Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0519856	05/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cody Regional Health Dba/West Park Co Hospital	707 Sheridan Ave, Cody, 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
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on patient test reports review and interview with staff, the laboratory failed to document the date and time it received specimens collected at satellite locations. The number of tests collected at satellite locations and sent to the laboratory was not determined. Findings include: 1. Patient test reports reviewed included documentation for the date and time specimens were collected and received. Patient specimens from approximately 6 satellite laboratory locations included the same time for specimens collected as the time received at the laboratory where testing was performed. 2. In an interview with the laboratory supervisor on 05/02/2018 at approximately 2:00 P.M., the supervisor confirmed the satellite locations entered the time they collected specimens and entered the time the satellite locations accessioned the specimens as the time the laboratory where testing was performed received the specimens. The laboratory supervisor also confirmed satellite facilities operate under separate CLIA numbers and are not located at the same address as the laboratory that performed and reported tests.
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 procedure manual review, lack of documentation, and interview with staff,

	the director failed to sign and date procedural changes prior to use for 6 of approximately 49 test changes reviewed. Findings include: 1. Procedure manual review failed to include the director's approval with signature and date prior to implementation of changes for: A. New instrumentation and testing location changes for transition from the Rapid Point Instrument to the iSTAT instrument and testing being performed by respiratory therapy staff for arterial blood gas testing. The director failed to approve the changes for quality control, daily start up, instrument calibration, and specimen collection. B. Procedural documentation modification for Microbiology testing to document each Gram negative organism presented for identification have the Oxidase test result recorded prior to placing the test into the instrument for identification and susceptibility testing. C. New procedures for Vitamin D and Parathyroid Hormone testing. 2. In an interview with staff on 05/03/2018 at approximately 6:30 P.M., staff confirmed approvals for the changes to the procedures had not been approved by the director prior to being used to test and report patient samples.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on iSTAT cartridge storage temperature records review, lack of documentation, manufacturer's cartridge storage requirements, and interview with staff, the laboratory failed to ensure cartridge storage temperatures were monitored and documented and corrective actions were documented for missing records for 8 of 8 months (September 2017 through April 2018) of testing reviewed. Findings include: 1. The laboratory iSTAT cartridge storage refrigerator temperature records failed to document storage temperatures were maintained for 4 days in September of 2017 (16th, 17th, 24th, and 25th); 8 days in October 2017 (1st, 4th, 8th, 9th, 10th, 16th, 18th, and 19th); 4 days in November 2017 (3rd, 4th, 11th, and 23rd); and 3 days in December 2017 where the laboratory failed to record the temperature on the 1st, 2nd and 3rd then tapered off to not recording temperatures at all from January 2018 through April 2018. 2. The iSTAT cartridge package included instructions to store the reagents form 2 to 8 degress C. 3. In an interview with arterial blood gas testing staff on 05/02/2018 at approximately 1:30 P.M., staff confirmed the laboratory did not document they follow iSTAT test cartridge manufacturer's instructions for cartridge storage temperature requirements.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through

	493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on arterial blood gas (ABG) approved individualized quality control plan (IQCP) review, lack of documentation, and interview with staff, the IQCP failed to include a written quality assessment plan as the third required element of an IQCP. The laboratory performed approximately 10 ABG tests per month. Findings include: 1. The laboratory IQCP reviewed for ABG testing failed to include a written quality assessment plan to describe the laboratory's process to monitor, evaluate, and if indicated, correct problems identified with, for example, quality control performance, testing personnel competency, patient test record retention, proficiency testing review and test report filing in the patient's tests record plus other quality items identified by the laboratory. 2. In an interview with staff on 05/02/2018 at approximately 1:30 P.M. staff confirmed their IQCP did not include the laboratory's quality assessment plan for ABG testing on the iSTAT instrument. Based on arterial blood gas (ABG) quality control records review, approved individualized quality control plan (IQCP) review, and interview with staff, the laboratory failed to follow the IQCP established for ABG testing to perform 3 levels of quality control for each iSTAT instrument monthly and with each new lot number of test cartridges for 8 of 8 months of testing reviewed (September 2017 through April 2018). The laboratory performs approximately 10 ABG tests per month. Findings include: 1. Quality control records review included documentation the laboratory performed two levels of quality control with each new lot number of test cartridges and monthly. 2. In an interview with staff on 05/02/2018 at approximately 1:30 P.M. staff confirmed they performed two levels of QC monthly and was not aware the IQCP stated they were to perform three levels of QC.
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 proficiency testing records review, lack of corrective actions documentation, and interview with staff, the laboratory director failed to ensure the laboratory documented review for 1 of approximately 24 proficiency testing results that was less than 100% over two years of proficiency testing records reviewed (May 2016 to May 2018) to identify problems that may affect patient testing. Findings include: 1. Proficiency testing records review failed to include documentation the laboratory director ensured that a 60% score for Phenytoin from the first American Proficiency Institute (API) event of 2017 was reviewed to identify problems that require corrective actions be taken. The laboratory reported for CH-01 the value of 10.3 mg /dl. The acceptable range was (5.1 to 8.6). The laboratory reported for CH-05 17.6 mg

	/dl. The acceptable range was 8.8 to 14.8. 2. In an interview conducted on 05/03/2018 at approximately 6:00 P.M. staff confirmed corrective action documentation was not recorded in proficiency testing records available for the Phenytoin proficiency testing failure and that patient testing was not reviewed during the same timeframe to ensure patient testing was not similarly affected.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) 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 new instrument verification documentation review, testing personnel competency evaluation records review, lack of documentation, and interview with staff, the director failed to ensure prior to testing patient specimens for complete blood count (CBC) tests, testing personnel demonstrated that they could perform all CBC testing operations reliably and to provide and report accurate results for 10 of 10 CBC testing persons. Findings include: 1. The laboratory implemented a new CBC test system in 2017. 2. Competency evaluations failed to include direct observation testing personnel were evaluated for competency in performing CBC testing on the new Sysmex XLN instrument. 3. In an interview conducted on 05/03/2018 at approximately 6:00 P.M., staff confirmed testing personnel were trained via on-line courses without direct observation testing personnel could perform CBC testing operations on the new instrument reliably to provide and report accurate results.
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 lack of documentation and confirmation by staff, the laboratory failed to ensure 11 of 11 testing personnel met the qualification requirements to perform moderate complexity testing arterial blood gas testing. (See 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 testing personnel qualification records review, lack of documentation, and interview with staff, 11 of 11 new testing personnel performing arterial blood gas (ABG) tests failed to document their educational benchmarks as required to qualify as moderate complexity testing personnel. The laboratory performed approximately 10 ABG tests per month. Findings include: 1. Personnel qualification records review failed to include testing personnel's qualifying educational benchmarks for 11 of 11 ABG testing personnel. 2. In an interview conducted on 05/02/2018 at approximately 1:30 P.M., the ABG section supervisor confirmed the testing personnel possessed respiratory therapy licensure in lieu of educational benchmarks as documentation to qualify as moderate complexity testing personnel. State licensure as respiratory therapists are not acceptable documentation to meet moderate complexity testing qualification.