

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2141314	(X3) Date Survey Completed 12/05/2023
Name of Provider or Supplier Wolverine Dermatology	Street Address, City, State 1673 Gezon Parkway Sw, Wyoming, 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
D3043	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: . Based on record review, lack of slides, and interview with Testing Personnel (TP) #5, the laboratory failed to retain its histopathology slides for at least 10 years for 1 (#4) of 9 Mohs' cases reviewed. Findings include: 1. A review for 1 (#4 performed on 12/19/2022) of 9 Mohs' cases reviewed, the surveyor requested the slides for the case, and they were not made available. 2. When queried on 12/04/2023 at 3:30 pm, TP5 was unable to find the slides for the case requested and the lab was continuing to try to locate. 3. An interview on 12/04/2023 at 3:30 pm, TP5 confirmed the laboratory had not retained the histopathology slides for case #4 listed above.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on lack of documentation and interview with Testing Personnel (TP) #5, the laboratory failed to perform and document the function checks for the Moh's surgery as required for the room temperature in the laboratory for 2 (8/09/2022 and 10/25/2022) of 9 dates reviewed. Findings include: 1. A record review revealed a lack of documentation of the room temperature for 2 (8/09/2022 and 10/25/2022) of 9 dates the laboratory processed Mohs' micrographic tissue specimens. 2. When queried on 12/04/2023 at 3:30 pm TP5 was not able to provide the surveyor the documentation to show the room temperature had been performed and documented. 3. An interview on 12/04/2023 at 3:30 pm, TP5 confirmed the laboratory failed to perform and document the room temperature function check.

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 Testing Personnel (TP) #5, the laboratory failed to document the daily function checks for the cryostats and the microscope cleaning on the maintenance log for 2 (8/09/2022 and 10/25/2022) of 9 dates reviewed. Findings include: 1. A record review of the "Cryostat Maintenance Log" and the "Microscope Log" revealed for 2 of 9 days reviewed, the daily cleaning of the instruments was not performed and documented as follows: a. cryostat #1 b. cryostat #2 c. microscope 2. An interview on 12/04/2023 at 3:30 pm TP5 confirmed the daily cleaning for the 3 instruments listed above was not performed and documented.

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 Testing Personnel (TP) #5, the laboratory failed to perform and document the Hematoxylin and Eosin (H&E) stain quality each day of testing for 2 (9/26/2023 and 10/04/2023) of 9 dates reviewed. Findings include: 1. A review of the "Mohs Quality Control Log" revealed a lack of documentation for the H&E stain quality for 2 (9/26/2023 and 10/04/2023) of 9 dates reviewed. 2. The surveyor requested documentation of the stain quality for the dates listed above and it was not made available. 3. An interview on 12/04/2023 at 3:30 pm, TP5 confirmed the H&E stain quality was not performed and documented on the dates listed above.