Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2199294	09/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lux Dermatology	1075 Roberta Ln Ste 102, Sparks, 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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on September 24, 2024. 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.
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 a review of the laboratory procedures, a random review of the biannual quality assessment reports from January 2023 through August 2024, and an interview with the office manager, the laboratory failed to follow the director approved policy to ensure positive patient identification and specimen integrity. Findings include: 1. A review of the director approved policy titled "Mohs Surgery Procedure," states that "Date, accession number, patient name, date of birth, site of tissue removal, total number of slides/levels processed, Mohs surgeon, and Mohs technician initials are written on the Mohs Surgery Patient Log." 2. A review of the Mohs Surgery Patient Log from May 16, 2024 through July 11, 2024 found that eight out of 13 date of birth were not documented. 3. A review of the Mohs Surgery Patient Log from May 16, 2024 through July 11, 2024 found that two out 13 initials for the Mohs technician were not documented. 4. A review of the director approved policy titled "Mohs Surgery Procedure," states that "Slides are labeled with the accession number, patient name and second patient identifier, stage and level, site/location, and date of surgery."

	5. A review of the slides included in the "Quality Assessment Checklist" from April 2023, patients with the accession numbers 23-20, 23-22, and 23-23, were only labeled with the stage. The laboratory failed to include the level per the laboratory's policy. 6. A review of the slides included in the "Quality Assessment Checklist" from January 2024 through June 2024, patients with the accession numbers 24-048 and 24-053, were only labeled with the stage. The laboratory failed to include the level per the laboratory's policy. 7. A review of the slides included in the "Quality Assessment Checklist" from April 2023, found that the patient with the accession number 23-19, had a date of birth recorded on the slide as 2/22/1965. The patient's correct date of birth is 4/19/1954. 8. An interview with the office manager confirmed these findings on September 24, 2024 at approximately 10:00 AM. The laboratory performs approximately 300 histopathology tests annually.
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 a review of laboratory records from January 2023 through August 2024 and an interview with the office manager, the laboratory failed to correctly document the temperature and humidity on Mohs surgery days. Findings include: 1. A review of the "Mohs Surgery Patient Log" indicated that Mohs surgery was performed on May 16, 2024. 2. A review of the "Room Temperature and Humidity Log," found that the laboratory failed to document the room temperature and humidity on May 16, 2024. 3. A review of the "Room Temperature and Humidity Log," found that the laboratory documented the room temperature and humidity on May 18, 2024 when no Mohs surgery was performed. 4. An interview with the office manager confirmed these findings on September 24, 2024 at approximately 10:00 AM. The laboratory performs 300 histopatholoy tests annually.
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 a review of laboratory records from January 2023 through August 2024 and an interview with the office manager, the laboratory failed to document reagent checks and quality controls (QC) for all dates of Mohs surgery. Findings include: 1. A review of the "Mohs Surgery Patient Log" indicated that Mohs surgery was performed

	on May 16, 2024. 2. A review of the "Mohs Quality Control Log," found that the laboratory failed to document the QC on May 16, 2024. 3. A review of the "Mohs Reagent Log," found that the laboratory failed to document the reagent check on May 16, 2024. 4. An interview with the office manager confirmed these findings on September 24, 2024 at approximately 10:00 AM. The laboratory performs 300 histopatholoy tests annually.