

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0724422	(X3) Date Survey Completed 08/21/2019
Name of Provider or Supplier Mackinac Island Medical Center	Street Address, City, State 7474 Market Street, Mackinac Island, 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
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with General Supervisor (GS), the laboratory failed to perform and document Sysmex XP-300 hematology analyzer weekly maintenance as required by the manufacturer for 2 (first week of October 2018 and first week of January 2019) of 104 weeks reviewed. Findings include: 1. A record review of the "XP-300" maintenance logs revealed a lack of documentation of weekly maintenance performed the first week of October 2018 and the first week of January 2019 as required by the manufacturer. Weekly maintenance includes "cleaning the SRV tray." 2. An interview on 8/21/19 at 10:45 am with the GS confirmed weekly maintenance had not been performed and documented for the Sysmex XP-300 hematology analyzer for the first week of October 2018 and the first week of January 2019.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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</p>

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 interview with the General Supervisor (GS), the laboratory failed to include the final test result in the test report for 2 (patient #6749198 and patient #18) of 18 patient charts audited. Findings include: 1. A record review of patient logs revealed patients had the following testing ordered: a. Patient #6749198 had a Complete Blood Count with Differential (CBC with Diff) ordered. b. Patient #18 had a potassium hydroxide (KOH) test ordered. 2. A patient chart audit exposed a lack of the following results: a. Patient #6749198 i. Lymphocyte percentage ii. Neutrophil percentage iii. Absolute lymphocyte count iv. Absolute neutrophil count b. Patient #18 KOH results 3. An interview at on 8/21/19 at 1:51 pm with the GS confirmed the above results were missing from the patient charts listed above.