

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D0038059	<b>(X3) Date Survey Completed</b> 01/24/2023
<b>Name of Provider or Supplier</b> Mackinac Straits Health System	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5465</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(8)(g)</p> <p>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-- Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with General Supervisor #2, the laboratory failed to use control materials of a similar matrix for its serum ketone testing using the AimTab Ketone Tablets for 2 (January 2021 to January 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's "QC log for Ictotest and Acetest" from 1/5/21 to 12/29/22 revealed the laboratory used urine controls to determine if the serum ketone AimTab Ketone test was acceptable. 2. An interview on 1/24/23 at 8:15 am with General Supervisor #2 confirmed the laboratory had been using urine controls for its serum ketone testing, not testing control materials in the same manner as patient specimens.</p>
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on observation and interviews, the laboratory failed to test its peripheral blood smear staining materials for predictable staining characteristics at least each day of patient testing for 2 (January 2021 to January 2023) of 2 years reviewed. Findings include: 1. The surveyor observed peripheral blood smear staining materials while touring the laboratory on 1/23/23 at 2:44 pm. 2. An interview on 1/23/23 at 3:45 pm with Testing Personnel #1 revealed the laboratory had not been documenting its peripheral blood smear staining materials for predictable staining characteristics at least each day of patient testing. 3. An interview on 1/23/22 at 3:50 pm with General Supervisor #2 confirmed the laboratory had not established a practice of documenting its peripheral blood smear staining materials for predictable staining characteristics and no documentation was present.