Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2122574	04/11/2019
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
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, patient test records review, patient chart records review, and interview with the laboratory director and the laboratory supervisor, the laboratory procedure manual failed to include the procedure for reporting venous blood gas analysis test results for 2 of 5 blood gas analysis reports reviewed. The laboratory performed approximately 10 to 20 blood gas tests per year. Findings include: 1. The laboratory procedure manual stated the laboratory reported the iSTAT test results into the patient's test record without differentiating between venous and arterial specimens. 2. Patient test records reviewed included the instrument printouts

	for pH, partial pressure carbon dioxide (pCO2), partial pressure oxygen (pO2), lactate, bicarbonate, base excess, and oxygen saturation. 3. Patient chart records reviewed included only the result for pH and lactate for patients 080420181342 and 120520181448. 4. In an interview conducted on 04/11/2019 at approximately 5:45 P. M., the department supervisor and the laboratory director confirmed the procedure did not specify that for venous specimens testing personnel were to report only the pH and lactate.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on lack of documentation, patient test reports review, patient chart records review, and interview with staff, the laboratory failed to establish and follow a written procedure to monitor, assess, and when indicated, correct problems identified in the post analytic portion of the testing process to document they monitored the accuracy test report results entered into the patient's chart record for blood gas tests and troponin I tests. The laboratory tested approximately 51 non waived tests per year. Findings include: 1. Patient test reports reviewed included instrument printout results for Troponin I for patient 103020181905; pH, partial pressure carbon dioxide (pCO2), partial pressure oxygen (pO2), lactate, bicarbonate, base excess, and oxygen saturation for patients #080420181342 and #120520181448. 2. Patient chart record review failed to include documentation there were complete test results for iSTAT blood gas tests in the patient's chart record for patient #080420181342 and #120520181448 (pH and lactate results only were reported); and failed to include iSTAT Troponin I results for patient #103020181905. 3. In an interview conducted on 04/11/2019 at approximately 5:55 P.M., the department supervisor and the director confirmed they did not include a method to review patient chart record test result entries to monitor the accuracy and reliability for entering tests ordered for emergency transported patients for blood gas and troponin I tests that did not have test results recorded in the patient's chart record for the tests that were performed.