

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2264181	(X3) Date Survey Completed 02/12/2026
Name of Provider or Supplier Mymichigan Health Medical Center Dermatologic	Street Address, City, State 4201 Campus Ridge Drive, Midland, 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 February 12, 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.
D3013	<p>FACILITIES CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with the senior manager, the laboratory failed to maintain histopathology tissue slides to ensure proper preservation for four (patients 7, 8, 9, and 10) of ten cases reviewed. Findings include: 1. A review of ten histopathology cases performed between 2/13/24 and 12/16/25 showed four cases with significant bubbling between the tissue and the coverslip on slides from the following patients: a. Patient #7 had testing performed on 05/06/2025. b. Patient #8 had testing performed on 07/15/2025. c. Patient #9 had testing performed on 10/14/2025. This patient had one slide with most of one section of tissue uncovered by the coverslip. d. Patient #10 had testing performed on 12/16/2025. 2. An interview on 2/12/26 at 11:38 am with the senior manager confirmed the presence of bubbles on patient histopathology slides listed above.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection.</p>

(a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

This STANDARD is not met as evidenced by:

. Based on record review, observation, and interviews, the laboratory failed to follow its specimen slides labeling policy for four (patients 7, 8, 9, and 10) of ten cases reviewed. Findings include: 1. A review of the the laboratory's "Labeling of Frozen Section Slides" policy revealed a section stating, "Slides are labeled either immediately before or after frozen sections are cut. Information to be written with a slide marking pen (or printed with label maker) on the frosted end of the slide must be obtained from the photo that was delivered with the tissues or the digital photo in the electronic medical record. It is acceptable to first use a marking pen to label slides, then apply the label at the end of the day. At minimum, the following must be included: a. Line 1- Surgery Accession (Case) # b. Line 2- Patient name c. Line 3- Stage # (Roman Numeral)/ Piece # (Number)/ section number (letter) i. A second or third slide on the same piece of tissue is noted with lower case letters (a, b, c etc.) next to the tissue piece # ii. Any other information needed (such as "tumor" or "check" or biopsy" or "CDM" (cut down middle)) can be noted in the free space in the middle of the frosted area." 2. An interview on 2/10/26 at 9:14 am with testing personnel #2 revealed the laboratory puts the printed stickers on the specimen slides at the end of each testing day when testing has concluded. 3. A review of 10 cases revealed slides with the stickers over the frosted section of the slide with marker underneath. The manual labeling lacked the patient's name and was not labeled in accordance with the policy above during the testing process for the following patients: a. Patient #7 had testing performed on 05/06/2025. b. Patient #8 had testing performed on 07/15/2025. c. Patient #9 had testing performed on 10/14/2025. d. Patient #10 had testing performed on 12/16/2025. 4. An interview on 2/12/26 at 10:21 am with the senior manager confirmed the above findings.

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 director, the laboratory failed to ensure testing personnel performing high complexity histopathology testing met education 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 (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 record review and interview with the laboratory director, the laboratory failed to ensure testing personnel performing high complexity histopathology testing met education requirements for three (testing personnel #2, #5, and #6) of six testing personnel listed on Form CMS-209. Findings include: 1. An interview on 2/10/26 at 9:13 am with testing personnel #2 and #3 revealed they both perform specimen inking, which is considered high complexity testing.. 2. A review of the laboratory's personnel records revealed the following testing personnel listed on Form CMS-209 as performing high complexity testing did not meet the minimum educational requirements: a. Testing personnel #2 started employment in April 2024. Training documentation indicated they were "satisfactory" and "is able to read and understand the map orientation and dye the tissue to properly correlate with the map." An associate of applied science degree and transcript was provided and lacked the minimum number of chemistry credits and combined biology, chemistry, and clinical laboratory science credits. b. Testing personnel #5 started employment in January 2025 and stopped in April 2025. Training documentation stated "observed/shows confidence/competence" for "Tissue inking and orientation" on 1/29/25. An email from a high school noting the graduation date was present. A transcript was provided in a word document with formatting issues including cut off pages, blank pages, and overlapping text. c. Testing personnel #6 had training documentation indicating they were "confident/competent" for "Tissue inking and orientation" on 4/28/25. A transcript was provided and lacked the minimum number of chemistry credits and combined biology, chemistry, and clinical laboratory science credits. 3. The surveyor

requested additional education documentation for the testing personnel listed above on 2/12/26 at 12:26 pm. 4. An interview on 2/10/26 at 1:24 pm with the laboratory director confirmed testing personnel #2, #5, and #6 had been performing specimen inking.