Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0409270	01/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mountrail County Medical Center	615 6th St Se, Stanley, ND	

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 record review, staff interview, and policy review, the laboratory failed to verify the accuracy and precision for 2 of 2 new test methods (microalbumin and creatinine) on the DCA Vantage analyzer implemented in October 2019 before reporting patient results. The laboratory performed approximately 200 patient microalbumin/creatinine tests on the DCA Vantage analyzer since implementation. Findings include: 1. Reviewed at 12:55 p.m. on 01/13/21, the laboratory's 2019 performance specification verification records for the DCA Vantage analyzer lacked evidence the laboratory verified the performance specifications for accuracy and precision for microalbumin and creatinine. 2. During interview at 1:55 p.m. on 01/13/21, the laboratory supervisor (#1) confirmed the laboratory began patient testing on the DCA Vantage for microalbumin and creatinine in October 2019, and the laboratory did not have evidence the laboratory director and/or technical consultant had verified the performance specifications for accuracy and precision. 3. Reviewed at 2:15 p.m. on 01/13/21, the policy "Method Evaluation," dated 01/28/86, stated, "Our laboratory will thoroughly evaluate any new methods before implementing them. The following steps will be used: . . . 2. Examine the method to determine whether it meets the established performance standards. . . . b. Determine between-day precision. . . . c. Between analyst precision. . . . d. Compare to reference method. . . ."

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 record review, procedure review, and staff interview, the laboratory failed to perform two levels of control each day of patient testing for microalbumin and creatinine on the DCA Vantage analyzer on 11 of 11 patient testing days in December 2020 (12/01, 12/03, 12/04, 12/07, 12/08, 12/09, 12/10, 12/11, 12/14, 12/28, and 12 /31). The laboratory performed approximately 12 patient tests in December 2020. Findings include: 1. Reviewed at 12:55 p.m. on 01/13/21, the December 2020 microalbumin and urine creatinine patient and quality control records lacked evidence the laboratory performed two levels of control on eleven patient testing days (12/01, 12/03, 12/04, 12/07, 12/08, 12/09, 12/10, 12/11, 12/14, 12/28, and 12/31). 2. Reviewed at 1:10 p.m. on 01/31/21, the procedure "Microalbumin/Creatinine Test," dated 08/23/19, stated, "Instrument: Siemens DCA Vantage Analyzer . . . Quality Control Run quality control specimens under the following conditions: - at regular intervals determined by laboratory procedures - when using a new shipment of reagents - when using new lot number of reagent . . ." The procedure failed to include a requirement to perform two levels of control each day of patient testing. 3. During interview at 1:55 p.m. on 01/13/21, the laboratory supervisor (#1) stated the laboratory thought the test was a waived method and confirmed the laboratory had not performed two levels of quality control each day of patient testing.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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 record review, staff interview, and policy review, the technical consultant failed to include the DCA Vantage analyzer in the annual competency evaluations for 2 of 2 sampled testing personnel (#1 and #2) in 2020. Findings include: 1. Reviewed at 9:50 a.m. on 01/13/21, the 2020 competency evaluation records for Testing Personnel #1 and #2 lacked evidence of completed competency evaluations for the DCA Vantage analyzer. 2. During interview at 1:35 p.m. on 01/13/21, the laboratory supervisor (#1) confirmed the competency evaluations for Testing Personnel #1 and #2 in 2020 did not include the DCA Vantage analyzer. 3. Reviewed at 2:15 p.m. on 01 /13/21, the policy "Delegation of Responsibility," dated 04/14/10, stated, ". . . Technical Consultant: . . . These responsibilities include: . . . h) Evaluates the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures . . ."