Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2199294	06/22/2021
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 initial certification survey conducted at your facility on 6/22/2021. 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.
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 Cryostat Temperature and Maintenance Procedure and Log and interview with the Regional Director, the laboratory failed to document the cryostat temperature each day of use as required by the procedure. Findings include: 1. A review of the Cryostat Temperature and Maintenance Procedure and Log from March to June 2021 revealed that the laboratory did not record the cryostat temperatures for the days Mohs procedures were performed in the laboratory on 3/19 /2021 and 4/24/2021. 2. A cryostat temperature record was dated for 3/18/2021 and no temperature was recorded for 4/21/2021. 3. The Regional Director confirmed the finding during the on-site survey on 6/22/2021 at approximately 10:30 AM. The laboratory performs approximately 300 histopathology tests annually.

D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's Mohs Quality Control Log and interview with the Regional Director, the laboratory failed to document the quality control results. Findings include: 1. A review of the Mohs Quality Control Log from March to June 2021 revealed that the laboratory failed to document the hematoxylin and eosin (H&E) stain results on the two days Mohs surgeries were performed, on 3/19/2021 and 4/24/2021. The columns to indicate "Pass/Fail" were left blank on the quality control log sheet. 2. The Regional Director confirmed the finding during the on-site survey on 6/22/2021 at approximately 10:45 AM. The laboratory performs approximately 300 histopathology tests annually.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES 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 review of the laboratory's temperature, maintenance, and quality control logs and interview with the Regional Director, the laboratory director failed to ensure that the quality assessment program was maintained to ensure the quality of the laboratory services. Findings include: 1. Review of the laboratory's Cryostat Temperature and Maintenance Procedure and Log and Mohs Quality Control Log from March to June 2021 revealed that temperature, maintenance and H&E stain records were not documented each day that Mohs surgeries were performed on 3/19 /2021 and 4/24/2021. 2. The laboratory director signed off on the log sheets on 12/14 /2020 and there was no indication of further review of the log sheets by the laboratory director. 3. The Regional Director confirmed the findings during the on-site survey on 6/22/2021 at approximately 10:45 AM. The laboratory performs approximately 300 histopathology tests annually.