

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0406574	(X3) Date Survey Completed 02/01/2023
Name of Provider or Supplier Bigfork Valley Hospital	Street Address, City, State 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of three performance verifications completed in 2022 was approved, signed, and dated by the laboratory director prior to implementation. Findings are as follows: 1. The laboratory performed Bacteriology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 02/01/23. 2. A Cepheid GeneXpert automated molecular diagnostic system was observed as present and available for use during the tour of the laboratory. The laboratory performed Clostridium difficile (C. diff) testing using this analyzer: 3. The performance verification (PV) for C. diff on the GeneXpert system was completed in January 2022 as indicated in the Cepheid C. Diff Validation records provided by the laboratory. The GS approved the PV results on 01/21/22. 4. The laboratory director's approval signature and date were not found in the PV documents. The laboratory was unable to provide LD approval of the PV upon request. 5. In an interview at 11:45 a.m. on 02/01/23, the GS confirmed the above finding. .</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:

. Based on observation and interview with laboratory personnel, the laboratory failed to label two of two secondary containers used for Hematology manual blood smears. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 02/01/23 at 8:05 a.m. 2. Two unlabeled glass jars containing liquid were observed as available for use in the laboratory during the tour. 3. The Technical Supervisor (TS) stated the unlabeled jars contained Camco Quik Stain II and water. These materials were used for differential staining for manual blood smears. 4. The source bottle for the Camco Quik Stain II was not available on date of survey to verify lot number or expiration date of the stain. 5. In an interview at 8:30 a.m. on 02/01/23, the TS confirmed the above finding. The TS indicated the unlabeled jars were filled on 01/27/23 and the source bottle had been discarded. .

D5431

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure function checks for one of three Chemistry analyzers were performed and documented as required from 04/01/21 through 02/01/23. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 02/01/23. 2. An Abbott i-STAT analyzer was observed as present and available for use during the tour. The laboratory used the i-STAT analyzer for Blood Gas testing. The i-STAT was also used as a back up analyzer for Basic Metabolic Panel, Troponin, and BNP testing. 3. The manufacturer required twice annual verification of the i-STAT thermal probe as indicated in the Abbott i-STAT System Manual. 4. Twice annual verification of the i-STAT thermal probe was not established in the I-STAT Procedure found in the laboratory's I-STAT manual. 5. Evidence of thermal probe verification performance between 04/01/21 and 02/01/23 was not found in laboratory records. The laboratory was unable to provide this documentation upon request. 6. In an interview at 3:40 p.m. on 02/01/23, the GS confirmed the above finding and indicated i-STAT thermal probe checks had not been performed. .