

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0615137	(X3) Date Survey Completed 12/15/2023
Name of Provider or Supplier Advanced Cosmetic Surgery & Dermatology	Street Address, City, State 276 Kingsbury Grade Ste 101, Stateline, NV	
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
D0000	<p>This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on December 15, 2023. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.</p>
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a random patient audit of six Mohs patients tested between the dates of February 14, 2022 and October 31, 2023, a review of the laboratory's example of how to complete the Mohs map, and an interview with the office administrator, the laboratory failed to ensure that the Mohs maps were correctly completed in order to ensure positive identification of the patient specimens from the time of collection of the specimen through completion of the testing. Findings include: 1. A random patient audit of six Mohs patients tested between the dates of February 14, 2022 and October 31, 2023 found that the laboratory failed to ensure that the date of surgery was consistent between the Mohs tracking log, Mohs map, and slides. The date of surgery was recorded as October 31, 2023 on the Mohs tracking log, and October 30, 2023 on the slides and Mohs map for one of six patients (initials GT). 2. A random patient audit of six Mohs patients tested between the dates of February 14, 2022 and October 31, 2023 found that the laboratory failed to complete the Mohs map as indicated by the example included with the director approved policies and procedures. The Mohs</p>

	<p>maps for two of six patients (initials MM and PD) did not have the number of levels of tissue sections identified on the maps. 3. An interview with the office administrator at approximately 2:30 PM on December 15, 2023, confirmed these findings. The laboratory performs approximately 5,559 histopathology tests annually.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a random patient audit of six Mohs patients tested between the dates of February 14, 2022 and October 31, 2023, a review of the temperature logs for the refrigerator and cryostat, a review of the director approved policies and procedures, and an interview with the office administrator, the laboratory failed to ensure that refrigerator temperatures were recorded daily and the cryostat temperatures were recorded on Mohs surgery days. Findings include: 1. A review of the temperature logs for the refrigerator revealed that the temperatures were not recorded daily for nine of nine months, as required by the director approved procedure titled, "7C3 Lab QC Procedures: CLIA checks." 2. A random patient audit of six Mohs patients tested between the dates of February 14, 2022 and October 31, 2023, revealed that the temperatures were not recorded on the six days of Mohs surgery that were randomly reviewed. The cryostat temperature is to be recorded on days on MOHS [sic] days per the director approved procedure titled, "7C3 Lab QC Procedures: CLIA checks." 3. An interview with the office administrator on December 15, 2023, at approximately 3:00 PM confirmed these findings. The laboratory performs approximately 5,559 histopathology test annually.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and an interview with the office administrator, the laboratory failed to ensure that laboratory reagents were discarded by their expiration dates. Findings include: 1. During the on-site survey on December 15, 2023, it was observed that two containers of Eosin-Y Alcoholic reagent with expiration dates of 2-31-2023 [sic] and 11-30-2023 were available for use. 2. An interview with the office administrator on December 15, 2023 at approximately 3:00 PM confirmed these findings. The laboratory performs approximately 5,559 histopathology tests annually.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on observation, review of laboratory records, and interview with the practice manager, the office administrator failed to ensure that the quality assessment (QA) programs identified failures in quality as they occur. Findings include: 1. The QA program failed to identify that specimen identity was not maintained throughout the preanalytic, analytic and postanalytic phases of testing. A random patient audit of six Mohs patients tested between the dates of February 14, 2022 and October 31, 2023, found that the laboratory failed to ensure that the Mohs maps were correctly completed in order to ensure positive identification of three of six patient specimens from the time of collection of the specimen through completion of the testing. Refer to D5203 2. The QA program failed to identify that expired reagents were available for use. Eosin-Y Alcoholic reagent with expiration dates of 2-31-2023 [sic] and 11-30-2023 were found available for use. Refer to D5417 3. The QA program failed to identify that temperatures for the refrigerator and cryostat were not being recorded as indicated by the director approved procedure. A review of the temperature logs for the refrigerator and cryostat found that the laboratory failed to ensure that refrigerator temperatures were recorded daily and the cryostat temperatures were recorded on Mohs surgery days. Refer to D5413 4. These findings were confirmed by the office administrator during the on-site survey on December 15, 2023 at approximately 3:00 PM. The laboratory performs approximately 5,559 histopathology tests annually.