

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0403675	(X3) Date Survey Completed 04/24/2025
Name of Provider or Supplier Bigfork Valley Laboratory-Floodwood	Street Address, City, State 810 Poplar Street, Floodwood, 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
D0000	. The Bigfork Valley Laboratory - Floodwood laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on April 24, 2025. The following standard-level deficiency was cited: 493.1256 Control procedures .
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10) (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to verify acceptability of new hematology quality control (QC) material for the single non-waived analyzer used by laboratory in 2023, 2024, and 2025. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 12:30 p. m. on 04/24/25. 2. A Sysmex XP-300 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Acceptability verification of new hematology QC material was required as established in the Sysmex XP-300 Automated Hematology Analyzer procedure, found in the Floodwood Lab Manual. Per the procedure, a minimum of 10 data points within the assay range for each level</p>

of QC material was required prior to placing new QC material into use. 4. Documentation of new hematology QC material acceptability verification was not found during review of laboratory records. The laboratory was unable to provide documentation of this process for 2023, 2024, and 2025 upon request. 5. The laboratory performed approximately 990 hematology tests annually as indicated on the Form CMS-116 obtained from the laboratory on date of survey. 6. In an interview at 2:25 p.m. on 04/24/25, the TC confirmed the above findings. .