Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2122574	06/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cody Regional Health, Ems Department	707 Sheridan Avenue, 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
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 proficiency testing record review and staff interview, the laboratory failed to ensure proficiency specimens included in an "Event" were analyzed in the same manner as a patient sample for 7 of 7 American Proficiency Institute (API) proficiency testing events reviewed from January 2019 to March 2021 for the subspeciality of routine chemistry and 2 of 2 API proficiency testing events from September 2020 to January 2021 for the specialty of hematology. The findings were: Review of the proficiency testing records showed each API event contained 5 unknown samples. Review of the instrument printouts showed each unknown sample was tested using the Abbott i-Stat analyzer #389026 and the i-Stat analyzer #390973. Interview with the department manager on 6/2/21 at 12:24 PM confirmed both of the i-Stat analyzers were used when testing the proficiency testing samples.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by:

	Based on the lack of documentation, review of the Abbott i-Stat operator's manual, and staff interview, the facility failed to follow the i-Stat manufacturer's instructions to perform daily function checks as required for 2 of 2 years reviewed (May 2019 to May 2021). The laboratory tested approximately 100 samples per year which included blood gases and hematocrit. The findings were: 1. Review of the routine Quality Control Log for three i-Stat point of care chemistry analyzers (two actively used in patient care and 1 in correlation study for future use), showed quality control and simulator function checks were being performed weekly, alternating between the work shifts. There was a lack of entry on days the analyzers were actually used for patient care. 2. Interview with the Director of Emergency Management Services on 6/2 /21 at 11:45 AM confirmed quality control testing and function checks were performed only once a week, on a set schedule, without regard to patient testing. 3. Review of the Abbott i-Stat operator's manual showed "Verify the performance of each handheld in the i-Stat System using the internal or external Electronic Simulator every 24 hours of use, or as needed for regulatory compliance. In the USA, verification is required every 8 hours for blood gases, hematocrit..."