

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0857120	(X3) Date Survey Completed 09/08/2021
Name of Provider or Supplier La Farge Clinic - Vmh	Street Address, City, State 206 N Mill Street, La Farge, WI	
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 surveyor review of maintenance logs for the Sysmex KX21N hematology analyzer from October 2020 through August 2021, and interview with testing personnel and the technical consultant, the laboratory did not perform cleaning of the sample rotor valve quarterly during two of three quarters. Findings include: 1. Review of hematology maintenance logs for the Sysmex KX21N from October 2020 through August 2021 showed cleaning of the sample rotor valve is required quarterly. The cleaning was only documented on May 5, 2021 during this time period. 2. Interview with testing personnel (staff C) on September 8, 2021 at 1:30 PM revealed the cleaning was performed when the analyzer prompted the operator. Further interview revealed the prompt is based on test runs rather than the quarterly requirement. 3. Interview with the technical consultant on September 8, 2021 at 1:30 PM confirmed the cleaning was not performed quarterly as required.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of performance evaluation records for five of seven testing personnel and interview with the technical consultant, the technical consultant did not document the 2019 annual evaluation of two of the five testing personnel reviewed. Findings include: 1. Review of annual performance evaluation records for five testing personnel revealed no evidence of documented evaluation for staff A and staff B at this laboratory in 2019. 2. Interview with the technical consultant on September 8, 2021 at 11:30 AM confirmed competency evaluations for staff A and B were not completed in 2019.