Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2176125	11/14/2022
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel files, review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, lack documentation, and staff interview, the technical consultant (TC) failed to complete a 6-month competency assessment for 1 of 3 (TP #3) testing personnel. In addition, an annual competency assessment had not been completed for the TC for 1 of 2 years reviewed (2021). The findings were: 1. Review of the personnel file for TP #3 showed an initial competency assessment had been completed on 4/7/21 and an annual competency assessment was completed on 2/2/22. There was no evidence the 6-month competency assessment had been completed. 2. Review of the personnel file for the TC showed no evidence a competency assessment had been completed in 2021. 3. Interview with the TC on 11 /14/22 at 2:10 PM confirmed the 6-month competency assessment for TP #3 had not been completed and was unable to locate his 2021 competency assessment.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on review of the ABX Pentra 60 C+ manufacturer's instructions for use (IFU), review of patient testing records, staff interview, and policy and procedure review, the laboratory failed to follow the manufacturer's instructions and review and resolve any instrument flags prior to reporting patient results for 7 of 21 (#1, #2, #3, #4, #6, #10, #21) patient test reports with flagged analytes reviewed. The findings were: 1. Review of the instrument printouts of patient testing showed the following concerns: a. Review of patient #1, dated 8/26/21, showed an exclamation point next to the white blood cell, neutrophil, lymphocyte, monocyte, eosinophil, and basophil counts. b. Review of patient #2, dated 8/26/21, showed an exclamation point next to the neutrophil, lymphocyte, monocyte, eosinophil, and basophil counts. c. Review of patient #3, dated 8/26/21, showed an exclamation point next to the neutrophil and lymphocytes counts. d. Review of patient #4, dated 8/26/21, showed an exclamation point next to the white blood cell, neutrophil, lymphocyte, monocyte, eosinophil, and basophil counts. e. Review of patient #6, dated 8/26/21, showed an exclamation point next to the neutrophil and lymphocyte counts. f. Review of patient #10, dated 6/24/21, showed the red blood cell and platelet counts were flagged with an exclamation mark. g. Review of patient #21, dated 3/11/22, showed an exclamation point next to the neutrophil and lymphocyte counts. 2. Interview with testing personnel #1 on 11/14/22 at 4:20 PM revealed she did not repeat patient samples when an exclamation point appeared on the instrument printout. 3. Review of the ABX Pentra 60 C+ policy and procedure, signed by the laboratory director on 9/28/20, failed to include a procedure for resolving the exclamation point flag prior to releasing patient results. 4. Review of the ABX Pentra 60 C+ IFU showed "6. Results Interpretation...6.1.2 Suspicion... A suspicion on a parameter is shown by "!". The sample must be rerun."
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to verify the statistical parameters of quality control material prior to use for 2 of 2 test systems reviewed (hematology, chemistry). The findings were: 1. There was no documentation the laboratory had verified new lot numbers of quality control material prior to being used on the hematology and chemistry analyzers. 2. Interview with the technical consultant on 11/14/22 at 3 PM confirmed the statistical parameters of the quality control materials had not been verified before use.