Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0381904	03/26/2026
Name of Provider or Supplier	**Street Address, City, State**	
Mymichigan Medical Center- Sault	500 Osborn Blvd, Sault Sainte Marie, 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 March 23, 2026 to March 26, 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: 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to test its clinical microscopy fern testing samples the same manner as it would test a patient for four (2024 CM-A and CM-B, 2025 CM-A and CM-B) of four proficiency testing events reviewed. Findings include: 1. A review of the laboratory's College of American Pathologists' proficiency testing records revealed the laboratory participated in the clinical microscopy (CM) events for fern testing for the following events in 2024 and 2025: a. CM-A 2024 b. CM-B 2024 c. CM-A 2025 d. CM-B 2025 2. An interview on 3/26/26 at 8:13 am with general supervisor #2 confirmed only obstetric providers are performing fern testing. 3. A review of the laboratory's provider-performed microscopy binder showed the laboratory created forms with the images from the proficiency testing events. The providers filled out these forms and dated their

	responses. 4. An interview on 3/25/26 at 10:55 am with general supervisor #2 revealed the laboratory creates these forms with the pictographs from the proficiency testing event and gives those to the provider to complete. Once completed, the forms are sent back to the laboratory. Testing is not completed in the laboratory or reported in the laboratory information system. 5. An interview on 3/25/26 at 12:02 pm with Obstetric Providers #1, #2, and #3 revealed they all record their interpretations of the proficiency testing pictographs in their office in another building separate from the laboratory.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on record review and interview with general supervisor #2, the laboratory failed to have the testing personnel performing fern testing attest to the routine integration of samples for four (2024 CM-A and CM-B, 2025 CM-A and CM-B) of four proficiency testing events reviewed. Findings include: 1. A review of the laboratory's College of American Pathologists' proficiency testing records revealed the laboratory participated in the clinical microscopy (CM) events for fern testing. 2. An interview on 3/26/26 at 8:13 am with general supervisor #2 confirmed only obstetric providers are performing fern testing. 3. A review of the laboratory's "Proficiency Testing Guidelines" policy revealed a section titled "Procedure" stating, "Tech who performed testing must sign the 'Attestation' page of the survey." 4. A review of the laboratory's College of American Pathologists' proficiency testing records for the clinical microscopy events revealed a lack of signed attestation statements for personnel performing fern testing for the following events: a. CM-A 2024 b. CM-B 2024 c. CM-A 2025 d. CM-B 2025 5. An interview on 3/25/26 at 10:48 am with general supervisor #2 confirmed the providers performing fern testing had not signed attestation statements.
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 general supervisor #2, the laboratory failed to follow its competency assessment policies to assess testing personnel performing fern testing for two (2024 and 2025) of two years reviewed. Findings include: 1. A review of the laboratory's "Training and Competency Assessment of Technical Personnel" policy revealed a section stating, "The competency of each person to perform his/her assigned duties is assessed. The goal is to evaluate the competency of all personnel and assure that employees maintain their competency to perform assigned duties. This process includes general operations, pre-analytic, analytic, and post-analytic steps used to produce a test results or set of results." and

	"The 6 elements of competency are: (Preanalytic, analytic and post analytic) 1. Direct observation of routine patient test performance including patient identification and preparation, specimen collection, handling, processing and testing. 2. Monitoring the recording and reporting of test results including reporting of critical results. 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records. 4. Direct observation of performance of instrument maintenance and function checks. 5. Assessment of test performance through testing preciously tested samples, blind testing of samples or external proficiency testing samples. 6. Evaluation of problem solving skills." 2. A review of the laboratory's "Provider Performed Microscopy Competency Assessment" document for 2024 and 2025 showed documentation of proficiency testing performance and did not address the six required elements of testing personnel competency as listed above for the four providers that performed fern testing. 3. An interview on 3/25/26 at 3:38 pm with general supervisor #2 confirmed competency assessments were not performed for testing personnel performing fern testing.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (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. This STANDARD is not met as evidenced by: . Based on record review and interview with general supervisor #2, the laboratory failed to verify the ABL 825 blood gas analyzer reference ranges used for one (2025) of one year since the laboratory initiated testing using the ABL 825. Findings include: 1. A review of the laboratory's verification of performance specification data for the ABL 825 blood gas analyzer revealed it was approved for testing by the laboratory director on 1/8/25. The data lacked documentation of how the laboratory verified the reference ranges used to interpret patient test results. 2. An interview on 3/24/26 at 1:43 pm with general supervisor #2 revealed the laboratory utilizes their health system's reference ranges for the ABL 825 and confirmed the reference ranges were not verified to ensure they were appropriate for the laboratory's patient population.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: . Based on record review and interview with general supervisor #1 and #2, the laboratory failed to evaluate the relationship of its hemoglobin testing between its ABL 825 and Sysmex XN-10 instruments for one (2025) of two years reviewed.

	Findings include: 1. A review of the laboratory's verification of performance specification data for the ABL 825 blood gas analyzer revealed it included hemoglobin testing and was approved for testing by the laboratory director on 1/8/25. 2. A review of the laboratory's method comparison data showed a lack of comparison and evaluation of the relationship between the ABL 825 hemoglobin test and the hemoglobin testing performed by the laboratory using the Sysmex XN-10 analyzers. 3. An interview on 3/25/26 at 1:47 pm with general supervisor #1 and #2 confirmed the ABL 825 instrument reports hemoglobin testing for patients and a method comparison process was not performed between the ABL 825 and the Sysmex XN-10 instruments.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to ensure testing personnel met the moderate complexity testing personnel educational requirements for two (testing personnel #20 and #22) of 36 total testing personnel listed on Form CMS-209. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to ensure testing personnel met the moderate complexity testing personnel educational requirements for two (testing personnel #20 and #22) of 36 total testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's personnel records revealed the following lacked educational records to show they met moderate complexity testing personnel requirements: a. Testing personnel #20 performed ROM Plus rupture of fetal membrane testing and documentation of a Canadian degree was provided. b. Testing personnel #22 performed ROM Plus rupture of fetal membrane testing and no education records were provided. 2. The surveyor requested the missing

	qualification records and foreign equivalency documentation for the Canadian degree on 3/23/26 at 2:44 am and the records were not made available. 3. The laboratory was granted an additional seven days to provide additional qualifications records, and none were received.