Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D1049790	09/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Rocky Mountain Oncology	6501 East 2nd Street, Casper, 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 and staff interview, the laboratory failed to review and evaluate proficiency testing results for 6 of 12 testing events reviewed from January 2020 through September 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 2020 API chemistry event #1 results showed the laboratory scored an 80% on glucose and phosphorus. b. Review of the 2020 API hematology event #2 showed the laboratory scored an 80% on eosinophils. c. Review of the 2020 API chemistry event #2 showed the laboratory scored an 80% on chloride and sodium. d. Review of the 2020 API hematology event #3 showed the laboratory scored an 80% on basophils. e. Review of the 2020 API chemistry event #3 showed the laboratory scored an 80% on calcium and chloride. f. Review of the 2021 API chemistry event #1 showed the laboratory scored an 80% on sodium and potassium. 2. Interview with the laboratory manager on 9/29/21 at 1:55 PM confirmed the laboratory had not investigated the reason for the 80% scores.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different

	concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) record review, review of the patient testing logs, lack of documentation, policy and procedure review, and staff interview, the laboratory failed to perform two levels of quality control each day of testing for blood urea nitrogen (BUN), creatinine (CREA), alanine aminotransferase (ALT), and chloride (Cl) on the Pentra 400 for 4 of 4 months reviewed (May, June, July, August 2021). This failure affected the test result for BUN on 74 patient samples on 5/4 and 5/5; the test result for CREA on 31 patient samples on 6/10; the test result for ALT on 108 patient samples on 7/26, 7/27, and 7/28; and the test result for Cl on 36 patient samples on 8/10. The findings were: 1. Review of the QC records showed gaps on the Levey-Jennings charts where no data points had been recorded. The following concerns were identified: a. On 5/4/21 the high level of QC for BUN was run 6 times between 7:37 AM and 9:58 AM with no acceptable value achieved. On 5/5/21 the high level of QC was run 18 times between 7:20 AM and 2:45 PM with an acceptable value achieved at 3:04 PM. Review of the patient testing logs showed 74 patient samples had been reported on 5/4 and 5/5. b. On 6/10/21 the low level of QC for CREA was run 4 times with no acceptable value achieved. Review of the patient testing logs showed 31 patient samples had been affected. c. On 7/26, 7/27, and 7/28 the low level of QC for ALT was run with no acceptable value achieved. Review of the patient testing logs showed 108 patient samples had been reported during that timeframe. d. On 8/10/21 the low level of QC for Cl was run with no acceptable value achieved. Review of the patient testing logs showed 36 patient samples had been affected. 2. There was no documentation to show what action was taken by the laboratory to attempt to correct the failure of the quality control. 3. Review of the "Weekly QC Review" for May, June, July and August showed QC was marked as "okay" and signed by the technical consultant. 4. Interview on 9/29/21 at 3:10 PM with the technical consultant confirmed acceptable QC had not been achieved on 5/4, 5 /5, 6/10, 7/26, 7/27, 7/28, and 8/10. In addition there was no documentation to show what actions were taken by the laboratory to correct the failure. 5. Review of the Pentra 400 procedure manual showed "1.1.10 Failure to obtain proper values may indicate calibration, control or reagent deterioration, instrument malfunction, or miscalibration. If any control results are outside the acceptable ranges perform the following: re-run the control; clean the system and re-run the control; open a new vial of control; recalibrate the system."
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 the new instrumentation and test method verification study and staff interview, the laboratory director failed to ensure the study was completed to

	verify the performance specification of precision and failed to sign the accuracy study for 1 of 2 test systems reviewed (ABX Pentra 60 C+) prior to patient testing. The laboratory performed approximately 74,600 hematology samples per year. The findings were: 1. Review of the new instrumentation and test method verification study, dated 10/11/19, showed studies for precision had been completed, however an analysis of the data to verify the performance specifications had not been included in the report. In addition, accuracy studies had been completed, however the laboratory director failed to sign the report as approved prior to patient testing. 2. Interview with the technical consultant on 9/29/21 at 3 PM confirmed the new instrumentation and test method verification study was incomplete.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on quality control (QC) record review, review of the patient testing logs, lack of documentation, policy and procedure review, and staff interview, the laboratory consultant failed to ensure remedial actions were taken when QC was outside of the acceptable ranges for blood urea nitrogen (BUN), creatinine (CREA), alanine aminotransferase (ALT), and chloride (Cl) on the Pentra 400 for 4 of 4 months reviewed (May, June, July, August 2021). This failure affected the test result for BUN on 74 patient samples on 5/4 and 5/5; the test result for CREA on 31 patient samples on 6/10; the test result for ALT on 108 patient samples on 7/26, 7/27, and 7/28; and the test result for Cl on 36 patient samples on 8/10. Refer to D5447.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on quality control (QC) record review, review of the patient testing logs, lack of documentation, policy and procedure review, and staff interview, the laboratory consultant failed to ensure patient test results were not reported when QC was outside of the acceptable ranges for blood urea nitrogen (BUN), creatinine (CREA), alanine aminotransferase (ALT), and chloride (Cl) on the Pentra 400 for 4 of 4 months reviewed (May, June, July, August 2021). This failure affected the test result for BUN on 74 patient samples on 5/4 and 5/5; the test result for CREA on 31 patient samples on 6/10; the test result for ALT on 108 patient samples on 7/26, 7/27, and 7/28; and the test result for Cl on 36 patient samples on 8/10. Refer to D5447.