

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0381904	<b>(X3) Date Survey Completed</b>  02/28/2018
<b>Name of Provider or Supplier</b>  Mymichigan Medical Center- Sault	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to perform and evaluate the performance specifications for the loaner Cytyc ThinPrep 2000 Cytology Processor and the laboratories primary Cytyc ThinPrep 2000 Cytology Processor when returned from preventive maintenance before being put into use. Findings include: 1. On February 28, at 11:35 a.m., record review revealed an invoice showing the laboratory received a loaner Cytyc ThinPrep 2000 Cytology Processor on May 19, 2017 for use while the laboratories primary instrument was having preventive maintenance performed. 2. On February 28, 2018 at 11:35 a.m. when queried, testing personnel #8 and #9 as listed on the CMS-209 were not able to provide the surveyor with documentation to show the loaner instrument and the serviced instrument had performance specifications evaluated and documented prior to being put into use. 3. During the interview on February 28, at 11:35 a.m., testing personnel #8 and #9 confirmed the performance specifications were not performed and documented prior to use.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p>

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory failed to perform and document the weekly maintenance for the hematology XE 5000 instrument for nine (June-August 2016 and May, August, October, and November 2017) of 24 months reviewed. Findings include: 1. On February 28, 2018 at 12:45 p.m., record review of the "Sysmex XE-5000 SN A2893 Maintenance Log" revealed there is one task to be performed weekly - Power Down IPU. 2. On February 28, 2018 at 12:45 p.m., record review of the Sysmex XE-5000 Maintenance Log revealed the laboratory failed to perform and document the weekly maintenance task for nine of 24 months reviewed in 2016, 2017, and 2018 as follows: a. one of four weeks not performed - July 2016, May-June, August, and November 2017 b. two of four weeks not performed - June and August 2016 and October 2017 c. three of four weeks not performed - September 2016 3. During the interview on February 28, 2018 at 12:45 p.m., technical consultant #1 as listed on the CMS-209 confirmed the weekly maintenance was not performed as required by the manufacturer. \*\*\*Repeat Deficiency from June 26, 2012 and February 26, 2014 surveys\*\*\*