Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0381904	10/15/2020
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
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with General Supervisor #2 (GS2), the laboratory failed to follow procedures to verify the criteria for acceptability of Beckman Coulter iQ 200 ELITE microscopic urinalysis analyzer controls for 2 (October 2018 to October 2020) of 2 years. Findings include: 1. A review of the laboratory's established "Automated Urinalysis testing on the iRICELL iChem VELOCITY + iQ 200 ELITE" procedure revealed a section stating, "Parallel testing: Parallel testing between the old shipment or lot number and the new shipment or lot number of iQ control ensures that the system is operating within acceptable criteria. Run a new lot of control in parallel with the old lot so that approximately 5-10 values are obtained before placing the new control lot into service." 2. The surveyor requested documentation of the parallel testing for new lots or shipments of quality control material for the iQ 200 ELITE analyzer on 10/12/20 at 11:13 am and they were not made available. 3. An interview on 10/12/20 at 11:13 am with GS2

	confirmed the laboratory did not verify the criteria for acceptability of controls for the Beckman Coulter iQ 200 ELITE analyzer.
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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with General Supervisor #1 (GS1), the laboratory failed to perform a comparison of the iQ 200 ELITE microscopic urinalysis analyzer and the manual microscopic urine sediment methods at least twice annually for 2 (October 2018 to October 2020) of 2 years reviewed. Findings include: 1. During a tour of the laboratory on 10/12/20 at 8:08 am, the surveyor observed a Beckman Coulter iQ 200 ELITE microscopic urinalysis analyzer and an Olympus BH-2 microscope in the urinalysis section of the laboratory. 2. A review of the laboratory's test menu revealed the laboratory performs urine sediment examinations with both automated and manual methods. 3. The surveyor requested documentation of the performance of comparison testing for both automated and manual methods on 10/12/20 at 11:13 am and it was not made available. 4. An interview on 10/14/20 at 9:18 am with GS1 confirmed the laboratory did not perform comparison testing at least twice annually for both automated and manual microscopic urinalysis testing.
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 interviews with General Supervisor #1 (GS1) and General Supervisor #2 (GS2), the laboratory failed to provide patients receiving COVID-19 testing with the authorized fact sheets required for interpretation of results for 5 (May 2020 to October 2020) of 5 months reviewed. Findings include: 1. During a tour of the COVID-19 collection site on 10/13/20 at 10:32 am, the surveyor observed a provider giving a document titled "Exposure Guidelines" to patients during test collection. 2. A review of the "Exposure Guidelines" revealed the document did not contain the authorized fact sheets for COVID-19 testing. 3. An interview on 10/13 /20 at 10:32 am with GS1 and GS2 revealed the laboratory does not give patients authorized fact sheets for COVID-19 testing. 4. A review of the laboratory's test menu

	revealed it performs three methods for COVID-19 testing: a. Abbott ID NOW b. BD MAX BD BioGX SARS-CoV-2 c. Quidel Sofia SARS antigen FIA 5. A review of the laboratory's Abbott ID NOW manufacturer instructions for use revealed a section titled "Conditions of Authorization" stating, "Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 6. A review of the laboratory's BD BioGX SARS-CoV-2 Reagents for BD MAX system manufacturer instructions for use revealed a section titled "Conditions of Authorization" stating, "Authorized laboratories using the BioGX SARS-CoV-2 Reagents for BD MAX System will include with test result reports of the BioGX SARS-CoV-2 Reagents for BD MAX System test, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media. 7. A review of the laboratory's SOFIA SARS Antigen FIA manufacturer instructions for use revealed a section titled "Conditions of Authorization for the Laboratory" stating, "Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 8. An interview with the GS1 and GS2 on 10 /15/2020 at 10:00 am confirmed the laboratory had not been distributing the authorized Fact Sheets to patients according to the manufacturer's instructions. ***This is a repeat deficiency from the 3/1/16 recertification survey***
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: . Based on record review and interview with General Supervisor #1 (GS1), the Technical Consultant failed to ensure direct observations of patient test performance were evaluated during testing personnel competency assessments for Testing Personnel #14. Findings include: 1. A review of testing personnel competency assessments revealed a lack of documentation of direct observations for Testing Personnel #14 performed on 2/20/20 for the following departments: a. Hematology b. Coagulation c. Urinalysis d. Chemistry e. Serology 2. A review of the laboratory's established "Personnel" procedure revealed a section stating, "The Laboratory Co-Directors and Laboratory Leads are responsible for assigning employees in their department various tasks to measure competence. these tasks may include written tests, proficiency testing survey specimens, or completing a physical task such as performing tests on instruments." 3. An interview on 10/13/20 at 8:48 am with GS1 confirmed the competency assessment for Testing Personnel #14 did not have documentation of the observation of patient test performance.
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

	This STANDARD is not met as evidenced by: . Based on record review and interview with General Supervisor #2 (GS2), the Technical Consultant failed to evaluate the recording and reporting of results in competency assessments for personnel performing the ROM PLUS fetal fibronectin test kit for 2 (October 2018 to October 2020) of 2 years reviewed. Findings include: 1. A review of ROM PLUS fetal fibronectin testing personnel competency assessments revealed a lack of documentation of the evaluation of recording and reporting of test results from October 2018 to October 2020. 2. An interview on 10/13/20 at 10:10 am with GS2 confirmed the Technical Consultant did not evaluate the recording and reporting of test results during competency assessments.