Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0519784	03/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Niobrara Community Hospital	921 S Ballencee Ave, Lusk, WY	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory director or his designee failed to attest to the routine integration of the American Proficiency Institute (API) proficiency tests into the patient workload for 9 of 18 proficiency testing events reviewed from July 2021 through December 2022. The findings were: 1. Review of the proficiency testing records showed attestation statements with the following concerns: a. The 2022 API chemistry core event #2 was not signed by the laboratory director or his designee. b. The 2022 API chemistry core verification event #2 was not signed by the laboratory director or his designee. c. The 2022 API chemistry core event #3 was not signed by the laboratory director or his designee. d. The 2022 API hematology event #2 was not signed by the laboratory director or his designee. e. The 2022 API hematology event #3 was not signed by the laboratory director or his designee. f. The 2022 API microbiology event #2 was not signed by the laboratory director or his designee. g. The 2022 API microbiology event #3 was not signed by the laboratory director or his designee. h. The 2022 API immunology event #3 was not signed by the laboratory director or his designee. i. The 2022 API chemistry miscellaneous event #2 was not signed by the laboratory director or his designee. 2. Interview with the technical consultant on 3/8/23 at 12:52 PM revealed the previous technical consultant had resigned in June of 2022 and confirmed the attestation statements had not been signed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)

	The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the API (American Proficiency Institute) proficiency testing (PT) records, lack of documentation, and staff interview, the laboratory director (LD) failed to review and evaluate proficiency testing results for 11 of 18 testing events reviewed from July 2021 to December 2022. The findings were: 1. Review of the API proficiency testing records failed to include documentation the laboratory director had evaluated the proficiency test results. The following concerns were identified: a. Review of the API 2021 miscellaneous core event #2 showed no documentation the LD had reviewed the results. b. Review of the API 2022 chemistry core event #1 showed no documentation the LD had reviewed the results. This proficiency testing event showed lipase scored a 20%. c. Review of the API 2022 chemistry core event #2 showed no documentation the LD had reviewed the results. This proficiency testing event showed lipase scored a 20%. d. Review of the API 2022 chemistry core verification event #2 showed no documentation the LD had reviewed the results. e. Review of the API 2022 hematology event #1 showed no documentation the LD had reviewed the results. f. Review of the API 2022 hematology event #2 showed no documentation the LD had reviewed the results. g. Review of the API 2022 hematology event #3 showed no documentation the LD had reviewed the results. h. Review of the API 2022 microbiology event #1 showed no documentation the LD had reviewed the results. i. Review of the API 2022 microbiology event #2 showed no documentation the LD had reviewed the results. j. Review of the API immunology event #3 showed no documentation the LD had reviewed the results. k. Review of the API miscellaneous chemistry event #1 showed no documentation the LD had reviewed the results. 2. Interview with the technical consultant on 3/8/23 at 12:52 PM revealed the previous technical consultant had resigned in June of 2022 and confirmed the PT records did not show documentation of the LD's review of the results.
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 review of proficiency testing records and staff interview, the laboratory failed to at least twice annually verify the accuracy of the lipase analyte for 1 of 2 years (2022) reviewed. The laboratory performed approximately 72 patient lipase tests per year. The findings were: 1. Review of the American Proficiency Institute (API) proficiency testing records showed the laboratory failed 3 consecutive testing events for lipase; 2021 event #3, 2022 event #1, and 2022 event #3. Further review showed the error which caused the failures was resolved on 7/20/22; however, there was no evidence patient test results had been evaluated for accuracy. 2. Interview with the technical consultant (TC) on 3/9/23 at 11:18 AM revealed the failure of the lipase analyte on the proficiency testing events was due to the failure of the laboratory to enter a correlation factor into the test system. The error was corrected in July of 2022. The TC confirmed patient results had not been evaluated for accuracy.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 procedure manual review, lack of documentation, and staff interview, the laboratory failed to ensure the procedure manual contained all the required elements for 1 of 1 procedure manual reviewed (Alcor Miniised). The findings were: 1. Review of the laboratory's documentation showed the Alcor Miniised erythrocyte sedimentation rate manual was being used as the procedure guide. The operator's manual failed to include the reportable range as established by the verification procedure, the laboratory's system for entering results into the patient record, and a description of the course of action to take if the system became inoperable. 2. Interview with the technical consultant on 3/9/23 at 11:18 AM confirmed the laboratory's procedure manual was incomplete.
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 new instrument and new test method verification study review, lack of documentation, and staff interview, the laboratory failed to verify precision, verify the reportable range, and confirm the manufacturer's normal values were appropriate for the laboratory's patient population prior to patient testing for 2 of 2 new test verification studies reviewed (Alcor Miniised erythrocyte sedimentation rate, Siemens Dimension EXL high-sensitivity troponin I). The findings were: 1. Review of the 4/20

