Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D1035055	09/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Skin Cancer Surgery Center	6370 Sw Borland Rd Ste 200, Tualatin, OR	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of testing personnel (two TP) verification of accuracy presented during survey for my review for the years 2022, 2023 and 2024 year to date, the laboratory failed to perform twice annual verification of accuracy. Findings include: 1. Upon review of the written records for both TP # 1 and TP # 2, the following was revealed: 2024 TP # 1 1 event CTA Laboratories TP # 2 1 event In House by LD 2023 TP # 1 1 event CTA Laboratories TP # 2 1 event CTA Laboratories 2022 TP # 1 2 events CTA Laboratories TP # 2 0 events 2. Interview with the Office Manager and Mohs Tech #1 at 2:00 pm, confirmed that the documents I reviewed during survey, were all of the peer review / verification of accuracy documents since the last survey conducted 10/25/2022. 3. The laboratory reports performing 2000 mohs dermatopathological procedures annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's Mohs procedure manual, the laboratory failed to

	have a current Laboratory Director (LD) approved policy/ procedure regarding the bi-annual verification assessment of accuracy for dermatopathological slides created and stained during Mohs surgery at this site. Findings include: 1. Upon review of the policies and procedure manual for Mohs surgery, there was no Laboratory Director (LD) approved procedure for bi-annual verification of accuracy (Peer Review or slide sharing for Mohs slides created and interpreted on site). 2. Further review of the Mohs procedure manual revealed two (2) brief one (1) page descriptions for performing verification of accuracy, one (1) bi-annually and one (1) quarterly, but were also not approved or dated by the LD. 3. Neither of the two (2) un-approved briefs for performing verification of accuracy had been followed by the lab for 2022, 2023 and 2024 year to date. See below. 4. Brief #1 indicated sending 2 - 3 slides to another Dermatopathologist bi-annually, but did not indicate how the slides would be selected, to whom they would be sent or how they would be documented when returned. 5. Brief #2, titled Quality Assurance (QA) Protocol (IN - HOUSE) indicates "every 3 months"(quarterly) two (2) - three (3) random slides from each provider that were done in the last three (3) months" are given to the other provider at this location. The person selecting the slides is directed to "put a sticky note" indicating which slides have what current diagnosis, thus not making them random "blind samples". The reviewing provider then reviews the other providers slides and signs off. This procedure has not been approved or dated by the LD. There are only two (2) reviews for years 2022, 2023, 2024 year to date for TP # 2. One (1) performed in 2023 by Curtis Thompson Associates (CTA) and one (1) performed on 09/04/2024 in house by LD. 6. There was no approved procedure for Mohs surgery and the process involved from beginning to end, including patient preparation, tissue collection, orientation and mapping of the tissue sample(s), and slide staining procedure. 7. Interview with the Office Manager and Mohs Tech # 1 confirmed that there were no other LD approved Mohs procedures or records for QA or Peer Review / slide sharing for Mohs slides created on site in 2022, 2023 or 2024 year to date. 8. The laboratory reports performing 2000 Mohs surgeries annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the current procedure manual presented during survey and interview with the Office Manager and Mohs Tech # 1, the laboratory failed to ensure an approved and current Policy / Procedure manual was available for all testing personnel (TP). Findings include: 1. See D5291
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 review of the Clinic's three (3) Advantiks Cryo-stat maintenance records and interview with Mohs Tech # 1, the laboratory failed to ensure an approved temperature range for the three (3) Cryo-stats used for Mohs surgery were established and recorded every day the three (3) Advantik's Cryo-stats were in use for patient testing. Findings include: 1. Upon review of the laboratory's Opening Morning Routine, posted in the laboratory work area near the sink, states that the Cryo-stat should be turned on and brought to temperature at -31 degrees Celcius (C) upon opening the lab in the morning. 2. The written log for recording the Cryo-Stat temperature(s) each day showed no temperature range for the Cryo-stats. 3. The written temperature recordings for May, June and July 2024 showed temps ranging from -21 degrees Celcius (C) to -32 degrees Celcius (C). The number of days outside of the -31 degree C temperature range are as follows: Cryostat #A May/June 2024 13 /27 days were out of the -31 degree C range Cryostat #A July 2024 12/18 days were out of the -31 degree C range Cryostat #B May/June 2024 20/27 days were out of the -31 degree C range Cryostat #B July 2024 9/14 days were out of the -31 degree C range Cryostat #C May/June 2024 12/27 days were out of the -31 degree C range Cryostat #C July 2024 9/23 days were out of the -31 degree C range 4. The total number of days with Cryo-stat temperature recordings for all three (3) Advantik's Cryo-stats for May, June and July 2024 = 136 days. The total number of days the Cryo-stats were out of temperature range (-31 degrees Celcius) for May, June, July 2024 = 75 days or 55% of the time temperatures were recorded during these months. No corrective action (CA) could be demonstrated for any of the days with recordings other than -31 degrees Celcius. 5. Interview with Mohs Tech #1 at 1:45 pm revealed that she did not know what the temperature range was "for sure". She estimated it to be -28 degrees to -34 degrees Celcius. When asked if there was an approved temperature range for the three (3) Advantiks Cryo-stat's on site, she could not confirm this. 6. Interview with the Office Manager at 1:50 pm confirmed that there was no Laboratory Director approved temperature range for the three (3) Advantiks Cryo-stats on site. 7. The laboratory reports performing 2000 Mohs surgical procedures annually.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of a random Mohs patient report selected by the Office Manager while on site,dated 08/22/2024 and interview with the Office Manager and Mohs Tech #1, the laboratory failed to ensure that a Quality Assessment (QA) review of post analytical test results was in place to detect and correct errors in patient records. Findings include: 1. Upon request for a random Mohs surgical patient report during survey, this surveyor was asked if I also wished to review the dermatopathology report for this patient as well. I replied "yes". 2. Upon review of the two (2) printed documents presented for my review, it was noted that the diagnosis for the Mohs pathology report and the separate Dermatopathology report had two (2) different diagnoses. 3. The electronic medical record (EMR) for Mohs surgical patients used in

	this facility is EMA. The EMA report lists the Frozen Section diagnosis as Nodular Basal Cell Carcinoma - LEFT ALA, dated August 22, 2024. The microscopic diagnosis on the same report 2 lines below the above diagnosis is reported as "normal skin". 4. Review of the second report, titled "Dermatopathology Report" for the same patient, on the same day, from the same surgical site lists the diagnosis as "normal skin". 5. Interview with the Office Manager and Mohs Tech # 1 at 2:30 pm revealed that neither of them could explain this discrepancy in diagnosis. 6. Email received from the Laboratory Director (LD) regarding this discrepancy on 09/16/2024 confirmed that this was incorrect and that it is a "documentation workflow issue". 7. The laboratory reports performing 2000 dermatopathology Mohs surgeries annually.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's Policy and Procedure manual submitted for review during survey and interview with the Office Manager and Mohs Tech #1, the Laboratory Director (LD) failed to ensure a current and approved procedure manual was available for all testing personnel (TP) performing laboratory testing at this site. Findings include: 1. Upon review of the policy and procedure manuals presented for review while on site survey was being conducted 09/10/2024, no evidence of LD approval and date of approval could be found for any of the procedures contained therein. 2. Interview with the Office Manager and Mohs Tech #1 at 2:00 pm confirmed that there was no written evidence of LD approval for the manual. 3. The laboratory reports performing 2000 Mohs surgery procedures annually.