

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0404581	(X3) Date Survey Completed 12/06/2023
Name of Provider or Supplier Olmsted Medical Center - St Charles	Street Address, City, State 403 West 4th Street, St Charles, 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: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and/or document required weekly maintenance at the frequency required for one of one Hematology analyzer in 2022 and 2023. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:50 a.m. on December 6, 2023. 2. A Sysmex XP-300 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Manufacturer maintenance requirements for the Sysmex XP-300 analyzer were established in the Maintenance - Sysmex XP-300 procedure, located in the laboratory's electronic procedure manual. The maintenance requirements were also found on the monthly instrument maintenance logs used by laboratory staff daily in the laboratory. 4. Documentation of the weekly maintenance, clean the Sample Rotor Valve (SRV) tray on the XP-300, was not found for 74 of 91 weeks reviewed on monthly instrument maintenance log for 2022 and 2023. 5. In an interview at 1:06 p.m. on December 6, 2023, the TC confirmed the above findings. .</p>