Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0403795	(X3) Date Survey Completed 10/21/2021
Name of Provider or Supplier Bois Forte Medical Clinic	**Street Address, City, State** 5219 St John'S Drive, Nett Lake, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to complete a performance verification (PV) for one non-waived test implemented by the laboratory in 2021. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 10/21/21. 2. A Seimens DCA Vantage analyzer was observed as present and available for use during the tour of the laboratory. Microalbumin to Creatinine Ratio (ACR) was performed on this analyzer. 3. PV documentation for ACR on the DCA Vantage was not found during review of laboratory records. The laboratory was unable to provide a PV upon request. 4. A PV procedure was not found during review of laboratory procedure manuals. 5. The ACR Patient Result Sheet indicated 39 patients had received ACR testing since implementation on 04/12/21 through date of survey, 10/21/21 6. In an interview at 2: 15 p.m. on 10/21/21, TP1 confirmed the above finding. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations

	Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on document review, interview with laboratory personnel, and review of the FDA test classification database, the laboratory failed to ensure quality control testing (QC) was performed each day of non-waived Chemistry testing in 2021. Findings are as follows: The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 10/21/21. An Abaxis Piccolo Xpress analyzer and a Seimens DCA Vantage analyzer were observed as present and available for use. Complete Metabolic Panels, Basic Metabolic Panels, and Lipid Panels were performed on the Piccolo Xpress analyzer and Microalbumin to Creatinine Ratio (ACR) was performed on the DCA Vantage. A. Abaxis Piccolo Xpress 1. In an interview at 11:50 a.m. on 10/21/21, TP1 indicated approximately three serum specimens had been tested on the Piccolo Xpress analyzer since 07/26/21. The use of a serum specimen changed the classification of the test from waived to moderate complexity. 2. Piccolo Xpress QC performance was required every 30 days as established in the Use and Maintenance of the Chemistry Analyzer Piccolo Xpress procedure found in the Piccolo Waived Compliance Binder manual. 3. Laboratory records confirmed QC had been performed with new lots and every 30 days in the timeframe reviewed, July 2021 - October 2021. 4. An Individualized Quality Control Plan (IQCP) to reduce the frequency of QC was not found in laboratory records. The laboratory was unable to provide an IQCP upon request. 5. In an interview at 11:50 a. m. on 10/21/21, TP1 confirmed the above finding and indicated QC was not performed each day of serum specimen testing. TP1 was unable to determine the exact number of serum specimens tested on the Piccolo Xpress as this information had not been documented. B. Seimens DCA Vantage 1. ACR on the DCA Vantage was classified by the FDA as moderate complexity testing. 2. ACR QC performance was required with new lots and at regular intervals as established in the DCA Systems Microalbumin/Creatinine Reagent Kit procedure found in the DCA Vantage A1C manual. 3. Laboratory records confirmed QC had been performed with new lots and monthly in the timeframe reviewed, April 2021 - October 2021. 4. An Individualized Quality Control Plan (IQCP) to reduce the frequency of QC was not found in laboratory records. The laboratory was unable to provide an IQCP upon request. 5. The ACR Patient Result Sheet indicated 39 patients had received ACR testing since implementation on 04/12/21 through date of survey, 10/21/21 6. In an interview at 1: 30 p.m. on 10/21/21, TP1 confirmed the above finding. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Consultant failed to ensure competency was assessed at least semi-annually during the first year of patient specimen testing for one of one testing personnel hired in 2019.

	Findings are as follows: 1. The laboratory performed Hematology testing and Urine Sediment and KOH microscopic examinations as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 10/21/21. 2. A Cell-Dyn Emerald 22 hematology analyzer and a McKesson Lumion microscope were observed as present and available for use during the tour of the laboratory. 3. Testing Personnel 4 (TP4) received initial competency assessment in October 2019 as indicated in personnel records. 4. The Laboratory Personnel - Quality Assurance procedure, found in the CLIA Manual book, indicated new employees were assessed for competency twice in the first year of testing. 5. A semi-annual competency assessment for TP4 was not found during review of laboratory records. The laboratory was unable to provide the missing assessment upon request. 6. In an interview at 1:35 p.m. on 10/21 /21, TP1 confirmed the above finding. .