Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	23D0381904	04/26/2022
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
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 observation, record review, and interview with General Supervisor #2 (GS2), the laboratory failed to ensure reagents were labeled with an expiration date for 2 of 7 inking bottles observed in the grossing area. Findings include: 1. During a tour of the laboratory on 4/25/2022 at 7:58 am, the surveyor observed 2 of 7 inking bottles in use with no expiration date on the bottle as follows: a. Cancer Diagnostic, Inc. (CDI) - black ink b. Biochemical (BBC) Path-Mark 2. A review of the laboratory's "Policy for Labeling, Storing, Preparing, Evaluating, and Tracking Laboratory Reagent" in step 2 "Labeling" "All reagents prepared or opened within the laboratory must be labeled with the following information when applicable: A. Preparation/opened date and time if appropriate B. Expiration date C. Reagent identity, including lot number, strength, titer, and/or concentration D. Initials of person preparing/opening the reagent E. Precautionary or other miscellaneous information" 3. An interview on 4/25/2022 at 7:58 am, GS2 confirmed the 2 of 7 open inking bottles did not have an expiration date recorded on the bottle.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have

	deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . A. Based on observation and interview with General Supervisor #2 (GS2), the laboratory failed to ensure tissue marking dyes did not exceed their expiration date for 5 of 5 tissue marking dyes observed. Findings include: 1. During a tour of the laboratory on 4/25/2022 at 7:58 am, the surveyor observed the following Cancer Diagnostics, Inc. (CDI) tissue marking dyes had exceeded their expiration dates: black, yellow, green, red, and orange with an expiration date of 09/30/2021. 2. An interview on 4/25/2022 at 7:58 am, GS2 confirmed the CDI tissue marking dyes in use had exceeded their expiration dates. B. Based on observation and interview with General Supervisor #2 (GS2), the laboratory failed to ensure blood specimen collection tubes did not exceed their expiration date for 3 tubes (2 navy top and 1 red top) within 1 of 3 phlebotomy mobile trays observed. Findings include: 1. The surveyor observed 3 phlebotomy trays in the specimen collection area and found 2 navy top tubes with the expiration date of 2/28/22 and 12/31/21 along with a red top microtainer with the expiration date of 8/31/21 in one of the trays on 4/25/22 at 8:05 am. 2. A review of the laboratory's "Policy for Labeling, Storing, Preparing, Evaluating, and Tracking Laboratory Reagents" revealed a section stating, "Expired reagents or solutions will not be used except for in extenuating circumstances with the approval of a Chief Tech or Laboratory Director; and, providing quality control passes." 3. An interview on 4/25/22 at 8:06 am with GS2 confirmed the tubes exceeded their expiration date and were present in the phlebotomy tray.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on record review and interview with General Supervisor #2 (GS2), the laboratory failed to perform and document the monthly maintenance on the Sysmex CS-2500 coagulation instrument for 12 (February - March and May-November 2021 and January-March 2022) of 24 months reviewed. Findings include: 1. A record review of the monthly Sysmex "CS-2500" maintenance log revealed for 12 of 24 months in 2021 and 2022 there was a lack of documentation of the monthly clean filters as follows: a. 2021 - lack of documentation for February - March and May - November b. 2022 - lack of documentation for January - March 2. An interview on 4 /25/2022 at 1:18 pm, GS2 confirmed the laboratory failed to perform and document the monthly maintenance as written on the log sheet.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number

	and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #4 (TP4), the laboratory failed to perform a negative control at least every day of patient testing for its red blood cell unit ABO Rh typing and patient ABO Rh and antibody screens for 2 (April 2020 to April 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's quality control documentation for their manual tube method testing revealed the laboratory recorded only positive reactions and there was a lack of documentation of quality control performed to show the laboratory was able to obtain negative results for its ABO Rh and antibody screen testing each day of patient testing. 2. A review of the laboratory's "Blood Bank Quality Control (Daily)" stating, "This quality control program is to be used for the daily quality control evaluation of routine blood bank reagents. Laboratories must ensure that serologic test reagents are suitably reactive each day of use. A good quality control procedure will monitor procedures, reagents and equipment.", "Commercial quality control material (corQC) is used to evaluate the performance of any reagents associated with manual tube blood typing and tube/gel antibody screening. Manual quality control will be required each day of patient testing using these methods. Various reagents are used to evaluate the performance of reagents associated with less frequently used blood bank testing. Individual procedures identify necessary quality control needs in these instances." and "Control tolerance limits: All reagents must show reactivity pertinent to patient testing or unit retypes." 3. An interview on 4/26/22 at 8:45 am with TP4 confirmed the laboratory is not performing negative controls for its manual tube method for ABO Rh and antibody screen testing. 4. A review of patient records revealed 249 patients had tube typing, 157 cord blood patients had tube typing, 27 patients had antibody screens performed by the tube method, and 34 patients had anti-human globulin (AHG) crossmatches performed by tube method since April 2020.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #18 (TP18), the laboratory failed to identify the name and address of the laboratory performing the Immunohistochemical Evaluation on the patients final report for 1 (M000178076) of 7 patients reviewed. Findings include: 1. Record review revealed for 1 (M000178076) of 7 patients reviewed, the name and address of the laboratory performing the Immunohistochemical Evaluation (CK7, Pan CK, CD31, CD34, and CD68) was not present on the patients final report in the electronic medical records (EMR). 2. During

	the interview on 4/26/2022 at 9:36 am, TP18 confirmed the name and address of the testing laboratory was not present on the patient's final report in the EMR.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on record review and interview with General Supervisor #3 (GS3), the laboratory failed to make sure the competency assessment contained the 6 minimal procedures for evaluation for 2 (April 2020 to April 2022) of 2 years reviewed. Findings include: 1. Review of the Point-of-Care competency assessment for Rupture of Membranes (ROM) Plus test revealed the assessment did not contain the following procedures which constitutes part of the minimal requirements for assessment as follows: a. Monitoring the recording and reporting of patient test results. b. Review of test results, worksheets, quality control records, proficiency testing results, and preventive maintenance. c. Direct observation of performance of instrument maintenance and function checks. d. Assessment of problem solving skills. 2. Review of the competency assessments for 2 of 2 years revealed for 17 testing personnel in the Point-of-Care location the competency assessments were lacking the above procedures and evaluations by the GS3. 3. During the interview on 4/26/2022 at approximately 10:15 am, GS3 confirmed the competency assessments did not contain all 6 procedures.
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 interview with General Supervisor #3 (GS3), the laboratory failed to ensure the testing personnel met the qualification requirements at 493.1423. Findings include: 1. The laboratory failed to ensure testing personnel was qualified. 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 have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at

	least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on record review and interview with General Supervisor #3 (GS3), the laboratory failed to ensure testing personnel were qualified for 1 (Testing Personnel #30 [TP30]) of 17 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel records revealed a lack of qualification documentation for TP30 performing the Point-of-Care moderate complexity testing. 2. The surveyor requested qualification documentation for TP30 to show they were qualified to perform moderate complexity testing on 4/26/2022 at 10:15 am and it was not made available. 3. The laboratory was provided 7 days to supply documentation and it was not made available. .