Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2154953	08/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Skin Cancer & Dermatology Institute-Sparks	4814 Sparks Blvd, 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 August 27, 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.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of the laboratory refrigerator and freezer logs from March 2024 through July 2024, observation of the refrigerators used for reagent storage and an interview with the Clinical Research Manager, the laboratory failed to correctly indicate that two refrigerators were utilized by the laboratory so that the devices could be used according to the manufacturer's instructions. Findings include: 1. A review of the laboratory refrigerator and freezer logs from March 2024 through July 2024 found that the log contained a "refrig" column and a "freezer" column. Both columns had documented temperature recordings on the log. The temperatures documented in the freezer column were outside of the acceptable temperature range for a freezer. 2. Observation of the reagent storage area on August 27, 2024, found that there were two mini-refrigerators stacked on each other and available for use. 3. In an interview at approximately 10:00 AM, on August 27, 2024, one of the laboratory personnel indicated that the upper refrigerator was recorded in the "freezer" column and was used for laboratory supplies, including stains for histopathology. The lower

	refrigerator (with temperatures recorded in the "refrig" column) was used for pharmaceuticals. 4. The manufacturer did not indicate that either mini-refrigerator could be used as a freezer. The documented acceptable temperature range for the freezer was 5 degrees Fahrenheit or 15 degrees Celsius or colder. The mini-refrigerator for laboratory supplies was unable to reach these temperatures. The recorded temperature range was between approximately 28 and 40 degrees Fahrenheit. 5. An interview with the Clinical Research Manager on August 27, 2024, at approximately 10:30 AM confirmed these findings. The laboratory performs approximately 1,000 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 random review of six Moh's patient files and the associated laboratory logs from April 2023 through July 2024, a review of the temperature logs for the reagent storage refrigerator, and an interview with the Clinical Research Manager found the laboratory failed to define acceptable room temperatures for the Mohs laboratory from May 2024 through July 2024 and failed to define consistent acceptable temperature ranges for the freezer. Findings include: 1. A random review of six Moh's patient files and the associated laboratory logs from April 2023 through July 2024 found that there was no acceptable room temperature documented on the "Mohs Lab Daily/Weekly Maintenance" logs from May 2024 through July 2024, making it impossible to determine if the room temperatures were acceptable for testing. 2. A review of the laboratory refrigerator and freezer logs from March 2024 through July 2024 found that the acceptable temperature ranges were inconsistent between Fahrenheit and Celsius for the freezer. The acceptable range in Fahrenheit was "less than 5 degrees." The range is Celsius was "less than 15 degrees". Five degrees Fahrenheit is equivalent to -15 degrees Celsius. 3. An interview with the Clinical Research Manager on August 27, 2024, at approximately 10:30 AM confirmed these findings. The laboratory performs approximately 1,000 histopathology tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on observation of the testing supplies available during a walk-through of the facility on August 27, 2024, at approximately 11:00 AM, and an interview with the Clinical Research Manager, the laboratory failed to ensure that testing supplies

	available for use were not expired. Findings include: 1. During a walk-through of the facility on August 27, 2024 at approximately 11:00 AM, it was observed that the bottle of potassium hydroxide (KOH) available for testing (lot number: 2131) had expired on May 11, 2024. 2. An interview with the Clinical Research Manager on August 27, 2024, at approximately 11:00 AM confirmed these findings. The laboratory performs approximately 25 mycology tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a random review of six Moh's patient files and the associated laboratory logs from April 2023 through July 2024, and an interview with the Clinical Research Manager, the laboratory failed to document monthly maintenance for the cryostat as defined by the manufacturer. Findings include: 1. A random review of six Moh's patient files and the associated laboratory logs from April 2023 through July 2024, found the laboratory failed to document defrosting and cleaning the cryostat during the month of April 2023 on the "Mohs Lab Daily/Weekly Maintenance" logs. 2. The manufacturer's instructions for the cryostat indicate that the cryostat should be defrosted and cleaned at least once per month if the machine receives less than daily use. 3. A review of the April 2023 "Mohs Lab Daily/Weekly Maintenance" logs found that Mohs testing had been performed on 12 out of 20 business days. 4. An interview with the Clinical Research Manager on August 27, 2024, at approximately 11:00 AM confirmed these findings. The laboratory performs approximately 1,000 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 review of six Moh's patient files and the associated laboratory logs from April 2023 through July 2024, and an interview with the Clinical Research Manager, the laboratory failed to document quality controls for the Mohs slides on April 14, 2023. Findings include: 1. A random review of six Moh's patient files and the associated laboratory logs from April 2023 through July 2024, found the laboratory failed to document quality controls for the Mohs slides on the "Q.C. MOHS H&E Quality Documentation Chart" for April 14, 2023. 2. A review of the accession logs found that testing for a patient with the Mohs case number MS23-265 had been performed on April 14, 2023. 3. An interview with the Clinical Research Manager on August 27, 2024, at approximately 11:00 AM confirmed these findings. The laboratory performs approximately 1,000 histopathology tests annually.

