

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2003072	(X3) Date Survey Completed 12/20/2019
Name of Provider or Supplier Lake Region Healthcare Cancer Care &	Street Address, City, State 908 S Cascade, Fergus Falls, MN	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document required maintenance for 1 of 1 Hematology analyzers in 2018 and 2019. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 12:35 p.m. on 12/20/19. 2. A Sysmex XN-430 hematology analyzer was observed as present and available for use during the tour of the laboratory. The TC indicated this analyzer was implemented after the 10/28/19 COLA survey. The scope of CLIA validation survey focused on the analyzer in use from 12/24/17-10/28/19; a Sysmex XS-1000i. 3. Manufacturer requirements for daily, weekly, and monthly maintenance of the Sysmex XS-1000i analyzer were established in the Complete Blood Count on Sysmex XS-Series procedure located in the Sysmex XS Procedure Manual and the Sysmex XS-1000i Maintenance Log. 4. Documentation of the daily analyzer shut down was not found for 163 of 193 days reviewed in the following timeframe; 2018 - January, February, March, October, November, December, and 2019 - July, August, September. See below. 2018 Days missed January 20 of 22 days February 17 of 20 days March 21 of 22 days October 20 of 23 days November 17 of 22 days December 18 of 20 days 2019 July 18 of 22 days August 16 of 22 days September 16 of 20 days 5. Documentation of the weekly IPU power down was not found for 12 of 39 weeks reviewed in the following timeframe; 2018 - January, February, March, October, November, December, and 2019 - July, August, September. See below. 2018 Weeks missed January 3 of 4 weeks February 2 of 4 weeks March 3 of 4 weeks October 1 of 4 weeks December 3 of 4 weeks 6.</p>

Documentation of the monthly rinse was not found for 4 of 9 months reviewed in the following timeframe; 2018 - January, February, March, October, November, December, and 2019 - July, August, September. See below. Months missed 2018 January March October December 7. In an interview at 3:10 p.m., the TC confirmed the above finding.