Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2256333	10/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Concierge Dermatology & Skin Surgery Center	101 W Washington Street Suite 105, Marquette, 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
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 record review and interview with the Mohs Technician (MT), the laboratory failed to ensure positive patient identification throughout the testing process for 3 (#11,12, 15) of 15 patient test records reviewed. Findings include: 1. A record review of the laboratory patient log, patient test reports (3) and patient slides revealed misidentification as follows: a. Patient 11 with a date of service of 10/01 /2024 was identified on the patient log as #241. Review of the patient's medical record revealed the patient's Mohs Map and specimen slide identified the patient as #141. b. Patient 12 with a date of service of 10/01/2024 was identified on the patient log as #240. Review of the patient's medical record revealed the patient's Mohs Map and specimen slide identified the patient as #140. c. Patient 15 with date of service of 10 /08/2024. 2. An interview conducted on 10/23/2024 at 11:24 am with the Mohs Technician confirmed the patients listed above were incorrectly identified.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the mohs technician, the laboratory failed to establish a competency assessment policy for two (October 2022 to October 2024) of two years reviewed. Findings include: 1. A review of the laboratory's policies and procedures revealed a lack of competency assessment policy. 2. An interview on 10/23 /24 at 11:18 am with the mohs technician confirmed the laboratory had not established a competency assessment policy.
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 mohs technician, the laboratory failed to verify the accuracy of its gross specimen and microscopic tissue examination testing for one (2023) of two years reviewed. Findings include: 1. A review of the laboratory's "Mohs Quality Assurance" twice annual verification of accuracy testing reports revealed a lack of documentation of verification of accuracy testing performed in 2023. 2. An interview on 10/23/24 at 11:18 am with the mohs technician confirmed documentation of twice annual verification of accuracy was not available for 2023.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the mohs technician, the laboratory failed to perform thermometer calibration checks for its cryostat at least monthly for 10 (January 2023, February 2023, March 2023, May 2023, June 2023, July 2023, August 2023, September 2023, October 2023, December 2023, and January 2024) of 24 months reviewed. Findings include: 1. A review of the laboratory's "Quality Assurance Program" revealed a section titled, "Equipment Quality Control for Cryostats" stating, "Temperature calibration check is done monthly and recorded." 2. A review of the laboratory's "Maintenance Record for Cryostats" revealed a lack of temperature calibration checks for the following months: a. January 2023 b. February 2023 c. March 2023 d. May 2023 e. June 2023 f. July 2023 g. August 2023 h. September 2023 i. October 2023 j. December 2023 k. January 2024 3. An interview on 10/23/24 at 11:18 am with the mohs technician confirmed the laboratory had not performed and documented temperature calibration checks for its cryostat for the months listed above.
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 record review and interview with the Mohs Technician (MT), the laboratory failed to ensure test reports contained the name of the laboratory for 10 (1-10) of 10 patients reviewed. Findings include: 1. A review of 10 patient test reports revealed the following patients had the name "Lilly Dermatology" listed on the test report: a. Patient 1: 03/08/2023 b. Patient 2: 05/04/2023 c. Patient 3: 07/18/2023 d. Patient 4: 09/28/2023 e. Patient 5: 11/29/2023 f. Patient 6: 01/17/2024 g. Patient 7: 03 /19/2024 h. Patient 8: 05/14/2024 i. Patient 9: 08/12/2024 j. Patient 10: 10/01/2024 2. An interview conducted on 10/23/2024 at 11:25 am with Mohs Technician confirmed the laboratory did not include the laboratory's name listed on test reports. ***This is a repeated deficiency from the deficiency from the 2/6/23 initial certification survey. ***