Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0933577	03/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bois Forte Vermilion Clinic	1613 Farm Rd S, Tower, 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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure hematology proficiency testing samples from one of three 2021 PT events were tested consistent with the number of times the laboratory routinely tested patient specimens Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/16/23 at 10:05 a.m. An Abbott Cell-Dyn Emerald hematology analyzer was observed as present and available for use during the tour. 2. The laboratory performed proficiency testing (PT) for Hematology using the Medical Laboratory Evaluation (MLE) proficiency testing provider in 2021. 3. Hematology PT samples CL-01 through CL-05 from the 2021 MLE-M1 event were tested on multiple days as indicated on test result documents generated by the Abbott Cell-Dyn Emerald hematology analyzer. See below for date and time of day testing was performed. Sample 02/03/21 02/04/21 CL-01 9:15 3:11 CL-02 9:17 3:15 CL-03 9:18 3:18 CL-04 9:20 3:20 CL-05 9:22 3:28 4. In an interview at 12:14 p.m., TP1 confirmed the above finding and indicated patient specimens would not be tested in this manner. .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to perform and document activities used to verify the accuracy of two of two microscopic examinations performed in the laboratory at least twice annually in 2022. Findings are as follows: 1. The laboratory performed Urine Sediment and Skin KOH microscopic examinations as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 03/16/23. 2. The Laboratory performed proficiency testing using the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing provider in 2022. 3. Twice annual Urine Sediment and Skin KOH accuracy verification documentation was not found for 2022 during review of WSLH documents and laboratory records. The laboratory was unable to provide the missing accuracy verification documentation upon request. 4. The laboratory performed approximately 35 Urine Sediment examinations and four Skin KOH examinations annually as indicated on Form CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application for Certification provided by the laboratory on date of survey. 5. In an interview at 12:14 p.m. on 03/16/23, TP1 confirmed the above finding.
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 the single 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 03/16/23. 2. A Siemens DCA Vantage analyzer was observed as present and available for use during the tour of the laboratory. Microalbumin to Creatinine Ratio (UACR) testing on this analyzer was implemented on 03/04/21 as indicated in laboratory patient testing records. 3. PV documentation for UACR testing on the DCA Vantage was not found during review of laboratory records. The laboratory was unable to provide a PV upon request. 4. The Laboratory Equipment procedure found in the Lab Manual indicated test performance was verified prior to use. A PV procedure was not found in the Lab Manual. 5. The DCA Patient Test Sheet A1C and Microalbumin/Creat indicated 148 patients received UACR testing since implementation on 03/04/21 through date of survey, 03/16/23. See below Year Number of patients tested 2021 42 2022 80 2023 26 6. In an interview at 12:30 p.m. on 03/16/23, TP1 confirmed the above finding. .
D6055	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 whenever test

	methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant (TC) failed to document a competency evaluation for three of three testing personnel prior to testing patient specimens using a new Chemistry test 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 03/16/23. 2. A Siemens DCA Vantage analyzer was observed as present and available for use during the tour of the laboratory. Microalbumin to Creatinine Ratio (UACR) testing on this analyzer was implemented on 03/04/21 as indicated in laboratory patient testing records. 3. Employee training for new tests was required as established in the QA Policy and Procedure found in the Lab Manual. 4. UACR initial training and competency evaluation documents for tenured Testing Personnel TP1, TP2, and TP3 were not found during review of laboratory records. The laboratory was unable to provide these documents upon request. 5. The DCA Patient Test Sheet A1C and Microalbumin/Creat indicated 148 patients received UACR testing since implementation on 03/04/21 through date of survey, 03/16/23. See below Year Number of patients tested 2021 42 2022 80 2023 26 6. In an interview at 2:25 p.m. on 03/16/23, TP1 confirmed the above finding. .