Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0406574	05/02/2025
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
D0000	The Bigfork Valley Hospital 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 May1, 2025. The following standard-level deficiency was cited: 493.1251 Procedure manual .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 Chemistry reference intervals in the

	procedure manual in 2023 and 2024 for five of five blood gas chemistry analytes reviewed. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Technical Supervisor 1 (TS1) during a tour of the laboratory at 8:05 a. m. on 05/01/25. 2. An i-STAT blood analyzer was observed as present and available for use during the tour of the laboratory. The laboratory performed blood gas testing using the CG4+ cartridge on this analyzer. 3. Reference intervals for five of five venous blood gas analytes were discrepant with the i-STAT CG-4 procedure located in the I-STAT manual when compared to a patient test report from 09/16/23 reviewed on date of survey. See below. Analyte Report Procedure pO2 30-50 25-40 pCO2 38-48 36-50 pH 7.32-7.42 7.35-7.45 HCO3 24-32 25-30 Lactate 0.36-1.70 0.90-1.70 4. In an interview at 3:15 p.m. on 05/01/25, TS1 confirmed the above findings. 5. In a telephone conversation at 10:38 a.m. on 05/02/25, TS1 indicated the venous blood gas reference intervals in the i-STAT CG-4 procedure were incorrect. .