

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2212260	<b>(X3) Date Survey Completed</b>  03/16/2026
<b>Name of Provider or Supplier</b>  Art Of Dermatology, The	<b>Street Address, City, State</b>  43650 Garfield Rd, Clinton Township, 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>D0000</b>	<p>. An intial survey was performed on March 16, 2026, 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.</p>
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory owner (LO), the laboratory failed to establish verification of performance for histopathology microscopic tissue examinations prior to reporting patient test results for 8 (August 2025 through March 2026) of 8 months reviewed. Findings include: 1. Record review of 8 patient test reports revealed that verification of performance had not been conducted prior to reporting patient test results for the following patients: a. Patient 1 with a testing date of 08/16/2025 b. Patient 2 with a testing date of 09/24/2025 c. Patient 3 with a testing date of 10/01/2025 d. Patient 4 with a testing date of 11/05/2025 e. Patient 5 with a testing date of 12/03/2025 f. Patient 6 with a testing date of 01/07/2026 g. Patient 7 with a testing date of 02/11/2026 h. Patient 8 with a testing date of 02/26/2026 2. On 03/16/2026 at 10:30 am the surveyor requested documentation of verification of performance for histopathology microscopic tissue examinations; however, no</p>

documentation was provided. 3. On 03/16/2026 at 10:35 am, interview with the laboratory owner (LO) confirmed that verification of performance had not been established prior to reporting patient test results.

**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 laboratory owner (LO), the laboratory failed to ensure that 1 (TP2) of 2 testing personnel (TP) listed on the CMS-209 form met the educational requirements prior to performing high complexity testing. 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) (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 record review and interview with the laboratory owner (LO), the laboratory failed to ensure that 1 (TP2) of 2 testing personnel (TP) listed on the CMS-209 form met the educational requirements prior to performing high complexity testing.

Findings include: 1. Record review of the CMS-209 form revealed that TP2 was listed as personnel performing histopathology tissue examination; review of the laboratory's test menu revealed that histopathology microscopic tissue examination was categorized as high complexity testing. 2. Review of TP2's qualifications revealed a Bachelor of Arts degree in Computer Science from a foreign institution; however, the laboratory failed to provide documentation of foreign degree equivalency. Review also revealed an Associate degree in General Studies that did not demonstrate compliance with the educational requirements at 42 CFR 493.1489. 3. On 03/16/2026 at 11:25 am, the surveyor requested additional documentation to support that TP2 met the educational requirements to perform high complexity testing; however, no additional documentation was provided. 4. On 03/16/2026 at 11:30 am, interview with the LO confirmed that TP2 had been performing grossing, inking, cutting, and orienting of specimens since August 2025.