

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2141314	(X3) Date Survey Completed 08/31/2020
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to verify the accuracy of Mohs tissue examinations for 1 (July 2019 to July 2020) of 1 year reviewed. Findings include: 1. A record review of the laboratory's Mohs patient testing log revealed the laboratory started testing patients for Mohs tissue examinations 7/30/19. 2. A review of the laboratory's records revealed a lack of verification of accuracy documentation from July 2019 to July 2020. 3. An interview on 8/31/20 at 9:25 am with the Office Manager confirmed the laboratory did not perform verification of accuracy procedures for Mohs tissue examination testing.</p>
D5313	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to document the time it received Mohs tissue specimens for 5 (Patients #4-#8) of 5 patients reviewed. Findings include: 1. A review of patient testing records revealed a lack of documentation of the time the laboratory received specimens for the following patients with testing performed: a. Patient #4 on 7/31/19 b. Patient #5 on 11/19/19 c.</p>

Patient #6 on 2/2/20 d. Patient #7 on 5/26/20 e. Patient #8 on 8/4/20 2. An interview on 8/31/20 at 9:37 am with the Office Manager confirmed the laboratory had not been documenting the time specimens were received.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on record review and interview with the Office Manager, the laboratory to failed to ensure 2 (Testing Personnel #1 and #2) of 2 testing personnel performing Mohs tissue specimen gross examinations met the high complexity testing personnel qualification requirements. Refer to D6171.

D6171

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling,

handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

. Based on record review and interviews, the laboratory failed to ensure personnel performing gross examinations of Mohs tissue specimens were qualified for 2 (Testing Personnel #1 and #2) of 2 testing personnel. Findings include: 1. An interview on 8/31/20 at 8:12 am with Testing Personnel #1 revealed Testing Personnel #1 and Testing Personnel #2 performed Mohs tissue specimen gross examinations. 2. A record review of the laboratory's personnel records revealed a lack of qualification documentation for both Testing Personnel #1 and Testing Personnel #2. 3. A request by the surveyor for the qualification documents was made on 8/31/20 at 8:40 am and the documents were not made available. 4. An interview on 8/31/20 at 8:40 am with the Office Manager confirmed Testing Personnel #1 and Testing Personnel #2 did not meet the qualification criteria for high complexity testing personnel.