

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0725037	(X3) Date Survey Completed 07/16/2026
Name of Provider or Supplier Bigfork Valley Laboratory - Northome	Street Address, City, State 12052 Main St, Northome, 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 - Northome 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 July 16, 2026. The following standard-level deficiencies were cited: 493.1236 Evaluation of proficiency testing performance .
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate one unacceptable Hematology proficiency testing (PT) result out of fifteen challenges completed in 2024. Findings are as follows: 1. The laboratory performed moderate complexity Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 1:05 p.m. on 07/16/26. 2. The laboratory performed PT using the American Proficiency Institute (API) proficiency testing provider. 3. The laboratory received one unacceptable Lymphocyte (LYM) PT result of fifteen testing challenges completed in 2024 as indicated in the API 2024 Hematology 3rd Event Comparative Evaluation report. See below. 2024 - 3rd Hematology Event Test: LYM Sample: HSY-14 Laboratory result: 18.1 API expected result: 18.6-23.0 4. Unsatisfactory PT result investigation was required as established in the laboratory's Proficiency Testing procedure found in the Northome Lab Manual. 5. Investigation documentation for the unacceptable LYM score was not found during review of laboratory PT records. The laboratory was unable to provide investigation and corrective action records for this unacceptable PT result upon request. 6. In an interview at 2:15 p.m. on 07/16/26, the LD confirmed the above finding. .