Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0519862	06/03/2021
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the human chorionic gonadotropin (hCG) test records, review of the proficiency test records, and staff interview, the laboratory failed to enroll in an approved proficiency testing program for the regulated hCG analyte for 2 of 2 years of proficiency testing reviewed (May 2019 to May 2021). The laboratory performed approximately 38 serum pregnancy tests (hCG) per year. The findings were: Review of the proficiency test records from May 2019 through May 2021 showed no evidence the hCG analyte had been included in the endocrinology proficiency testing program. Interview with the general supervisor on 6/3/21 at 1:10 PM confirmed the laboratory did not perform proficiency testing for the hCG analyte.
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 12 of 21 proficiency testing events reviewed from May 2019 to May 2021. 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 2019 microbiology Event 1 PT results showed the laboratory scored an 80% for gram stains. There was no documentation the laboratory had evaluated the test results. b. Review of the 2019 hematology Event 1 PT results showed the laboratory scored an 80% for neutrophils. Review of the evaluation form showed it was signed by the general supervisor (GS) on 5/13/19 and signed by the laboratory director (LD) on 10 /22/19. There was no documentation the laboratory had evaluated the test results. c. Review of the 2019 chemistry Event 2 PT results showed the laboratory scored a 60% for gamma-glutamyl transferase (GGT). There was no documentation the laboratory had evaluated the test results. d. Review of the 2019 microbiology Event 2 PT results showed the laboratory scored a 60% for gram stains. There was no documentation the laboratory had evaluated the test results. e. Review of the 2019 Event 2 chemistry PT results showed the laboratory scored a 67% on urine toxicology. The evaluation form was signed by the GS on 12/11/19 and the LD on 12/12/19 with no investigative or corrective actions noted. f. Review of the 2019 hematology Event 3 PT results showed the laboratory scored an 80% on blood cell identification. The PT evaluation review page was not available. g. Review of the 2019 microbiology Event 3 PT results showed the laboratory scored a 40% on gram stain morphology. The evaluation was signed by the LD on 12/12/19 with no investigative or corrective actions noted. h. Review of the 2020 chemistry Event 1 PT results showed the laboratory scored an 80% for amylase and total triiodothyronine. Review of the evaluation form showed it was signed by the LD on 7/13/20 with no investigative or corrective actions noted. i. Review of the 2020 chemistry Event 2 PT results showed the laboratory scored an 80% on pH (acidity). There was no documentation the laboratory had evaluated the test results. j. Review of the 2020 chemistry Event 3 PT test results showed the laboratory scored 20% on pH and 40% on pCO2 (partial pressure of carbon dioxide). Review of the evaluation form showed it was signed by the GS on 10/20/20 and by the LD on 11/6/20 with no investigative or corrective actions noted. k. Review of the 2020 microbiology Event 3 PT results showed the laboratory scored a 60% on gram stains. Review of the evaluation form showed it was signed by the GS on 11/20/20 and by the LD on 3/9/21 with no investigative or corrective actions noted. l. Review of the 2021 chemistry Event 1 PT test results showed the laboratory scored 60% on brain natriuretic peptide and GGT. There was no documentation the laboratory had evaluated the test results. 2. Interview with the GS on 6/3/21 at 1:30 PM revealed there was no uniform time for review and signing the proficiency testing report. The GS stated "If there are no notes it was not investigated."
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 the laboratory's testing log, lack of documentation, and staff interview, the laboratory failed to have a system for verifying the accuracy of testing

	for wet mount preparations at least twice yearly for 1 year of testing reviewed (2020). The laboratory performed 3 wet mount preparations in 2020. The findings were: Review of the laboratory's 2020 testing log showed wet mount preparations had been performed. Review of the laboratory's documentation showed no evidence the procedure had been verified for accuracy. Interview with the general supervisor on 6/3 /21 at 11:15 AM confirmed the accuracy verification had not been completed.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to ensure blood collection tubes were not used beyond their expiration date in 2 of 2 blood collection sites (main lab and mobile tray). The findings were: Observation on 6/3/21 at 8:15 AM showed the general supervisor retrieved two EDTA blood collection tubes from the freezer and placed them in a cup of ice. Both tubes had an expiration date of 10/12 /20. Testing personnel (TP) #1 collected blood from the patient and used both of the expired tubes. Further observation showed 19 expired tubes were available at the main lab collection site and 4 expired tubes were located on the mobile tray. During the observation TP #1 confirmed the tubes were expired and discarded them at that time.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the CMS-209 Laboratory Personnel Report, review of personnel files, lack of documentation, and staff interview, the laboratory failed to ensure testing personnel were qualified to perform moderate complexity testing on the Abbott i-Stat analyzer (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a

	high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CMS-209 Laboratory Personnel Report, review of personnel files, staff interview, and lack of documentation, the laboratory failed to ensure testing personnel had the appropriate education required prior to testing patient specimens for 6 of 7 (#2, #3, #4, #5, #6, #7) testing personnel (TP) who performed moderately complex testing. The findings were: Review of the CMS-209 Laboratory Personnel Report showed the laboratory employed 7 testing personnel who performed moderate complexity testing. Review of the laboratory's personnel files showed no evidence of the required qualifications for TP #2, #3, #4, #5, #6, and #7. Interview with the general supervisor (GS) on 6/3/21 at 1:15 PM revealed the testing personnel were nurses who performed testing on the Abbott i-Stat analyzer. Interview with the GS on 6/3/21 at 10:25 AM and again by telephone on 6/7/21 at 2:06 PM confirmed the documentation was not available.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS-209 Laboratory Personnel Report, review of personnel files, review of proficiency testing records, review of the human chorionic gonadotropin (hCG) patient test records, lack of documentation, and staff interview, the laboratory director failed to ensure testing personnel had the appropriate education (D6102), ensure policies and procedures were in place to evaluate competency of testing personnel (D6103), ensure the laboratory was enrolled in proficiency testing (D6088), and ensure proficiency testing results were reviewed and evaluated (D6091).
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the human chorionic gonadotropin (hCG) test records, review of the proficiency test records, and staff interview, the laboratory director failed to ensure the laboratory was enrolled in an approved proficiency testing program for the regulated hCG analyte for 2 of 2 years of proficiency testing reviewed (May 2019 to May 2021). The laboratory performed approximately 38 serum pregnancy tests (hCG) per year (refer to D2000).
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure 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 proficiency testing records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 12 of 21 proficiency testing events reviewed from May 2019 to May 2021 (refer to D5211).
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the CMS-209 Laboratory Personnel Report, review of personnel files, and lack of documentation, the laboratory director failed to ensure testing personnel had the appropriate education required prior to testing patient specimens for 6 of 7 (#2, #3, #4, #5, #6, #7) testing personnel (TP) who performed moderately complex testing (refer to D6065).
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of personnel files, lack of documentation and staff interview, the laboratory director failed to ensure policies and procedures were established to ensure the general supervisor was competent and maintained competency. The findings were: Review of the laboratory's personnel files showed no evidence the general supervisor's competency evaluation had been completed in 2019. Interview with the general supervisor on 6/2/21 at 4:40 PM confirmed there was no documentation the competency evaluation for 2019 had been completed. An additional interview with the general supervisor on 6/7/21 at 2:06 PM verified the laboratory did not have a policy and procedure in place in regard to competency evaluations.