Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0038059	10/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mackinac Straits Health System	1140 N State Street, Saint Ignace, 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
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: . A. Based on record review and interview with Technical Consultant, the laboratory failed to follow its competency assessment policy for 6 of 9 testing personnel listed on Form CMS-209 for the Sysmex XN-550 installed in March 2023. Findings include: 1. Review of the laboratory's "Competency Assessment" policy, Page 1, Paragraph 3, "Schedule," states, "New employees (or current employees performing new test procedures) will be evaluated initially, at six months and annually thereafter." 2. Record review of Sysmex Analyzer XN-550 Training Checklists and Competency Assessments revealed that 6-month competency assessments were not conducted for 6 of 9 testing personnel: a. Testing Personnel #1 completed initial training on 3/28/2023 and one competency assessment performed on 12/22/23. b. Testing Personnel #2 completed initial training on 3/03/2023 and one competency assessment performed on 12/11/23. c. Testing Personnel #4 completed initial training on 3/01/2023 and one competency assessment performed on 12/11/23. d. Testing Personnel #6 completed initial training on 3/10/2023 and one competency assessment performed on 12/11/23. e. Testing Personnel #7 completed initial training on 7/05/2023 and one competency assessment performed on 7/05/23. f. Testing Personnel #8 completed initial training on 3/03/2023 and competency assessments on 12/05/23 and 11/04/24. 3. An interview with the Technical Consultant on 10/01/2024 at 11:30 am confirmed the 6-month competency assessments for testing personnel using the Sysmex Analyzer XN-550 had not been performed in accordance with the laboratory's policy.. B. Based on record review and interview with Technical Consultant, the laboratory failed to follow its competency assessment policy for its immunohematology Ortho Diagnostic Gel

	Card testing for 4 of 5 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's "Competency Assessment" policy revealed a section stating, "New employees (or current employees performing new test procedures) will be evaluated initially, at six months and annually thereafter." 2. A record review of the Blood Bank Gel Card Training Checklists and competency assessments revealed that a 6-month competency assessment was not conducted for the following testing personnel: a. Testing Personnel #1 completed initial training on 1/11/2024 with no documented competency assessment. b. Testing Personnel #2 completed initial training on 1/17/2024 with no documented competency assessment. c. Testing Personnel #4 completed initial training on 10/27/2023 with no documented competency assessment. d. Testing Personnel #6 completed initial training on 10/24 /2023 with no documented competency assessment. e. Testing Personnel #8 completed initial training on 1/8/2024 with no documented competency assessment. 3. An interview with the Technical Consultant on 10/01/2024 at 11:30 am confirmed the 6-month competency assessment for gel card testing had not been performed in accordance with the laboratory's policy.
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: Based on observation, record review and interview with Technical Consultant (TC) the laboratory failed to ensure reagents and supplies were not used beyond expiration dates for five (one bottle of Direct Coombs Control, two bottles of Contrad70 Access Reagent, and two bottles of Internal Reference Solution (ISE)) reagents observed. Findings include: 1. The surveyor observed on 10/01/2024 at 9:15 am 1 of 1 bottle of Direct Coombs Control (expired 08/13/2024) in Blood Bank available for use. 2. A review of the Blood Bank patient log revealed that 1 patient was tested with expired reagent on 08/28/2024. 3. An interview with TC on 10/01/2024 at 10:30 am confirmed the reagent was expired. 4. The surveyor observed on 10/02/2024 at 9:30 am 2 of 2 bottles of CONTRAD70 reagent (expired 06/27/2024) for the Beckman Coulter Access 2 Immunoassay Analyzer. 5. An interview with the TC on 10/02/2024 at 9:30 am confirmed that the reagents were expired and available for use. 6. The surveyor observed on 10/02/2024 at 8:15 am 2 of 2 boxes of ISE Internal Reference Solution reagent (lot # 2534, expired 5/24/2024) was available for use. 7. An interview with the TC on 10/02/2024 at 9:30 am confirmed that the reagents were expired and available for use.