D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of the temperature logs for the reagent storage refrigerator, room temperature logs for the KOH testing area, and an interview with the Clinical Research Manager found the laboratory failed to document corrective action when temperatures were out of range. Findings include: 1. A review of the laboratory's reagent storage refrigerator logs from March 2024 through July 2024 found that the refrigerator temperature was out of range for five of 17 recorded dates in July 2024. No corrective action was documented. 2. The laboratory reagent refrigerator temperatures were out of range for one of 20 recorded dates in May 2024. No corrective action was documented. 3. The laboratory failed to record the laboratory reagent refrigerator temperature for five of 21 working days in April of 2024. No corrective action was documented. 4. The laboratory failed to record the refrigerator temperature for two of 22 working days in May of 2024. No corrective action was documented. 5. A review of the room temperature logs for the KOH testing area found that the room temperature was out of range 41 out of 119 recorded dates between January 2023 and June 2023. No corrective action was documented. 6. A review of the room temperature logs for the KOH testing area found that the room temperature was out of range 40 out of 124 recorded dates between July 2023 and December 2023. No corrective action was documented. 7. A review of the room temperature logs for the KOH testing area found that the room temperature was out of range 21 out of 128 recorded dates between January 2024 and June 2024. No corrective action was documented. 8. A review of the room temperature logs for the KOH testing area found that the room temperature was out of range seven out of 36 recorded dates between July 1, 2024 and August 27, 2024. No corrective action was documented. 9. An interview with the Clinical Research Manager on August 27, 2024, at approximately 11:00 AM confirmed these findings. The laboratory performs approximately 1,000 histopathology and 25 mycology tests annually.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a random review of six Moh's patient files and the associated laboratory logs from April 2023 through July 2024, a review of the temperature logs for the reagent storage refrigerator, room temperature logs for the KOH testing area, and an interview with the Clinical Research Manager, the laboratory failed to establish and follow their Quality Assurance (QA) policy. Findings include: 1. There was no documented review of the "Q.C. MOHS H&E Quality Documentation Chart" for April 2023. The director approved control chart included a place to indicate that the data had been

	reviewed. The laboratory failed to detect the missing Hemotoxylin and Eosinophil stain (H&E) controls on April 14, 2023. (Refer to D5473) 2. The laboratory failed to establish a QA plan to review the reagent storage refrigerator temperature logs. Six out of range temperatures were undetected between April 2024 and July 2024. (Refer to D5785) 3. The laboratory failed to establish a QA plan to review the reagent storage refrigerator temperature logs. The failure of the laboratory to record refrigerator temperatures for seven dates between April 2024 and July 2024 was undetected. (Refer to D5785) 4. The laboratory failed to establish a QA plan to review the room temperature logs for the KOH testing area. There were 109 undetected out of range room temperatures between January 2023 and August 2024. (Refer to D5785) 5. An interview with the Clinical Research Manager on August 27, 2024, at approximately 11:00 AM confirmed these findings. The laboratory performs approximately 1,000 histopathology and 25 mycology tests annually.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the roster provided on the CMS-209 form, a review of the annual competency assessments, and an interview with the Clinical Research Manager, the technical supervisor failed to ensure that Testing Personnel number three (TP3) on the CMS-209 had documented annual competency assessments. Findings include: 1. A review of the competency assessments for the testing personnel listed on the CMS-209 form found that there were no annual competency assessments documented between September 2022 and August 2024 for TP3. 2. In an interview on August 27, 2024, at approximately 10:00 AM, the Clinical Research Manager indicated that TP3 performs KOH testing. The Clinical Research Manager also confirmed that there were no competency assessments available for TP3. The laboratory performs approximately 25 mycology tests annually.