Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0930898	09/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Thomas Dermatology	1801 Mesquite Ave, Lake Havasu 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 Frozen Biopsies and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the subspecialty of Histopathology at least twice annually during 2023. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of Frozen Biopsy testing at least twice annually during 2023. 2. The facility personnel interviewed on 9/26/24 at 11:45 AM confirmed the laboratory failed to verify the accuracy of Frozen Biopsy testing testing at least twice annually during 2023. 3. The laboratory's reported annual test volume for Frozen Biopsy interpretations is 84.
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 lack of temperature records for the room temperature and the cryostat from August 2022 through December 2023 and interview with the facility personnel, the laboratory failed to monitor and document the room temperature where dermatopathology reagents are utilized and stored and failed to monitor and document the temperature of the cryostat used in conjunction with Mohs and Frozen Biopsy testing. Findings include: 1. The laboratory processes specimens and interprets dermatopathology slides in conjunction with Mohs surgery and Frozen Biopsies, with an approximate annual test volume of 1,740. 2. No documentation of the room temperature was presented for review from August 2022 through December 2023, to indicate the laboratory monitored and documented the temperature of the room where dermatopathology reagents are utilized and stored each day of testing. 3. No documentation of the cryostat temperature was presented for review from August 2022 through December 2023, to indicate the laboratory monitored and documented the temperature of the cryostat used on each day of testing. 4. The facility personnel interviewed on 9/26/24 at 12:00 PM confirmed that the laboratory failed to monitor and document the cryostat temperature and the room temperature of the laboratory from August 2022 through December 2023.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of Mohs test reports and Frozen Biopsy test reports maintained in the Electronic Health Record (EHR) and interview with the facility personnel, one out of three Mohs test reports reviewed in the EHR failed to include the final test result and two out of two Frozen Biopsy test reports failed to include the gross description. Findings include: 1. One out of three Mohs test reports (MR# 34468 from 4/24/23) reviewed in the EHR during the survey failed to include the final test result. 2. Two out of two Frozen Biopsy test reports (MR# 53021 from 1/09/24 and #40982 from 4 /16/24) reviewed in the EHR failed to include the gross description. 3. The facility personnel interviewed on 9/26/24 at 11:35 AM confirmed the test reports indicated above failed to include the final test result for Mohs and failed to include the gross description, respectively. 4. The laboratory's reported annual test volume under the subspecialty of Histopathology is 1,740.