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (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 #2, the laboratory failed to perform control procedures for its Complete Blood Count (CBC) testing using the Sysmex XN-550 analyzer after it had changed reagents for 38 patients tested between the reagent change and the next run of controls. Findings include: 1. A review of the laboratory's CBC analyzer, Sysmex XN-550, reagent change history revealed both the Lysercell WDF and the Fluorocell WDF reagents were change on 9 /30/23 at 12:58 pm and 12:56 pm respectively. 2. A review of the laboratory's control results revealed the controls performed on 9/30/24 were performed at 00:26 am and 12:28 pm with the next control run performed on 10/1/24 at 00:29 am. 3. A review of the patients receiving CBC testing using the Sysmex XN-550 between 9/30/24 at 12: 58 pm and 10/1/24 at 00:29 am revealed 38 patients had been tested. 4. A review of the laboratory's "CBC (XN-550)" procedure revealed a lack of process for performing control procedures after a change in reagents. 5. A review of the laboratory's "Sysmex Automated Hematology Analyzer XN-L Series XN-550 Basic Operation" manufacturer's instructions revealed a section titled "3.2.2 When QC analysis is performed" stating, "QC is performed at the following times. a. Before sample analysis b. After replacement/replenishment of reagents c. After instrument maintenance d. When there is a concern about the accuracy of analysis values." 6. An interview on 10/1/24 at 11:08 am with Testing Personnel #2 confirmed controls had not been performed after the replacement of both the Lysercell WDF and the Fluorocell WDF reagents when changed on 9/30/24 before patients were tested.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with General Supervisor #2, the laboratory failed to store its BD Discs for Differentiation and Susceptibility for three (Sensi-Disc Novobiocin, Taxo Disc, and Sensi-Disc Susceptibility Test) of three disc containers currently in use. Findings include: 1. The surveyor observed a sterile cup containing three susceptibility disc cartridges attached to dispensing devices in the microbiology room stored at room temperature on 10/1/24 at 2:52 pm. Each disc container had a label indicating the storage temperature range of -20 degrees C to 8 degrees C. 2. A review of the laboratory's "BD BBL Taxo Discs for Differentiation of Group A Streptococci" manufacturer's instructions revealed a section titled "Storage Instructions" stating, "On receipt, store at -20 to +8 degrees C. After use, store vial or cartridge to protect product integrity at 2 to 8 degrees C. Use oldest discs first and discard expired discs. Allow containers to come to room temperature before opening. Return unused discs to the refrigerator when application of discs has been completed. Vials and cartridges from which discs have been frequently removed during one week and discs left out overnight in the laboratory should be discarded, or the discs should be tested for performance with control organisms prior to continued use." 3. A review of the laboratory's "BD BBL Sensi-Disc Antimicrobial Susceptibility Test Discs" manufacturer's instructions revealed a section stating, "On receipt, store discs at -20 degrees C to 8 degrees C. If the laboratory refrigerator is frequently opened and closed, and a suitable temperature is not maintained, place there a supply sufficient

	only for use within a week. Discard expired discs. Also, cartridges from which have been frequently removed during a week and discs left out overnight in the laboratory should be discarded or else the discs should be tested for acceptable performance prior to continued use." 4. A review of the laboratory's "BD BBL Taxo Discs for Differentiation of Pneumococci" manufacturer's instructions revealed a section titled "Storage Instructions" stating, "On receipt, store at -20 to +8 degrees C. After use, store vial or cartridge at 2 to 8 degrees C to protect product integrity. The expiration date applies to unopened containers stored as directed. Do not open until ready to use. Use oldest discs first and discard expired discs. Allow containers to come to room temperature before opening. Return unused discs to the refrigerator. Discard containers which have been left out overnight." 5. An interview on 10/1/24 at 2:52 pm with General Supervisor #2 revealed the current disc cartridges in use are kept at room temperature and the rest are kept in the refrigerator. The disc cartridges may be in use for up to a few months before the cartridges are depleted and a new one is opened. Controls for the discs are performed once a quarter. No corrective action was performed.