	/22 new instrument verification study for the Alcor Miniised erythrocyte sedimentation rate test method failed to show the performance specification of precision and the reportable range had been verified by the laboratory prior to testing patient samples. In addition, the laboratory failed to confirm the manufacturer's normal values were appropriate for the laboratory's patient population. 2. Review of the 4/11/22 new method verification study for the Siemens Dimension EXL high-sensitivity troponin I analyte failed to show the manufacturer's normal values were appropriate for the laboratory's patient population. 3. Interview with the technical consultant on 3/9/23 at 11:18 AM confirmed the verification studies were incomplete.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and staff interview, the laboratory failed to have a system in place to ensure the reportable range was verified and evaluated at least every 6 months using testing materials with values at the zero or minimal level, the mid-level, and the upper-level of the reportable range for the CHEM8+ test cartridge (sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, total carbon dioxide, hematocrit, and hemoglobin) and the CG4+ test cartridge (pH, partial pressure of oxygen, partial pressure of carbon dioxide) performed on the Abbott iSTAT instrument; electrolytes performed on the Siemens Dimension EXL; and the Alere Triage D-dimer analyte for 2 of 2 years of testing reviewed (2021, 2022). The findings were: 1. Review of the laboratory's documentation showed a calibration verification study for electrolytes was performed on the Siemens Dimension EXL on 6/17/21, 11/21/21, and 1/14/22. There was no evidence the results of the calibration study had been evaluated. In addition a calibration verification had not ben completed from 1/14/22 to 3/9/23. 2. Review of the laboratory's documentation for the Alere Triage D-dimer test showed a calibration study was performed on 2/23/22 and 9/26/22. There was no evidence the results of the calibration study had been evaluated. 3. Review of the laboratory's documentation showed tests performed on the Abbott iSTAT analyzer had calibration studies which

	had been completed; however, there was no evidence the results of the calibration study had been evaluated. 4. Interview with the technical consultant on 3/9/23 at 11: 18 AM confirmed the laboratory did not have a system in place to ensure calibration verifications studies were completed and evaluated as required.
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 review of quality control (QC) records, patient testing logs, and staff interview, the laboratory failed to perform two levels of QC each day of testing for the Siemens DCA Vantage urine albumin/creatinine (microalbumin) test procedure for 14 months of testing reviewed (1/1/22 to 3/1/23). This failure affected 8 patient microalbumin tests. The findings were: 1. Review of the QC records and patient testing logs for the Siemens DCA Vantage albumin/creatinine test procedure showed the following concerns: a. A microalbumin test was performed on patient #221645 on 2/24/22 with the last documented QC being performed on 1/28/22. b. A microalbumin test was performed on patient #223252 on 5/2/22 with the last documented QC being performed on 4/29/22. c. A microalbumin test was performed on patient #225797 on 8 /15/22 with the last documented QC being performed on 7/31/22. d. A microalbumin test was performed on patient #226874 on 9/27/22 with the last documented QC being performed on 8/25/22. e. A microalbumin test was performed on patient #227138 on 10/11/22 with the last documented QC being performed on 9/28/22. f. A microalbumin test was performed on patient #227986 on 11/21/22 with the last documented QC being performed on 10/26/22. g. A microalbumin test was performed on patient #230445 on 1/25/23 with the last documented QC being performed on 11/29 /22. h. A microalbumin test was performed on patient #231146 on 3/1/23 with the last documented QC being performed on 2/17/23. 2. Interview with the technical consultant on 3/9/23 at 11:18 AM confirmed QC had not been performed each day of patient testing as required.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, patient testing logs, and staff interview, the laboratory failed to perform a positive and negative control each day of testing for the Bio-Rad Tox/See Rapid Urine Drug Screen Test for 1 year of testing reviewed (2022). This failure affected 50 patient urine drug screen tests. The findings

