Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0519862	08/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
So Big Horn Co Hospital	388 Us Hwy 20 South, Basin, 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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, review of personnel files, review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel report, policy and procedure review, and staff interview, the laboratory failed to ensure proficiency test results with a score of less than 100% were evaluated for 2 consecutive survey cycles 6/3/21 and 8/11/22. (D5211). In addition the laboratory failed to ensure competency assessments were completed as required (D5209) and an ongoing quality assessment program was in place (D5291).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel files, review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, lack of documentation, policy

	and procedure review, and staff interview, the technical supervisor (TS) failed to complete an initial competency assessment for 2 of 6 (TP #1, TP #2) new testing personnel prior to patient testing on the ABBOTT iSTAT instrument. In addition, an annual competency assessment had not been completed for 1 of 4 testing personnel (TP #3) operating the ABBOTT iSTAT instrument for 1 of 2 years reviewed (2021). The findings were: 1. Review of the personnel file for TP #1 showed he was hired on 6 /27/22 and a "6 month" competency assessment had been completed on 8/7/22 (2 months post-hire date). There was no evidence the TS had completed an initial competency assessment prior to TP #1 independently testing patient samples. 2. Review of the personnel file for TP #2 showed she was hired on 5/12/22 and a "6 month" competency assessment had been completed on 8/5/22 (3 months post-hire date). There was no evidence the TS had completed an initial competency assessment prior to TP #2 independently testing patient samples. Interview with TP #2 on 8/10/22 at 8:07 PM revealed the TS had provided training when she was hired and then the TS had given her a "refresher last week". 3. Review of the personnel file for TP #3 showed no evidence an annual competency assessment was completed in 2021. 4. Interview with the TS on 8/11/22 at 11:36 AM confirmed the laboratory did not have documentation of the initial competency assessments for TP #1 and TP #2 or the annual competency assessment for TP #3. 5. Review of the "Competency assessments" policy and procedure, last reviewed 6/9/21, showed "All testing personnel for the laboratory will be assessed upon hire, at 3 months, 6 months and 1 year for competency. Annual assessments will be conducted thereafter...Non Laboratory testing personnel 1. Proficiency i. Emergency room and Critical Access Hospital nurses are trained to perform dipstick urinalysis, waived diagnostic tests and the use of the IStat. Training will be documented...The Laboratory Director will review all competency assessment forms for all employees to ensure proper training is complete."
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 proficiency testing records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 4 of 17 proficiency testing events reviewed from May 2021 to August 2022. The findings were: 1. Review of the American Proficiency Institute (API) proficiency testing (PT) report failed to include documentation the laboratory had evaluated test scores of less than 100%. The following concerns were identified: a. Review of the 2021 API Microbiology Event #3 PT results showed the laboratory scored an 80% on gram stain morphology. There was no documentation the laboratory had evaluated the test results. b. Review of the 2022 API Microbiology Event #1 PT results showed the laboratory scored an 80% on gram stain morphology and an 80% on the gram stain. There was no documentation the laboratory had evaluated the test results. c. Review of the 2022 API Microbiology Event #2 PT results showed the laboratory scored an 80% on gram stain morphology. There was no documentation the laboratory had evaluated the test results. d. Review of the 2022 API Chemistry Event #1 PT results showed the laboratory scored an 80% on pH and an 80% on blood alcohol. There was no documentation the laboratory had evaluated the test results. 2. Interview with the technical supervisor on 8/11/22 at 11:33 AM confirmed the PT scores of less than

	100% had not been investigated. THIS IS A REPEAT DEFICIENCY, last cited on 6/3/21.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on policy and procedure review, lack of documentation, and staff interview, the laboratory failed to follow written procedures to monitor, assess, and correct problems in the general laboratory system for 2 of 2 years reviewed (2021, 2022). The findings were: 1. Review of the laboratory's documentation showed no evidence an ongoing quality assessment program was in place. 2. Review of the policy and procedure titled "QA/PI (Quality Assurance/Performance Improvement), last revised on 1/23/13, had not been signed and approved by the current laboratory director. 3. Interview with the technical supervisor on 8/11/22 at 11:33 AM revealed she participated in the hospital's quality assurance program, however she did not have a system in place to monitor, assess, and when indicated, correct identified problems within the laboratory.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to ensure written procedures were readily available to laboratory personnel for 4 of 6 IQCPs [individual quality control plan] (Microbiology using the Microscan, Microalbumin using the DCA Vantage instrument, Troponin I testing on the Abbott iSTAT instrument, BNP (B-type Natriuretic Peptide) testing on the Abbott iSTAT instrument). The findings were: 1. Interview with testing personnel #4 on 8/11/22 at 9 AM revealed she was unaware of where a written quality control procedure was located for the ABBOTT iSTAT instrument. Further, TP #4 stated the technical supervisor (TS) used a monthly planner to keep track of when quality control was due and then transferred the information to a dry erase calendar on the wall. 2. Observation on 8/11/22 at 11:15 AM showed the TS retrieved a flash drive from her desk drawer and printed out the IQCP for Microbiology, Microalbumin, Troponin I, and BNP. 3. Interview with the TS on 8/11/22 at 11:30 AM revealed she kept the procedures on the flash drive because the hospital would change her computer without notice.
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 3 of 5 procedure manuals reviewed (ABBOTT iSTAT, DCA Vantage, Miniised). The findings were: 1. Review of the ABBOTT iSTAT procedure manual used for testing blood gases, Troponin I, BNP (B-type Natriuretic Peptide), and a basic metabolic panel, last revised 4/9/18 and not signed by the laboratory director, showed the laboratory was using the operator's manual as the procedure manual. The operator's manual failed to include the laboratory's system for entering results in the patient record, the laboratory's quality control plan, and a description of the course of action to take if a test system became inoperable. 2. Review of the DCA Vantage procedure manual dated 10/7/13 showed the laboratory was using the operator's manual as the procedure manual. The operator's manual failed to include the laboratory's system for entering results in the patient record and a description of the course of action to take if a test system became inoperable. 3. Review of the Alcor Scientific Miniised erythrocyte sedimentation rate analyzer policy and procedure, signed by the laboratory director on 6/23/21, failed to include a description of the course of action to take if a test system became inoperable. 4. Interview with the technical supervisor on 8/11/22 at 8:15 AM revealed she had not submitted the ABBOTT iSTAT procedure manual to the laboratory director for review and confirmed the laboratory's procedure manuals were incomplete.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on policy and procedure review, lack of documentation, and staff interview the laboratory director failed to sign, and date as approved 6 of 11 policies and procedures (individual quality control plans for BNP (B-type Natriuretic Peptide, Troponin I, Microalbumin, and Microscan antibiotic screening, the quality assurance/performance improvement (QA/PI) procedure, ABBOTT iSTAT procedure manual) reviewed. The

