Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2176125	05/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Rocky Mountain Oncology Lander	15 Shrine Club Rd, Lander, 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
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 1 of 2 testing events reviewed from November 2020 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% for 2021 Event 1. Results showed the laboratory scored an 80% for chloride. There was no documentation the laboratory had evaluated the test result. 2. Interview with the technical consultant on 5/5/21 at 10:54 AM revealed he was unaware of the requirement.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.

	(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of patient test records, lack of documentation, and staff interview, the laboratory failed to include gender in the test requisition information to ensure the correct normal range was used for 10 of 10 test requisitions reviewed (#1, #2, #3, #4, #5, #6, #7, #8, #9, #10). The lab performed approximately 7 CBCs (complete blood counts) per day. The findings were: 1. Review of patient test requisitions from 11/5/20 through 3/4/21 showed the test requisition failed to include the patient's gender. 2. Review of patient test records included different normal ranges for female and male patients. 3. Interview with the technical consultant on 5/5/21 at 11:10 AM confirmed gender had not been included on the test requisition.
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 2 of 2 procedure manuals reviewed (ABX Pentra 60 C+, ABX Pentra 400). The findings were: 1. Review of the ABX Pentra 60 C+ hematology analyzer procedure manual signed by the laboratory director on 9/18/20 showed the manual was provided by the manufacturer and did not contain all of the required sections. The procedure manual failed to include the following: a. The reportable range for white blood cells, red blood cells, platelets, hemoglobin, lymphocytes, monocytes, neutrophils, eosinophils, and basophils test results. b. The reference intervals or normal values. c. The panic or alert values. d. The procedure for entering and reporting the results. e. A description of what to do if the operating system became inoperable. 2. Review of the ABX Pentra 400 chemistry analyzer procedure manual prepared by the technical consultant on 9/1/20 and signed by the laboratory director on 9/18/20 showed the manual was provided by the manufacturer and did not contain all of the required

	sections. The procedure manual failed to include the following: a. The procedure manual directed the operator to contact the Technical Support Center for information pertaining to each analyses' interfering substances, however failed to include any guidance for interfering substances such as hemolysis, lipidemia, or bilirubinemia. b. The reportable range for alanine aminotransferase (ALT), albumin, alkaline phosphatase, aspartate transaminase (AST), total bilirubin, calcium, chloride, creatinine, glucose, potassium, sodium, total protein, and blood urea nitrogen (BUN). c. The reference intervals or normal values. d. The panic or alert values. e. The procedure for entering and reporting the results. e. A description of what to do if the operating system became inoperable. 3. Interview with the technical consultant on 5/5 /21 at 11 AM revealed he was unaware of the requirements for the procedure manual.
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 staff interview, the laboratory director failed to approve 1 of 3 procedure manuals (Specimen Collection and Processing/Basic Laboratory Safety manual) reviewed. The findings were: 1. Review of the Specimen Collection and Processing/Basic Laboratory Safety manual showed no documentation the director had signed and dated the procedure manual. 2. Interview with the technical consultant on 5/5/21 at 11:30 AM confirmed the procedure manual had not been approved by the laboratory director.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of instrumentation method verification records, lack of documentation, and staff interview, the laboratory director failed to evaluate and approve the results of the reportable range evaluation or establish normal ranges for 2 of 2 new analyzers (Pentra 60 C+, Pentra 400). The findings were: 1. Review of the method verification records for the Pentra 60 C+ hematology analyzer showed the reportable range had been verified, however the laboratory director had not signed the report as approved. 2. Review of the method verification records for the Pentra 400 chemistry analyzer and the Pentra 60 C+ hematology analyzer showed no documentation the normal range had been established. 3. Interview with the technical consultant on 5/5/21 at 11 AM confirmed the reportable range evaluation had not been signed by the laboratory director. In addition, the normal ranges had not been established for the laboratory.

D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation and staff interview, the laboratory director failed to ensure the laboratory had established a quality assessment plan for general laboratory, pre-analytic, analytic, and post-analytic systems for complete blood cell counts and comprehensive metabolic profiles. The findings were: 1. The laboratory procedure manual failed to include a quality assurance plan that included the items the laboratory reviews, the frequency of review, and the method they used to document the review in the following areas: a. General laboratory tasks which include proficiency testing review, testing personnel competency procedures, and complaint documentation and resolution. b. Pre-analytic tasks which include specimen collection, patient identification verification, specimen labeling, storage, and transportation. c. Analytic tasks which include review of quality control, instrument preventive maintenance, reagent replacement and test record logs. d. Post-analytic tasks which include test report accuracy. 2. Interview with the technical consultant on 5/5/21 at 11:25 AM confirmed the laboratory had not established a quality assessment plan.