	were: 1. Review of the QC records and patient testing logs for the Bio-Rad Rapid Urine Tox/See Drug Screen Test showed the following concerns: a. 16 patient tests were performed between 2/14/22 and 5/12/22 with the last documented QC being performed on 2/6/22. b. 22 patient tests were performed between 5/29/22 and 8/16/22 with the last documented QC being performed on 5/13/22. c. 6 patient tests were performed between 8/19/22 and 9/15/22 with the last documented QC being performed on 8/17/22. d. 2 patient tests were performed on 9/25/22 with the last documented QC being performed on 9/16/22. e. 4 patient tests were performed between 10/4/22 and 10/22/22 with the last documented QC being performed on 10/3 /22. 2. Interview with the technical consultant on 3/9/23 at 11:18 AM confirmed QC had not been performed each day of patient testing as required.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's documentation, review of Bio-Rad quality control (QC) manufacturer's ranges, Unity QC monthly evaluation reports, American Proficiency Institute (API) proficiency testing records, and staff interview, the laboratory failed to develop a procedure to ensure the verification of quality control material was acceptable for 1 of 2 quality control crossover studies reviewed (BIO-RAD liquid assayed quality control material). This failure led to daily quality control failure, 3 consecutive proficiency testing failures, and affected 72 patient samples from January 2022 through July 2022 for the analyte of lipase. The findings were: 1. Review of Bio-Rad lot # 45890 liquid assayed multiqual manufacturer's recommended ranges showed the level 1 control had a range for lipase of 51.8 U/L to 81.9 U/L with a mean of 66.9 U/L; the level 3 control had a range for lipase of 383 U/L to 467 U/L with a mean of 425 U/L. The following concerns were identified: a. Review of the QC verification study for level 1 showed the laboratory had obtained 16 out of 20 results with a value above 81.9 U/L. The laboratory determined the range for lipase to be 69 U/L to 99 UL with a mean of 84 U/L. The standard deviation was determined to be 7.5. b. Review of the QC verification study for level 3 showed the laboratory had obtained 20 out of 20 results with a value above 467 U/L. The laboratory determined the range for lipase to be 466 U/L to 550 U/L with a mean of 508 U/L. The standard deviation was determined to be 21. c. Review of the API chemistry core proficiency testing records showed the laboratory scored 40% on event #3 of 2021, and 20% on event #1 and event #2 of 2022. d. Review of the March 2022 Unity QC monthly report showed the level 1 data for lipase was excluded from the peer group data due to the laboratory's results being outside of the acceptable values. The level 3 data

	showed a peer group of one. The Unity QC report showed a warning of "! The tests listed below may require investigation or review!" This report was not signed by the laboratory director until 3/6/23. e. Review of the May 2022 Unity QC monthly report showed the level 1 data for lipase was excluded from the peer group data due to the laboratory's results being outside of the acceptable values. The level 3 data showed a peer group of two. The Unity QC report showed a warning of "!The tests listed below may require investigation or review!" This report was not signed by the laboratory director until 3/6/23. 2. Review of a corrective action report dated 7/20/22 showed the laboratory had contacted Siemens technical support and it was determined the inaccurate results for lipase were due to the failure to enter a correlation factor into the test system. Once this was corrected the lipase results obtained were within the manufacturer's ranges. 3. Interview with the technical consultant on 3/8/23 at 12:52 PM revealed the previous technical consultant had resigned on 6/13/22 and the lipase issue had been resolved before she began in August of 2022. 4. Telephone interview with the laboratory director on 3/9/23 at 10:54 AM revealed he did not recall the failure of lipase on the proficiency testing events and did not routinely review the laboratory's quality control data. Further the laboratory director stated he did not visit the laboratory on a routine basis; however, tried to come every 2 to 3 months and would complete a quality assurance (QA) checklist at each visit. Review of the QA checklists showed the laboratory director last visited the laboratory on 3/18/22.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of new instrument and new test method verification studies, proficiency testing records, Bio-Rad quality control (QC) manufacturer's ranges, Unity QC monthly evaluation reports, patient testing logs, lack of documentation, and staff interview, the laboratory director failed to verify precision, verify the reportable range, and confirm the manufacturer's normal values were appropriate for the laboratory's patient population prior to patient testing (D5421), failed to attest to the routine integration of the American Proficiency Institute proficiency tests into the patient workload (D2009), failed to review and evaluate proficiency testing records (D5211), failed to ensure a procedure was developed to verify quality control material before use (D5469), and failed to ensure two levels of quality control were performed each day of patient testing (D5447, D5449).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on new instrument and new test method verification study review, lack of documentation, and staff interview, the laboratory director failed to verify precision, verify the reportable range, and confirm the manufacturer's normal values were appropriate for the laboratory's patient population prior to patient testing for 2 of 2 new test verification studies reviewed (Alcor Miniised erythrocyte sedimentation rate, Siemens Dimension EXL high-sensitivity troponin I). Refer to D5421.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory director or his designee failed to attest to the routine integration of the American Proficiency Institute (API) proficiency tests into the patient workload for 9 of 18 proficiency testing events reviewed from July 2021 through December 2022. Refer to D2009.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the API (American Proficiency Institute) proficiency testing (PT) records, lack of documentation, and staff interview, the laboratory director (LD) failed to review and evaluate proficiency testing results for 11 of 18 testing events reviewed from July 2021 to December 2022. Refer to D5211.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's documentation, review of Bio-Rad quality control (QC) manufacturer's ranges, Unity QC monthly evaluation reports, American Proficiency Institute proficiency testing records, patient testing logs, and staff interview, the laboratory director failed to ensure a procedure was developed to verify quality control material before use for 1 of 2 quality control crossover studies reviewed (Bio-Rad liquid assayed quality control material). Refer to D5469. In addition, the laboraoty director failed to ensure two levels of QC was performed each day of patient testing. Refer to D5447 and D5449.