	findings were: 1. Review of the procedure manual for the ABBOTT iSTAT used for testing blood gases, Troponin I, BNP, and a basic metabolic panel, last revised 4/9/18 showed the manual had not been signed by the laboratory director. 2. Review of the individualized quality control plans (IQCP) showed the following concerns: a. Review of the IQCP for ABBOTT iSTAT BNP cartridges showed the plan was issued on 8/23 /16 and had not been signed by the laboratory director. b. Review of the IQCP for ABBOTT iSTAT Troponin I testing showed the plan was issued on 8/23/16 and had not been signed by the laboratory director. c. Review of the quality control plan for microalbumin/creatinine testing on the DCA Vantage showed the plan was issued on 9 /19/16 and had not been signed by the laboratory director. d. Review of the IQCP for antibiotic sensitivity testing performed on the Microscan analyzer showed the plan was issued on 3/17/17 and had not been signed by the laboratory director. 3. Review of the QA/PI procedure last revised on 1/23/13 showed it had not been signed by the laboratory director. 4. Interview with the technical consultant on 8/11/22 at 10:54 AM revealed it was her expectation individual quality control plans be reviewed by the laboratory director on an annual basis.
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 3 new test verification studies reviewed (Siemens Dimension, Alcor Miniised). Since implementation the laboratory had performed approximately 8,864 chemistry tests, which included 38 analytes, on the Siemens Dimension analyzer and 295 erythrocyte sedimentation rates (ESR) on the Alcor Miniised. The findings were: 1. Review of the 6/17/21 new instrument verification study for the Alcor Miniised ESR test failed to show the performance specification of precision and 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. The verification study was signed by the laboratory director on 6/23/21. 2. Review of the 5/4/22 new instrument verification study for the Siemens Dimension failed to confirm the manufacturer's normal values were appropriate for the laboratory's patient population. 3. Interview with the technical supervisor on 8/11/22 at 9:06 AM confirmed the verification study did not include the performance specification of precision or reportable range. In addition, the TS revealed the laboratory continued to use the normal values that had been used with the previous method that had been discontinued.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)

	For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the new instrument and new test method verification study, review of the ThermoFisher Scientific CW 3 Cell Washer manufacturer's instructions for use, and staff interview, the laboratory failed to define a function check protocol to ensure system performance which is necessary for accurate and reliable test results for 1 of 1 cell washer/centrifuge (ThermoFisher Scientific CW 3). The findings were: 1. Review of the new instrument and new test method verification study showed a revolution per minute and timer check was documented at the time of installation on 7/30/21. 2. Review of the ThermoFisher Scientific CW3 Cell Washer manufacturer's instructions for use showed no function check protocols were provided by the manufacturer. 3. There was no documentation the laboratory had defined a function check protocol. 4. Interview with the technical supervisor on 8/10/22 at 4:10 PM confirmed function checks had not been performed on the CW 3 Cell Washer.
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 lack of documentation, review of the Abbott iSTAT manufacturer's instructions, and staff interview, the laboratory failed to verify the reportable range 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), the CG4+ test cartridge (pH, partial pressure of oxygen, partial pressure of carbon dioxide, BNP, and the Troponin I test cartridge analyzed on the Abbott i-STAT instrument for 2 of 2 years of testing (2021, 2022) reviewed. The laboratory performed approximately 1,175 patient tests annually using the Abbott iSTAT instrument. The findings were: 1. Review of the laboratory's records showed no documentation the reportable range of the analytes tested on the Abbott i-STAT instrument had been verified at least twice yearly. 2. Review of the Abbott i-STAT manufacturer's instructions showed "Calibration verification procedure is intended to verify the accuracy of results over the entire measurement range of a test as may be required by regulatory or accreditation bodies." 3. Interview with the technical supervisor on 8/11/22 at 11:33 AM confirmed the calibration verification studies had not been completed.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of the ABBOTT iSTAT troponin I patient test records, lack of documentation, and staff interview, the laboratory failed to ensure the laboratory's test records included the identity of the personnel who performed 1 of 4 (#1) patient tests reviewed. The findings were: 1. Review of the test record for patient #1 failed to show the identity of the testing personnel performing the test. The test was collected by an emergency room nurse on 7/17/22 at 4:06 AM. The instrument print-out showed the test was performed by operator #337; however the laboratory did not have a list of the operator numbers used by testing personnel. 2. Interview with the technical supervisor (TS) on 8/10/22 at 2:39 PM confirmed the laboratory's test records did not include the identity of the testing personnel. In addition, the TS stated the laboratory did not have a list of the operator numbers used by testing personnel on the ABBOTT iSTAT instrument.