Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2098524	03/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Skin Cancer And Dermatology Center, The	5199 N Royal Drive, Traverse City, MI	

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 record review and interview with the Laboratory Liaison (LL) and the Office Manager (OM), the laboratory failed to verify the accuracy of its microscopic tissue examination testing at least twice annually for 2 (March 2020 to March 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's verification of accuracy documentation revealed the following: a. 2020 - no cases sent out twice annually b. 2022 - no cases sent out for 1 of 2 twice annually 2. An interview on 3/21 /2022 at 10:05 am, the LL and OM confirmed the twice annual verification of accuracy testing for its microscopic tissue examinations was not performed and documented.
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 record review and interview with the Laboratory Liaison (LL) and Office Manager (OM), the laboratory failed to follow quality assurance policies for 2 (March 2020 to March 2022) of 2 years reviewed. Findings include: 1. A review of the

	laboratory's established "Quality Assurance" program, the laboratory failed to complete the "Monthly Patient Quality Assurance Checklist" for 2 (March 2020 to March 2022) of 2 years reviewed. 2. A record review revealed a "CLIA Lab Modification/Correction" dated March 1, 2022 stated "Begin to implement monthly patient quality assurance review." 3. An interview on 3/21/2022 at 10:07 am, the LL and OM confirmed the laboratory had not followed the monthly quality assurance program.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Liaison (LL) and Office Manager (OM), the laboratory failed to have test requests for frozen section biopsies from an authorized person for 2 (M20-573 and FB21-005) of 10 patient test requests reviewed. Findings include: 1. A review of patient test requests revealed a lack of an order in the patients electronic medical record (EMR) from an authorized person for the following frozen section biopsies: a. M20-573 performed on 11/05/2020 b. FB21-0005 performed on 12/21/2022 2. An interview on 3/21/2022 at 10:55 am, the LL and OM confirmed there was no test request in the EMR for the 2 patients listed above.
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 record review and interview with the Laboratory Liaison (LL) and the Office Manager (OM), the laboratory failed to ensure the Hematoxylin and Eosin (H&E) stain case number was recorded, performed, and documented each day of patient testing for 2 (March 2020 to March 2022) of 2 years reviewed. Findings include: 1. A review of the "Quality Assurance" section on the bottom of the "Laboratory Control Staining" log states, "The first case submitted to the mohs lab which consists of normal tissue will be stained for H&E, documented on the control sheet as the QA. This slide will be kept in the file with the case." 2. A review of the laboratory's "Laboratory Control Staining" log for the H&E stain quality revealed for 2 of 2 years reviewed the following days the case number which the quality of the stain was performed on was not recorded on the log as follows: a. 11/4/2021 b. 12/7-9 /2021 c. 12/13-14/2021 3. A chart audit revealed for 2 of 2 years the H&E stain was not recorded on the "Quality Control Staining" log for the following Mohs' and frozen section cases: Mohs" a. 1/18/2021 - M21-032 b. 5/25/2021 - M21-265 c. 7/12/2021 - M21-365 d. 9/01/2021 - M21-512 Frozen Sections a. 2/22/2021 - M21-117 b. 8/18

	/2021 - M21-457 c. 10/28/2021 - M21-669 4. An interview on 3/21/2021 at 9:46 am, the LL and OM confirmed there was no documentation on the stain log of the stain case number, stain quality performed, and documented each day of patient testing
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 record review and interview with the Laboratory Liaison (LL) and Office Manager (OM), the laboratory failed to document corrective action for improper temperature of the histopathology cryostat instrument for 19 days (January to March 2021) of 2 years of documents reviewed. Findings include: 1. A record review of the "Cryostat" temperature logs revealed for 19 days in 2021 of 2 years of documents reviewed the cryostat was below the stated range of -21 degree C to -30 degrees C and no corrective action was documented as follows: 2021 a. February 25 and March 1 cryostat temperature was -17 degree C b. March 2 cryostat temperature was -17.6 degree C c. February 4 and 22-23 cryostat temperature was -18 degree C d. February 1, 8-9, 11, 15-16, 18, March 8-9 cryostat temperature was -19 degree C e. January 28 and March 4, and 15-16 cryostat temperature was -20 degree C 2. A record review of the "Cryostat" log at the bottom of the page states "The cryostats should be maintained at -21*C to -30*C for best mohs sectioning. Any variance out of range will be recorded and reported to the supervisor, immediately. If the range variance cannot be repaired, the console will not be used until serviced." 3. A interview on 3/21 /2022 at 9:35 am, the LL and OM confirmed that no corrective action was documented for the cryostat temperatures out of the stated range.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Mohs' . Based on document review and interview with the Laboratory Liaison (LL) and Office Manager (OM), the laboratory failed to establish a system to ensure the transcribed Mohs' surgery site were accurately reported in the laboratory information system (LIS) for 4 of 14 Mohs' cases reviewed. Findings include: 1. Record review revealed for 4 of 14 Mohs' cases reviewed, the Mohs' surgical site on the pre-op biopsy report, the Mohs' map, the Mohs' log did not match the location on the final report in the LIS system as follows: a. M20-177 performed on 5/04/2020 i. pre-op biopsy report and Mohs' map - nasal dorsum ii. Mohs' log and LIS report - nasal

	supratip b. M21-512 performed on 9/01/2021 i. pre-op biopsy report - right medial forehead ii. Mohs' map - right forehead iii. Mohs' log and LIS report - right superior central forehead c. M21-694 performed on 11/04/2021 i. pre-op biopsy report and Mohs' map - right superior temple (superior marked through and mid recorded on Mohs' map) ii. Mohs' log and LIS report - right mid temple d. M22-161 performed on 3/03/2022 i. pre-op biopsy report and Mohs' map - left nasal sidewall ii. Mohs' log and LIS report - left nasal ala 2. An interview on 3/21/2022 at 10:55 am, the LL and OM confirmed the locations on the pre-op biopsy report, Mohs' map, Mohs' log and the final LIS report were not consistent with the tumor site. Frozen Section . Based on record review and interview with the Laboratory Liaison (LL and the Office Manager (OM), the laboratory failed to establish a system to ensure the frozen section log was complete and/or the typed final report filed in the notebook or scanned into the laboratory information system (LIS) for 2 (March 2020 to March 2022) of 2 years reviewed. Findings include: 1. Record review revealed for 6 of 10 frozen section cases reviewed, the Mohs' log was complete and/or the typed final report filed in the designated notebook as follows: a. M20-306 performed on 7/27/2020 i. no typed final report in the notebook or scanned into LIS b. M20 -450 performed on 9/28/2020 i. documentation not recorded on Mohs' log ii. no typed final report in the notebook or scanned into LIS c. M20-573 performed on 11/05/2020 i. documentation not recorded on Mohs' log ii. no typed final report in the notebook or scanned into LIS d. M21-117 performed on 2/022/2021 i. no typed final report in the notebook or scanned into LIS e. M21-285 performed on 5/07/2021 i. no typed final report in the notebook or scanned into LIS f. FB21-005 performed on 12/21/2021 i. no typed final report in the notebook (ended up performing Mohs' procedure) or scanned into LIS 2. When queried on 3/21/2022 at 10:55 am, the LL and OM were not able to provide the survey the documents requested. 3. An interview on 3/21/2022 at 10:55 am, the LL and OM confirmed the Mohs' log was not completely filled out for the case, the final typed report was not in the notebook, and there was no final report scanned into the LIS. ***Repeat Deficiency from the 11/14/2019 survey***