Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2232198	09/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Adrian Dermasurgery Center	1136 Country Club Rd Suite C, Adrian, 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
D0000	A recertification survey was performed on September 5, 2025 by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following condition-level deficiency: 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: . Based on observation and interviews with testing personnel #2 and #3, the laboratory failed to ensure proper preservation of histopathology tissue slides for three (Patients #1, #4, and #6) of 10 patient cases reviewed. Findings include: 1. The surveyor observed the slides showing excessive air bubbles over the tissue sections and increased staining precipitate for the following histopathology patient cases: a. Patient #1 had mohs surgery performed on 8/15/25. b. Patient #4 had mohs surgery performed on 11/15/24. c. Patient #6 had mohs surgery performed on 10/14/24. 2. An interview on 9/5/25 at 10:52 am with testing personnel #2 and #3 confirmed the slides for the patient cases listed above included excessive air bubbles, leading to improper preservation of tissue.
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 testing personnel #3, the laboratory failed to follow competency assessment policies for two (testing personnel #1 and #3) of three testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's "Competency Assessment" policy revealed a section stating, "To assess the competency of each person to perform his/her assigned duties following training, but before the person performs patient testing. thereafter, competency will be assessed during the first year (for a new employee) at least semiannually. Once an employee has performed their duties for one year, competency will be assessed annually." 2. A review of personnel competency assessment records revealed a lack of competency assessment records for testing personnel #1 and #3. 3. An interview on 9/5/25 at 10:59 am with testing personnel #3 confirmed competency assessment records for the personnel listed above were not available.
D5787	TEST RECORDS CFR(s): 493.1283(a) (a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #2, the laboratory failed to document the time specimens were received into the laboratory for seven (Patients #1-7) of nine patient test records reviewed. Findings include: 1. A review of nine mohs surgery tissue maps revealed a lack of documentation of the time histopathology tissue specimens were received into the laboratory for the following patients: a. Patient #1 had mohs surgery on 08/15/2025. b. Patient #2 had mohs surgery on 06/27 /2025. c. Patient #3 had mohs surgery on 06/13/2025 d. Patient #4 had mohs surgery on 11/15/2024. e. Patient #5 had mohs surgery on 11/08/2024. f. Patient #6 had mohs surgery on 10/14/2024. g. Patient #7 had mohs surgery on 07/08/2024. 2. An interview on 9/5/25 at 10:32 am with testing personnel #2 confirmed the patients receiving mohs surgery histopathology testing listed above did not have the time specimens were received in the laboratory documented.
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by:

	. Based on a lack of documentation and interview with testing personnel #2, the laboratory director failed to be onsite at least once every six months between January 2025 and September 2025. Findings include: 1. A review of the laboratory's records revealed a lack of documentation supporting the laboratory director had been present between January 2025 and September 2025. 2. An interview on 9/5/25 at 11:06 am with testing personnel #1 revealed that since the laboratory hired a different mohs surgeon in July 2024, the laboratory director had not been present at the laboratory.
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 observation, record review, and a lack of documentation, the laboratory failed to ensure personnel performing high complexity histopathology specimen grossing were qualified. 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 (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (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. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: . Based on observation, record review, and a lack of documentation, the laboratory failed to ensure personnel performing high complexity histopathology specimen grossing were qualified for one (testing personnel #2) of three testing personnel listed on Form CMS-209. Findings include: 1. The surveyor observed testing personnel #3 drop off an uninked histopathology tissue specimen in the laboratory on 9/5/25 at 9:02 am prior to leaving the laboratory area. 2. An interview on 9/5/25 at 9:02 am with testing personnel #2 revealed that since the new mohs surgeon started in July 2024, testing personnel #2 had been performing specimen inking. 3. A review of testing personnel #2's qualification records revealed an "Associate of Science General Science Concentration", which did not meet the requirements for a degree in a laboratory science or medical laboratory technology. 4. The surveyor requested testing personnel #2's transcripts and either documentation of completion of a clinical laboratory training program or documentation of at least three months of training in histopathology prior to the performance of patient testing on 9/5/25 at 9:13 am and the record were not made available. 5. The laboratory was granted seven days after the survey to provide the missing documents, and none were received.