Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0930898	08/22/2022
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
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 lack of histopathology slides for review, review of pathology test report and interview with the facility personnel, the laboratory failed to retain histopathology slides for at least 10 years from the date of examination. Findings include: 1. The laboratory performs the microscopic interpretation of frozen biopsies, with an approximate annual test volume of 48. 2. The laboratory failed to produce evidence of the histopathology slide from the frozen biopsy performed on October 6, 2020 for MR# MM0000012573. 3. During the survey conducted on August 22, 2022 at approximately 10:40am, the facility personnel stated that the slide for the frozen biopsy indicated above could not be located.
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 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 and 2021. Findings include: 1. No documentation was presented for review during the survey conducted on August 22, 2022 to indicate the laboratory verified the accuracy of the microscopic interpretation (reading/diagnosis) of Mohs specimens at least twice annually during 2020 and 2021. 2. No documentation was presented for review during the survey conducted on August 22, 2022 to indicate the laboratory verified the accuracy of the microscopic interpretation (reading/diagnosis) of Frozen Biopsy specimens at least twice annually during 2020 and 2021. 3. The facility personnel interviewed on 8/22/22 at approximately 10:25am confirmed that the laboratory failed to verify the accuracy of the histopathology testing indicated above at least twice annually during 2020 and 2021. 4. The laboratory performs approximately 360 Mohs tests and 48 Frozen Biopsies annually.
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 review of quality assessment (QA) policies and interview with the facility personnel, the laboratory failed to monitor, assess and correct problems identified in the general laboratory systems. Findings include: 1. The laboratory performs testing under the sub-specialty of Histopathology, with an approximate annual test volume of 408. 2. The laboratory's established policy QA policy presented for review failed to include information to monitor, assess and when indicated, correct problems identified with the verification of accuracy process for Mohs and Frozen Biospy testing. See D5217 for specific findings. 3. No other QA documentation was presented for review during the survey to indicate the laboratory monitored the verification of accuracy process during 2020 and 2021. 4. The facility personnel confirmed that the laboratory's QA processes failed to monitor, assess and correct problems identified in the general laboratory systems, which include problems related to the performance of the verification of accuracy.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's microscope maintenance policy and interview with the facility personnel, the laboratory failed to document the annual preventative

	maintenance of the microscope used in patient testing under the sub-specialty of Histopathology. Findings include: 1. During the survey conducted on August 22, 2022, no documentation was presented for review from 2020 and 2021 to indicate the laboratory performed and documented annual preventative maintenance on the microscope used for reading patient slides. 2. The facility personnel acknowledged that there was no documentation of annual preventative maintenance from 2020 and 2021 for the microscope used by the laboratory to read patient slides under the sub-specialty of Histopathology
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 the laboratory's pathology test reports for Frozen Biopsy interpretations performed in 2020 and interview with the facility personnel, the laboratory failed to include the gross description on the test report reviewed during the survey. Findings include: 1. The laboratory performs Frozen Biopsy interpretations, including the gross description, under the sub-specialty of Histopathology, with an approximate annual test volume of 48. 2. During the survey conducted on August 22, 2022, one out of one pathology test reports reviewed [MR# MM000012573, from 10 /06/20] failed to include the gross description. 3. The gross description (including weighing, measuring, describing color, specific orientation for diagnostic interpretation, and other characteristics of the tissue) must be included on the pathology test report. 4. The facility personnel confirmed that the biopsy test report reviewed during the survey failed to include the gross description as described above.