Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D1020539	(X3) Date Survey Completed 08/15/2022
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	This Statement of Deficiencies was created as a result of an on-site initial CLIA certification survey conducted at your facility on August 15, 2022. 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.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a random patient audit between the dates of September 17, 2020 and June 27, 2022, and an interview with the location manager and back office lead, the laboratory failed to retain patient test records. Findings include: 1. A random patient audit of six patients between the dates of September 17, 2020 and June 27, 2022 revealed that the patient record did not include the Mohs Map for the patient identified by the number 2267748, who had Mohs surgery on November 22, 2021. 2. The findings were confirmed during an interview with the location manager and the back office lead conducted on August 15, 2022 at approximately 12:00 PM. The laboratory performs approximately 500 histopathology tests annually.
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 random patient audit between the dates of September 17, 2020 and June 27, 2022, a review of the Mohs Quality Assurance Manual, and an interview with the location manager and the back office lead, the laboratory failed to follow the director approved policy and procedure to ensure positive identification of the patient specimens from collection through completion of testing and reporting of results. Findings include: 1. A random patient audit revealed that the laboratory failed to follow the director approved policy and procedure for the assignment of case numbers for the Mohs surgery for six of six patients reviewed who had Mohs surgery between the dates of September 17, 2020 and June 27, 2022. The format for the case numbers assigned was the last two digits of the year, followed by a dash and numbered consecutively for each year. 2. The director approved policy and procedure entitled, "Mohs Quality Assurance Manual" stated, "The case number will consist of the Mohs surgeons (sic) first initial of their last name, the first initial of the office location, the last number of the year, a hyphen and then starting with the number one continue in numerical order." 3. A random patient audit of six patients who had Mohs surgery between the dates of September 17, 2020 and June 27, 2022 revealed that the laboratory failed to ensure that the Mohs records for the patient tested on September 17, 2020, identified by the number 4913563, were consistent on the Mohs log, the Mohs map and the final operative report. The Mohs log indicated that the surgery consisted of two stages. The Mohs map and the final operative report indicated that the surgery consisted of one stage. 4. The findings were confirmed during an interview conducted with the location manager and the back office lead on August 15, 2022 at approximately 10:30 AM. The laboratory performs approximately 500 histopathology tests annually.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the director approved policy and procedure entitled, "Proficiency Testing Mohs Histopathology", a review of the laboratory records for the twice per year verification of accuracy, and an interview with the location manager and the back office lead, the laboratory failed to ensure that twice per year verification of accuracy was completed for 2020, 2021, and the first half of 2022, in accordance with the director approved policy and procedure. Findings include: 1. The director approved policy and procedure entitled, "Proficiency Testing Mohs Histopathology" stated, "Proficiency testing will be performed bi-annually. It is to be sent out and returned by the end of June and Dec. (sic) The Mohs Surgeon is subjected to a peer review. Ten (10) cases every 6 months, regardless of how many labs they are the Lab Directors (sic) of or visit. Cases will be selected at random for review that include Stages 2-4 or greater." 2. A review of the laboratory records revealed that for 2020,

	four cases were reviewed in June, 2020 for twice per year verification of accuracy for one dermatologist performing Mohs surgery during that year. 3. There were no records of twice per year verification of accuracy for one dermatologist performing Mohs during 2021. 4. There were no records of twice per year verification of accuracy for two dermatologists performing Mohs during the first half of 2022. 5. The findings were confirmed during an interview with the location manager and back office lead conducted on August 15, 2022 at approximately 10:15 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 records for the temperature monitoring and maintenance records for the cryostat, and an interview with the location manager and back office lead, the laboratory failed to ensure that records of the cryostat temperatures, daily and annual maintenance were maintained. Findings include: 1. There were no records for the cryostat temperature monitoring and daily maintenance for the cryostat used for the processing of Mohs specimens for 2021. 2. There were no records of annual preventative maintenance for the cryostat used for the processing of Mohs specimens for 2020 and 2021. 3. The findings were confirmed during an interview with the location manager and the back office lead conducted on August 15, 2022 at approximately 11:45 AM The laboratory performs approximately 500 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 an audit of patient final test reports and email correspondence with the location manager on August 16, 2022, the laboratory failed to indicate on the final patient test report the name of the laboratory in which the patient testing was performed. Findings include: 1. The laboratory failed to have the name of the laboratory, Leavitt Medical Associates of Nevada, on the patient final test report. 2.

	The patient final test report revealed "Advanced Dermatology and Cosmetic Surgery" as the name of the laboratory where the histopathology testing was performed. 3. This was confirmed by email correspondence received on August 17, 2022 1:05 PM at approximately from the location manager. The laboratory performs approximately 500 histopathology procedures 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 a review of the director approved policy and procedure entitled "Mohs Quality Assurance Manual", and an interview with the location manager and the back office lead, the director failed to ensure that the established quality assessment policy was maintained to assure the quality of laboratory services and to detect failures in quality when they occurred. Findings include: 1. There were no records for quality assessment available at the time of survey for 2020, 2021 and the first half of 2022. 2. The director approved policy and procedure entitled, "Mohs Quality Assurance Manual", in the section entitled, "Post-Analytical" stated, "The Mohs Op-report /Flowsheet will contain the unique case number, number of states and number of pieces for each stage. the QA process will check that this is done for all cases. On a quarterly basis, the Histotechnician or Director of Laboratory Operations will review ten (10) percent of cases done during the previous quarter. This process will include pulling the patient charts, the Mohs log, and slides. They will be checked to make sure that the op-report, map, Mohs log and slides are accurate. If there are any discrepancies, it will be noted on the Quarterly QA form and corrective action will be taken to prevent this from happening again." 3. The findings were confirmed during an interview with the location manager and the back office lead conducted on August 15, 2022 at approximately 10:45 AM. The laboratory performs approximately 500 histopathology tests annually.