

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2256333	<b>(X3) Date Survey Completed</b>  02/06/2023
<b>Name of Provider or Supplier</b>  Concierge Dermatology & Skin Surgery Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:                      . Based on observation, record review, and interview with the Mohs Technician, the laboratory failed to perform annual maintenance for its microscope and cryostat according to its policy for 8 (June 2022 to February 2023) of 9 months reviewed. Findings include: 1. A review of the laboratory's "Quality Assurance Program" revealed a section titled "Equipment Quality Control for Microscopes" stating, "Grounding check is monitored and recorded yearly" and a section titled "Equipment Quality Control for Cryostats" stating, "Preventive maintenance and grounding check is done yearly." 2. The surveyor observed the laboratory's equipment on 2/6/23 at 12:56 pm revealed the following had stickers indicating service was due in June 2022: a. Avantik QS12 Cryostat b. Olympus BX45 Microscope 3. An interview on 2/6/23 at 1:01 pm with the Mohs Technician confirmed maintenance for the microscope and cryostat had not been performed according to the laboratory's policy.</p>
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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</p>

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, the laboratory failed to include the name of the laboratory on its test reports for 7 (Patients 22-18, 22-79, 22-140, 22-186, 22-200, 23-9 and 23-43) of 7 patient test reports reviewed.

Findings include: 1. A review of 7 patient test reports revealed the following patients had the name "Lilly Dermatology" listed on the test report: a. Patients 22-18 b. Patient 22-79 c. Patient 22-140 d. Patient 22-186 e. Patient 22-200 f. Patient 23-9 g. Patient 23-43 2. An interview on 2/6/23 at 2:02 pm with the Mohs Technician confirmed the laboratory had the incorrect name listed on the laboratory's test reports.