10pm confirmed that the laboratory failed to follow established QA policies and procedures, to monitor, assess and correct problems identified with the postanalytic systems and failed to ensure Mohs maps are scanned into the patient's EMR as indicated in laboratory policy.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) logs and interview with the facility personnel on February 2, 2023, the laboratory director failed to ensure that the QC program is maintained to assure the quality of laboratory services provided. Findings include: 1. The laboratory failed to perform and document control procedures on Mohs specimens from May 31, 2022 through January 10, 2023. See D5473 for specific findings. 2. The facility personnel interviewed on February 2, 2023 at 12:15pm confirmed that the laboratory director failed to ensure that the laboratory's established QC program was maintained to assure the quality of laboratory services provided. 3. The laboratory initially reported performing approximately 360 patient tests annually.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of quality assessment policies and procedures, the laboratory director

	failed to ensure that the quality assessment program is established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5291, D5791 and D5891 for findings.