

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2181522	(X3) Date Survey Completed 03/04/2025
Name of Provider or Supplier Mi Health Clinic	Street Address, City, State 4707 Mcleod Drive East, Saginaw, 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	<p>A validation survey was performed on March 4, 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 93, effective April 24, 2003) for the following condition-level deficiencies: 493.1250 Condition: Analytic systems. 493.1409 Condition: Laboratories performing moderate complexity technical consultant. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.</p>
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: . Based on direct observation and interviews, the laboratory failed to operate as a separate laboratory to comply with 493.55 for two (March 2023 to March 2025) of two years reviewed. Findings include: 1. The surveyor observed the laboratory testing area at Laboratory A included equipment and supplies to capture digital images of histopathology and cytopathology patient slides on 3/4/25 at 9:16 am. 2. An interview on 3/4/25 at 9:30 am with technical consultant #2 revealed Laboratory A performed histopathology grossing and slide preparation and cytopathology slide preparation. Some slides or digital images are read at Laboratory A, while most are digitally imaged, and those images are sent to Laboratory B (23D2243041) along with some physical slides to be read. Laboratory B does not have histopathology or cytopathology subspecialties on their certificate. 3. An interview on 3/4/25 at 3:13 pm with the laboratory director confirmed the slide and digital image reading is performed at both locations but indicated on the test report to have been reported under Laboratory A. .</p>

<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to follow its urinalysis test procedure (refer to D5401) and failed to perform and document immunohistochemical (IHC) stain positive and negative reactivity each time of use (refer to D5475).</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with technical consultant #2, the laboratory failed to follow its urinalysis test procedure for four (Patients 1, 2, 3, and 5) of five patient urinalysis test reports reviewed. Findings include: 1. A review of the laboratory's "Routine Urinalysis" test procedure revealed a section stating, "Specimens may be kept for up to 24 hours if refrigerated at 4 degrees C." 2. A review of the patient urinalysis test reports showed patients had testing performed and reports beyond the specimen stability requirements: a. Patient #1 collected 12/19/24 at 5:11 pm and testing was performed on 12/23/24 at 12:15 pm. b. Patient #2 collected 9/26/24 at 8:43 am and testing was performed on 9/27/24 at 9:20 am. c. Patient #3 collected 1/24/24 at 2:32 pm and testing was performed on 1/25/24 at 3:30 pm. d. Patient #5 collected 5/21/24 at 4:37 pm and testing was performed on 5/23/24 at 4:02 pm. 3. An interview on 3/4/25 at 2:35 pm with technical consultant #2 confirmed the patient testing listed above was performed beyond specimen stability.</p>
<p>D5475</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g)</p> <p>(e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory director, the laboratory failed to perform and document immunohistochemical (IHC) stain positive and negative reactivity each time of use for three (Patients 9, 10, and 11) of three patients with IHC stains reviewed. Findings include: 1. A review of patients with IHC staining</p>

results on their test reports revealed a lack of documented positive and negative reactivity of stains with each use for the following: a. Patient #9 with the test report date of 6/5/24 for a shave biopsy of the torso back using the MART-1 IHC stain. b. Patient #10 with the test report date of 11/11/24 for a left superior lateral malar cheek shave biopsy with KI67 IHC stain. c. Patient #11 with the test report date of 3/10/24 for a bladder biopsy with p53 and Ki67 IHC stains. 2. An interview on 3/4/25 at 3:13 pm with the laboratory director confirmed the positive and negativity of IHC stains had not been documented each time of use.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

. Based on record review and a lack of documentation, the laboratory failed to have a qualified technical consultant to oversee its moderate complexity urinalysis testing. Refer to D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) 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; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for

which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

. Based on record review, the laboratory failed to have a qualified technical consultant to oversee its moderate complexity urinalysis testing for one (technical consultant #2) of two technical consultants listed on Form CMS-209. Findings include: 1. A review of the technical consultant #2's qualification records revealed a Bachelor of Science in Medical Laboratory Science and no evidence of least two years of training or experience or both in nonwaived urinalysis testing. 2. The surveyor requested the additional training or experience documentation for technical consultant #2 on 3/4/25 at 11:19 am and it was not made available. 3. The laboratory was granted an additional seven days to provide missing documentation, and it was not 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, the laboratory failed to ensure testing personnel performing histopathology 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 record review, the laboratory failed to ensure testing personnel performing histopathology grossing were qualified for one (testing personnel #3) of four testing personnel listed on Form CMS-209. Findings include: 1. A review of the testing personnel #3's records revealed a total of 24 total hours of science courses with 12 credits of biology, 11 credits of chemistry, and one credit of medical technology. There was a lack of either clinical laboratory training program completion or at least three months documented training in histopathology prior to performing patient testing. 2. The surveyor requested the additional clinical laboratory training program completion or at least three months documented training in histopathology prior to performing patient testing on 3/4/25 at 12:45 pm and it was not made available. 3. The laboratory was granted an additional seven days to provide missing documentation, and it was not received.