Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0381904	06/26/2024
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
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: . Based on record review and correspondence with General Supervisor #1, the laboratory failed to designate the program used for compliance when it enrolled in two programs for compatibility testing for 2 (second and third events of 2022) consecutive events receiving unsatisfactory results. Findings include: 1. A review of the laboratory's proficiency testing information reported to CMS revealed the laboratory was enrolled in two compatibility testing programs and one of the programs noted unsatisfactory performance in the second and third events of 2022. The laboratory had not designated one program used to monitor proficiency testing performance compliance. 2. A review of the laboratory's compliance history revealed a lack of proficiency testing desk review performed due to the two consecutive unsatisfactory events. 3. An email received on 7/1/24 at 2:54 pm from General Supervisor #1 confirmed the laboratory had not previously designated which program for compatibility testing was to be used for compliance monitoring.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory

	is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to successfully participate in proficiency testing for compatibility testing. Refer to D2181.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on record review and interview with General Supervisor #1, the laboratory failed to achieve satisfactory results in compatibility proficiency testing for two (second and third events of 2022) consecutive testing events. Findings include: 1. A review of the laboratory's proficiency testing records revealed the following scores for compatibility testing: a. 2022 Second event, 80% b. 2022 Third event, 80% 2. An interview on 6/26/24 at 12:12 pm with General Supervisor #1 confirmed the laboratory had not obtained satisfactory results for the two events listed above in compatibility testing.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: . Based on observation and interviews, the laboratory failed to follow its venipuncture blood specimen collection procedures for one patient specimen collection observed. Findings include: 1. The surveyor observed Phlebotomist #1 performing venipuncture utilizing a butterfly needle on a patient in the Emergency Room at 11:00 am on 06/25

	/2024. The blood collection began with a blue top sodium citrate vacutainer, followed by a gold top serum separator vacutainer, another blue top sodium citrate vacutainer, a green top lithium heparin vacutainer, and finally, two purple top EDTA vacutainers consecutively. The first blue vacutainer tube was discarded. 2. An interview with Phlebotomist #1 at 11:05 am on 06/25/2024 indicated a blue top vacutainer is initially used as a primer to ensure adequate blood flow for all vacutainers. 3. A review of the laboratory's "Specimen Collection: Venipuncture" procedure revealed a section stating, "To avoid possible test result error due to cross contamination from tube additives, the recommended order of draw is: 1. Blood culture bottle 2. Coagulation (sodium citrate) tube (eg, blue top) 3. Serum tube with or without clot activator, with or without gel (eg, red top) 4. Heparin tube with or without gel plasma separator (eg, green top) 5. EDTA (eg, lavender top) 6. Glycolic inhibitor (eg, grey top)" Based on interview with GS1 and GS2 at 12:12 pm on 06/25/2024, it was confirmed that the venipuncture observed did not align with the laboratory policy.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on direct observation and interviews the laboratory failed to include expiration dates on labels for two bottles of decolorizer in microbiology and 12 chemistry controls observed. Findings include: 1. The surveyor observed one aliquot of decolorizer in Microbiology on 06/25/2024 at 2:15 pm which did not include the expiration date on the label as well as no expiration date on parent container label. 2. The surveyor observed 12 Chemistry Controls (LIST) on 06/26/2024 at 9:28 am, did not include the expiration date on the label: a. Liquichek Unassayed Chemistry Control (Human) levels one and two with an open date of "6/25." b. Liquichek Urine Chemistry Control levels one and two with an open date of "6/16" and "6/20" respectively. c. Liquichek Immunology Control level one with an open date of "4/22 /24." d. Liquichek Ethanol/Ammonia Control levels one and three with an open date of "6/22." e. Liquichek Spinal Fluid Control levels one and two with an open date of "5/29" and "5/31" respectively. f. MAS Bilirubin Liquid Assayed Bilirubin controls levels one, two, and three with the open date of "5/20/24." 3. A record review of laboratory policy for reagent labeling was requested and confirmed policy "Medical Supply Storage, Handling, & Verification" for labeling reagents under section "Storage and Handling" under the section "Medical Supplies" on page 1 and 2: #1. "Are stored and handled as defined by the laboratory and following the manufacturer's instructions. #2. "Used within their indicated expiration date for patient testing." #5. "Reagents, calibrators, controls, stains, chemicals, and solutions are properly labeled as applicable and appropriate with the following elements. d. Expiration date" 4. Interview with Testing Personnel #6 at 9:28 am on 06/26/2024 confirmed that reagents and controls were not labeled as indicated by the laboratory policy.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f)

	(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. 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 stain positive and negative reactivity each time of use for 2 (June 2022 to June 2024) of 2 years reviewed. Findings include: 1. A review patient test records revealed the following patients had testing using immunohistochemistry staining without documentation of positive and negative reactivity of controls each time of use: a. Pathology Patient #3 with testing performed on 5/2/22. b. Pathology Patient #5 with testing performed on 5/28/24. c. Pathology Patient #7 with testing performed on 5/17/24. 2. An interview on 6/24/24 at 2:22 pm with the Laboratory Director confirmed the laboratory had not been recording positive and negative reactivity of the immunohistochemical stains used.