

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2199294	(X3) Date Survey Completed 01/10/2023
Name of Provider or Supplier Lux Dermatology	Street Address, City, State 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 1/10/2023. 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.
D5417	<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 review of the Reagent Log, observation, and an interview with the laboratory manager, the laboratory failed to document the reagent check for the hematoxylin and eosin stains each day of patient testing. Findings include: 1. Review of the Reagent Log revealed that there was no documentation of the reagent lot numbers and expiration dates for the hematoxylin and eosin stains during 2021 and 2022. 2. No hematoxylin or eosin stains were available in the lab to verify expiration dates. 3. The laboratory manager indicated the Mohs technician brought the stains when they were on site and verified that the reagent lot numbers and expiration dates were to be recorded each day of Mohs procedures in an interview on 1/10/2021 at approximately 11:45 PM. The laboratory performs approximately 300 histopathology tests per year.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p>

(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 review of the patient testing records, Staining Reagent Procedure and Log, and an interview with the laboratory manager, the laboratory failed to document the reagent check for the hematoxylin and eosin stains each day of patient testing.

Findings include: 1. Review of patient testing records revealed that Mohs procedures were performed on 3/18/2021, 4/24/2021, 7/2/2021, 9/17/2021, 10/15/2021, and 12/22/2021. 2. Review of the Staining Reagent Procedure and Log revealed that there was no documentation of the quality control for the hematoxylin and eosin stains on 7/2/2021, 9/17/2021, and 10/15/2021. 3. The laboratory manager confirmed these findings in an interview on 1/10/2021 at approximately 11:45 PM. The laboratory performs approximately 300 histopathology tests per year.