Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0899072	06/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mitchell Medical Center	1209 10th Street, Port Huron, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to rotate proficiency testing samples among all testing personnel routinely performing patient testing for 6 (1 event in 2021, 3 events in 2020, and 2 events in 2019) of 6 testing events reviewed. Findings include: 1. Review of the laboratory's CMS-209 form revealed it had 4 testing personnel for moderate complexity testing. 2. A review of the laboratory's American Proficiency Institute (API) proficiency testing attestations revealed Testing Personnel #1 performed testing for all specimens in the following proficiency testing events: a. 2021 Hematology /Coagulation 1st Event b. 2020 Hematology/Coagulation 3rd Event c. 2020 Hematology/Coagulation 2nd Event d. 2020 Hematology/Coagulation 1st Event e. 2019 Hematology/Coagulation 3rd Event f. 2019 Hematology/Coagulation 2nd Event 3. A review of the laboratory's "Proficiency Testing" procedure revealed a section stating, "If more than one person is running the lab tests they will alternate the running of the samples each time they arrive. It there are more than 3 techs each tech will be in the rotation so that a different tech runs one sample. If there are more than five tech, the rotation will continue with the next testing event." 4. An interview on 6 /14/21 at 4:15 pm with TC1 confirmed the laboratory did not rotate its proficiency testing specimens among its routine testing staff.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . The laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to perform and document calibration procedures when calibration verification failed to meet the laboratory's acceptable limits. Refer to D5437. 2. The laboratory failed to perform calibration verification at least every 6 months. Refer to D5439.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to perform and document calibration procedures when calibration verification failed to meet the laboratory's acceptable limits for 1 (Thyroxine) of 25 analytes requiring calibration verification procedures. Findings include: 1. A review of the laboratory's "Linearity/Calibration Verification" reports revealed Thyroxine, performed on 6/7/21, had the following results: a. Slope of 0.833 b. Y-intercept of 2.058 c. R-Squared of 0.561 2. A review of the laboratory's "Linearity/Calibration Verification" reports revealed Thyroxine had a note stating "rerun FT4". 3. A review of the laboratory's "Calibration Verification" procedure revealed a lack of acceptance criteria used to determine when calibration verification procedures are acceptable. 4. A review of the laboratory's test records revealed a total of 10 patients had testing performed after the calibration verification procedures for Thyroxine were performed. 5. An interview on 6/14/21 at 4:15 pm with TC1 confirmed the calibration verification for Thyroxine was not acceptable and additional calibration verification procedures or corrective action had not been performed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;

	(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), the laboratory failed to perform calibration verification at least every 6 months for 1 (December 2021) of 3 required calibration verification events. Findings include: 1. A review of the laboratory's "Linearity/Calibration Verification" reports revealed the calibration verification was performed on the following dates: a. 6/7/21 b. 6/10/20 c. 12/7/19 3. A review of the laboratory's "Calibration Verification" procedure revealed a section stating, "Calibration verification will be performed every six months. Calibration verification will be performed on all analytes that have less than a three point calibration." 5. An interview on 6/14/21 at 4:15 pm with TC1 confirmed the calibration verification had not been performed every 6 months.