

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D1011156	(X3) Date Survey Completed 12/19/2024
Name of Provider or Supplier Las Vegas Skin & Cancer Clinics-Summerlin	Street Address, City, State 653 N Town Center Dr Ste 214, Las Vegas, 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 19, 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.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a random patient audit between the dates of October 14, 2023 and December</p>

9, 2024, a review of the laboratory policy and procedure manual, and an interview with the Director of Regulatory Compliance, the laboratory failed to ensure that the available procedure manual included a procedure for the performance and documentation of the Hematoxylin and Eosin (H&E) Stain quality control for Mohs testing. Findings include: 1. A random patient audit between the dates of October 14, 2023 and December 9, 2024 revealed that there was no documentation of the H&E stain quality available for the dates of November 26, 2024 and December 18, 2024. 2. A review of the laboratory procedure manual revealed that there was no director approved procedure for the documentation of the H&E stain quality for Mohs testing. 3. The Director of Regulatory Compliance confirmed the findings during an interview conducted on December 19, 2024 at approximately 10:00 AM. The laboratory performs approximately 100 Histopathology 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 random patient audit between the dates of October 14, 2023 and December 9, 2024 and an interview with the Director of Regulatory Compliance, the laboratory failed to ensure that the Hematoxylin and Eosin (H&E) Stain quality control for Mohs testing was read and documented each day of use. Findings include: 1. A random patient audit between the dates of October 14, 2023 and December 9, 2024 revealed that there was no documentation of the H&E stain quality control available for the dates of November 26, 2024 and December 18, 2024. 2. The Director of Regulatory Compliance confirmed the findings during an interview conducted on December 19, 2024 at approximately 10:00 AM. The laboratory performs approximately 100 Histopathology tests annually.

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 a random patient audit between the dates of October 14, 2023 and December 9, 2024 and an interview with the Director of Regulatory Compliance, the laboratory failed to ensure that the correct address of the laboratory was included on the final Mohs operative report for the date of November 26, 2024. Findings include: 1. A

random patient audit between the dates of October 14, 2023 and December 9, 2024 revealed that the the correct address of the laboratory was not on the final operative report for case number SU-WH24-004. 2. The address found on the final operative report was 630 South Rancho Drive, Suite E., Las Vegas, NV 89106-4873. 3. The finding was confirmed during an interview with the Director of Regulatory Compliance on December 19, 2024 at approximately 11:00 AM. The laboratory performs approximately 100 Histopathology tests annually.