

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2098524	(X3) Date Survey Completed 08/28/2023
Name of Provider or Supplier Skin Cancer And Dermatology Center, The	Street Address, City, State 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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD) and the Mohs' Technician (MT), the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to follow its procedure for proficiency testing. Refer to D5401 B.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: A. Based on record review and interview with the Mohs' Technician (MT), the laboratory failed to follow its procedure for the "CLIA Regulations / Manual" for 17 (March 2022 to August 2023) of 17 months the manual was in use. Findings include: 1. A record review of the "Mohs' Procedure Manual" revealed the manual was signed</p>

on 11/11/2019. 2. A review of the "CLIA Regulations / Manual" procedure states "The manual must be reviewed / updated annually. The Laboratory Director must document any reviews / updates." 3. A record review revealed for 17 (March 2022 to August 2023) of 17 months the "Mohs' Procedure Manual" was in use a lack of documentation of the annual review by the Laboratory Director. 4. An interview on 8/28/2023 at 11:25 am, the MT confirmed the 'Mohs Procedure Manual" was not reviewed annually for 17 months. B. Based on observation, record review, and interview with the Laboratory Director (LD), the laboratory failed to follow its procedure for proficiency testing for 2 (M22-460 and M23-169) of 6 cases reviewed. Finding include: 1. The surveyor observed the laboratory was performing proficiency testing every 6 months by sending out 2 cases to be reviewed by an outside "Board Certified Dermatopathologist." 2. A record review of the proficiency testing cases revealed for 2 (M22-460 and M23-169) of the 6 cases, the returned diagnosis by the referring physician showed "positive for tumor" while the in-house showed negative. 3. A review of the Proficiency Testing "Mohs Micrographic Surgery Skin Specimen" procedure states "Upon receipt of the pathology report from the Dermatopathologist, diagnosis of the slide specimen will be matched to the in-house diagnosis by the physician. If the diagnoses match, the reports are attached and placed in the "Proficiency Testing" located in the quality control manual. In the event the pathology report from the Dermatopathologist does NOT match the in-house diagnosis by the physician, an identical slide will be sent, by the tech or risk manager to another outside laboratory chose from the list below, for microscopic examination." 4. An interview on 8/28/2023 at 1:58 pm, the LD confirmed the 2 cases were not sent out for further review by another Dermatopathologist and that the list to choose from was blank.

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 and interview with the Mohs' Technician (MT), the laboratory failed to ensure tissue marking dyes used in histopathology testing did not exceed their expiration dates for 3 (Tissue Marking Dyes - red, violet, and orange) of 7 tissue marking dyes observed. Findings include: 1. The surveyor observed 7 tissue marking dyes in the laboratory in use on 8/28/2023 at 10:25 am and the following had exceeded their expiration date: a. Tissue Marking Dye red lot #122213 expiration date 5/31/2023. b. Tissue Marking Dye violet lot #122226 expiration date 5/31/2023. c. Tissue Marking Dye orange lot #095946 expiration date 3/31/2022. 2. An interview on 8/28/2023 at 10:25 am, the MT confirmed the tissue marking dyes listed above had exceeded their expiration dates.

D5800

POSTANALYTIC SYSTEMS
CFR(s): 493.1290

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall

quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

. The laboratory failed to meet applicable postanalytic system requirements. Findings include: 1. The laboratory failed to establish a system to ensure the transcribed Mohs' surgery site was accurately transcribed from the Pathology report onto the Mohs' log, Moh's map, and the visit note. Refer to D5801.

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:

. Based on record review and interview with the Mohs' Technician (MT), the laboratory failed to establish a system to ensure the transcribed Mohs' surgery site was accurately transcribed from the Pathology report onto the Mohs' log, Moh's map, and the visit note for 5 (M22-215, M22-394, M22-613, M22-724, M22-927) of 8 Mohs' cases reviewed. Findings include: 1. A record review revealed for 5 of 8 Mohs' cases reviewed, the anatomical site transcribed from the Pathology Report onto the Mohs' log, Mohs' map, and/or visit note was not transcribed accurately as follows: a. M22-215 performed on 4/04/2022. i. Pathology report - left inferior posterior helix. ii. Mohs' log, Mohs' map, and visit note - left superior helix. b. M22-394 performed on 6/16/2022. i. Pathology report - right cheek ii. Mohs' log, Mohs' map, and visit note - right superior preauricular cheek. c. M22-613 performed on 8/30/2022. i. Pathology report, Mohs' log, and Mohs' map- right cheek ii. Visit note - right superior lateral buccal cheek. d. M22-724 performed on 10/06/2022. i. Pathology report - presternalis region upper ii. Mohs' log - presternalis upper iii. Mohs' map - location changed to left medial superior chest. iv. Visit note - only noted left medial superior chest. e. M22-927 performed on 12/12/2022. i. Pathology report, Mohs' log, and Mohs' map - scalp ii. Visit note - right superior parietal scalp 2. A review of the "Mohs Surgery Documentation Policy & Procedure" signed by the Laboratory Director on 4/12/2022 states: " 1. Mohs surgery site locations(s) shall match in all of the following: a. Pre-op Biopsy Report b. Mohs Map c. Mohs Log d. Final Report in EMR 2. Once Dr. Leithauser examines the patient, and if she determines that the pre-op biopsy location is not accurate, she will write the original location (from the pre-op biopsy report) on the Mohs Map and cross it off with a single line. The correct location will be added next to the incorrect, crossed off location. 3. All other reporting, including the Mohs' Log and the Final EMR Report, will match in location. 4. All staff is to ensure all locations are correct and this will also be confirmed by the Clinical Manager and Dr. Leithauser upon report finalization." 2. An interview on 8/28/2023 at 12:51 pm, the MT confirmed the above incorrectly transcribed anatomical sites just prior to and post the new procedure being signed by the Laboratory Director.