

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0038059	(X3) Date Survey Completed 04/11/2019
Name of Provider or Supplier Mackinac Straits Health System	Street Address, City, State 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on review of the "Gram Stain" log and interview with the Technical Supervisor #1 (TS1), the laboratory failed to retain the microbiology quality control documents for two years. Findings include: 1. Record review of the daily "Gram Stain" quality control log revealed a lack of documentation of quality control on the day of testing (3/8/2019) for patient specimen number 622822. 2. Record review revealed quality control from February 22, 2019 to March 19, 2019 was not retained. 3. During the interview on April 11, 2019 at 11:00 am, the TS1 confirmed the quality control data was not available to the surveyor. ***Repeat Deficiency from 10/8/14***</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
 . Based on surveyor review of the "Blood Bank Incubator Temperature Log", review of procedures, and an interview with the Technical Supervisor #2 (TS2), the laboratory did not have a defined acceptable temperature range for the Blood Bank Incubator for two (April 2017 to April 2019) of two years. Findings include: 1. Review of "Blood Bank Incubator Temperature Log" revealed acceptable temperature ranges were missing from the logs. 2. The laboratory did not have a policy with an acceptable temperature range for the Blood Bank Incubator. 3. Interview with the TS2 on 4/11/19 at 10:00 am confirmed an acceptable temperature range was absent from the log and a policy.

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 surveyor review of records and an interview with the Technical Supervisor #2 (TS2), the laboratory failed to perform calibration verifications for Total Bilirubin and Direct Bilirubin assays for at least once every six months for one of two events in 2018. Findings include: 1. Record review revealed the laboratory lacked documentation of the calibration verification for one event (September 2018) for Total Bilirubin and Direct Bilirubin assays. 2. Interview with the TS2 on 4/10/19 at 3:18 pm confirmed there was no valid calibration verification performed for Total Bilirubin or Direct Bilirubin for the September 2018 event. ***Repeat Deficiency from 10/8/14 and 10/23/12***

D5449

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g)

The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. A. Based on surveyor review of quality control records, review of procedures, and an interview with the Technical Supervisor #2 (TS2), the laboratory failed to perform negative controls for 9 of 9 forward, reverse, screening, and compatibility tests in blood bank in 2017. Findings include: 1. Review of quality control records revealed a lack of documentation for negative control values for the following blood banking daily control testing: a. Anti-A b. Anti-B c. Anti-D d. A1 Cells e. B Cells f. Anti-Human Globulin g. Screening Cells I and II 2. Review of the laboratory's "Blood Bank Quality Control" procedure did not contain instructions for negative control testing. 3. Interview with TS on 4/11/19 at 9:07 am confirmed the negative controls were not performed and documented each day of patient testing. B. Based on surveyor review of the patient testing log book, review of procedures, and interview with the Technical Supervisor #2 (TS2), the laboratory failed to perform Rh controls in parallel with patient testing according to laboratory procedure for 50 of the 53 patients reviewed. Findings include: 1. Review of patient testing log from 1/2/19 to 4/10/19 showed Rh control testing was not performed on 50 of the 53 patients tested. 2. Review of the laboratory's "Rh Typing" procedure stated, "An Rh control serum should be performed in parallel with each test." 3. Interview with TS2 on 4/11/19 at 9:07 am confirmed Rh control was not performed with each patient.