

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D1020539	(X3) Date Survey Completed 03/14/2024
Name of Provider or Supplier Leavitt Medical Associates Of Nevada	Street Address, City, State 861 Coronado Center Dr Ste 100, Henderson, 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 March 14, 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>
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 November 21, 2022 and February 12, 2024 and an interview with laboratory personnel, the laboratory failed to maintain positive identification of two of six patient specimens from the time of collection through completion of testing and reporting of results. Findings include: 1. A random patient audit of six Mohs patients tested between the dates of November 21, 2022 and February 12, 2024 revealed that specimen identification information was not consistent from collection of the specimen through the final reporting of results. 2. A review of patient records for case number KH23-112, tested on March 20, 2023 revealed that the number of stages or layers of Mohs surgery was not consistent on the Mohs log, Mohs slides, Mohs map and the final operative report. The Mohs log and the Mohs slides indicated that there were four stages or layers. The Mohs map and the final operative report indicated that there were three stages or layers. 3. A review of patient records for case number KH24-071, tested on February 12, 2024 revealed that the site of Mohs surgery was not</p>

consistent on the Mohs log, Mohs slides, Mohs map and the final operative report. The Mohs log and the Mohs slides indicated that the site of the Mohs surgery was the left distal wrist. The Mohs map and the final operative report indicated that the site of the Mohs surgery was the left dorsal wrist. 4. The finding was confirmed during an interview with the lead medical assistant on March 14, 2024 at approximately 11:00 AM. The laboratory performs approximately 500 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 the laboratory maintenance and temperature logs between the dates of September, 2022 and March of 2024, and an interview with the lead medical assistant on March 14, 2024 at approximately 11:15 AM, the laboratory failed to ensure that the cryostat temperatures were documented on days of Mohs surgery between the months of January 2023 and December 2023. Findings include: 1. There was no documentation of the cryostat temperatures on the days of Mohs surgery between the months of January 2023 and December 2023. 2. The finding was confirmed during an interview with the lead medical assistant on March 14, 2024 at approximately 11:15 AM. The laboratory performs approximately 500 histopathology tests annually.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of the log entitled "High Complexity Laboratory Operations Checklist", a review of the Mohs specimen logs for the months of January through March, 2024, a review of the laboratory maintenance and temperature logs for 2023, and an interview with the lead medical assistant conducted on March 14, 2023, at approximately 10:00 AM, the laboratory failed to ensure that the daily and weekly quality assessment activities designated on the High Complexity laboratory Operations Checklist on each day of Mohs surgery was documented between January 2024 and March 2024, and the laboratory failed to detect and correct the failure to document cryostat temperatures during calendar year 2023. Findings include: 1. A review of the Mohs specimen log and a review of the log entitled "High Complexity Laboratory Operations Checklist", which was implemented in January 2024, revealed

that the daily items to be completed were not documented on each day of Mohs surgery during the months of January, February and March 2024. A. A review of the Mohs specimen log for January 2024 revealed that the laboratory performed Mohs surgery on 1/8/24, 1/15/24, 1/22/24, and 1/29/24. The "High Complexity Laboratory Operations Checklist" was completed for the daily and weekly activities on 1/22/24 only. B. A review of the Mohs specimen log for February 2024 revealed that the laboratory performed Mohs surgery on 2/5/24, 2/12/24, 2/19/24, and 2/26/24. The "High Complexity Laboratory Operations Checklist" was completed for the daily and weekly activities on 2/26/24 only. C. A review of the Mohs specimen log for March 2024 revealed that the laboratory performed Mohs surgery on 3/4/24, and 3/11/24. The "High Complexity Laboratory Operations Checklist" was completed for the daily and weekly activities on 3/11/24 only. D. The findings were confirmed during an interview with the lead medical assistant on March 14, 2023 at approximately 10:00 AM. 2. A review of the 2023 maintenance and temperature logs revealed that the laboratory failed to detect and correct the failure to document temperatures for the cryostat between the months of January 2023 and December 2023. (refer to D5413) The laboratory performs approximately 500 histopathology tests annually.