Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0406574	12/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bigfork Valley Hospital	258 Pine Tree Drive, Bigfork, 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
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 unacceptable Chemistry and Hematology proficiency testing (PT) results for 4 analytes in 2017 and 4 analytes in 2018. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/19/18 at 8:10 a.m. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 2. The laboratory received unacceptable PT results from API in 2017 and 2018 for the analytes listed below. Chemistry Event Sample Test* Lab API result 2017-3 CH-11 Vanc 38.9 25.7-38.7 CH-14 Vanc 10.1 5.9-10.0 2018-2 CH-10 LDL 42 44-67 2018-3 HCG-13 HCG 1264 994-1237 CH-13 LDL 42 15-41 Hematology Event Sample Test Lab API result 2017-1 XE-01 Mono 7.6 7.9-12.2 2017-2 XE-07 Neut 50.5 44.0-50.2 2018-1 XE-03 IG Ab 3.01 2.28-2.95 3. An investigation of the unacceptable PT results was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 4. In an interview on 12/19/18 at 10:50 a.m., the GS confirmed a documented investigation of the unacceptable results was not performed. * Note Vanc Vancomycin LDL Low-density Lipoprotein HCG Human Chorionic Gonadotropin Mono Monocytes Neut Neutrophils IG Ab IG Absolute
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty

	assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of Microbiology, Chemistry and Hematology proficiency testing (PT) scores when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/19/18 at 8:10 a.m. 2. The laboratory performed PT using the American Proficiency Institute PT provider. 3. Three PT results from 2017 and six PT results from 2018 were not graded due to lack of consensus. See below for sample identifications (ID) and analytes. 2017 Sample ID Analyte UR-06 Levofloxacin UR-06 Piperacillin/tazobactam UR-11 Susceptibility 2018 Sample ID Analyte UDS-02 Opiates CM-15 B-type Natriuretic Peptide CH-11 Low Density Lipoprotein BFM-02 Body Fluid Microscopy BL-01 Blood Culture UP-06 Piperacillin /tazobactam 4. The API expected results data summaries were not present in laboratory records. Evaluations for accuracy of the non-graded results were not found during review of laboratory documents. The laboratory was unable to provide evaluations of non-graded results upon request. 5. In an interview on 12/19/18 at 9:40 a.m., the GS confirmed the non-graded PT results had not been evaluated for accuracy.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to include accurate Hematology reference ranges in the procedure manual. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/19/18

	at 8:10 a.m. 2. A Sysmex XT 4000 hematology analyzer and an ELITechGroup Excyte M ESR analyzer were observed as present and available for use during the tour of the laboratory. 3. The reference ranges in the Sysmex XT 4000 procedure located in the Hematology manual did not reflect the reference ranges on the patient test report reviewed on date of survey. See below. Analyte* Procedure Report MCH 27.0-34.0 26-35 PLT 137-381 163-439 4. The reference range in the Excyte Sedimentation Rate procedure located in the Hematology manual did not reflect the reference range on the patient test report reviewed on date of survey. See below. Analyte Procedure Report ESR 0-15 0-10 5. In an interview on 12/19/18 at 3:20 p.m., the GS confirmed the above findings. *Note MCH Mean Corpuscular PLT Platelets ESR Erythrocyte Sedimentation Rate
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to maintain an information or record system (patient testing log) for non-interfaced test systems or manual test kits. Findings are as follows: 1. The laboratory performed Microbiology and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/19/18 at 8:10 a.m. 2. Patient testing logs for the non-interfaced Excyte M ESR analyzer and the Wampole C. Diff Quik Chek Complete manual test kit were not present in laboratory records. The laboratory was unable to provide patient testing logs for these tests upon request. 3. In an interview on 12/19/18 at 3:20 p.m., the GS confirmed the above finding and stated patient testing logs were not used for non-interfaced analyzers or manual test kits.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical supervisor failed to ensure 1 of 1 new testing personnel received documented initial training in 2018. Findings are as follows: 1. The laboratory performed Microbiology, Diagnostic Immunology, Chemistry, Hematology and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/19/18 at 8:10 a.m. 2. Review of personnel records indicated documentation of initial training

	in 2018 for Testing Personnel 4 (TP4) was incomplete for the following Specialties: Microbiology Diagnostic Immunology Chemistry Hematology Immunohematology 3. The laboratory was unable to provide the missing training documents upon request. 4. In an interview on 11/08/18 at 10:15 a.m., the GS stated TP4 was working independently in the laboratory and confirmed initial training documentation was incomplete.