Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D1049790	08/21/2023
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
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 the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, review of personnel records, policy and procedure review, and staff interview, the laboratory failed to ensure the technical consultant's competency assessment had been completed for 2 of 2 years reviewed (2021, 2022). The findings were: 1. Review of the CMS 209 Laboratory Personnel Report showed 1 technical consultant for the specialties of Hematology and Chemistry. 2. Review of the personnel files for the technical consultant showed no documentation a competency assessment had been completed in 2021 or 2022. 3. Review of the "Employee Competency" procedure, provided by the laboratory, failed to include a system to evaluate the duties and responsibilities of the technical consultant. 4. Interview with the technical consultant on 8/21/23 at 3:35 PM confirmed the required competency assessments had not been completed and the policy and procedure failed to include a system to evaluate the duties and responsibilities of the technical consultant.
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 review of the CMS-116 form, procedure manual review, and staff interview, the current laboratory director failed to sign, and date as approved the laboratory's procedure manuals. The findings were: 1. Review of the CMS-116 form, dated 8/16 /23, showed a change of laboratory director had occurred since the last survey conducted on 9/29/21. 2. Review of the laboratory's procedure manuals failed to include the current laboratory director's signature and date of approval. 3. Interview with the technical consultant on 8/21/23 at 3:35 PM revealed the change in laboratory director occurred the first week of August 2023. The technical consultant confirmed the laboratory's policies and procedures had not been signed as approved by the current laboratory director.
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 patient test reports, the TOSOH AIA analyzer manufacturer's instructions for use, and staff interview, the laboratory failed to follow the manufacturer's instructions to include the prostate specific antigen (PSA) test assay method used on 2 of 2 PSA patient test reports (patient #1, patient #2) reviewed. The laboratory performed approximately 730 PSA tests per year. The findings were: 1. Review of the TOSOH AIA 360 analyzer manufacturer's instructions showed "... Because of differences in reagent specificity and assay methods, the concentration of PSA in a given specimen may vary with devices from different manufacturers. Values obtained with different assay methods cannot be used interchangeably. It is mandatory that results reported by the laboratory to the physician include the identity of the assay used..." The following concerns were identified: a. Review of the PSA test report for patient #1, dated 1/18/23, and for patient #2, dated 2/9/23, failed to include the test assay method. 2. Interview with the technical consultant on 8/21/23 at 5:06 PM confirmed the patient test reports did include the test assay method.
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 lack of documentation, review of the McKesson Variable Speed Centrifuge Operation Manual, and staff interview, the laboratory failed to follow the manufacturer's instructions to perform function checks every 3 months for 2 of 2 years (2021, 2022) reviewed. The findings were: 1. Review of the laboratory's documentation showed no evidence the revolutions per minute (RPM) or the timer was checked as directed. 2. Review of the McKesson Variable Speed Centrifuge

	Operation Manual, provided by the laboratory, showed "...Calibration...The centrifuge timer should be checked for accuracy at least every 3 months. The timer is an electronic timer designed to be accurate to 5min +/- 10sec. The speed should fall within +/- 150 RPM of 3,400 RPM." 3. Interview with the technical consultant on 8/21 /23 at 3:15 PM confirmed the function checks on the centrifuge had not been performed.
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 (QC) material prior to use for 2 of 3 test systems reviewed (Horiba Pentra C400, TOSOH AIA 360). The findings were: 1. Review of the QC records for the Horiba Pentra C400 analyzer showed the normal QC lot number 21053 was put into use on 10/3/22 and the abnormal QC lot number 21052 was put into use on 11/9/22 for the testing of routine chemistry. There was no documentation the laboratory had verified the new lot numbers of quality control material prior to being used on the chemistry analyzer. 2. Review of the QC records for the TOSOH AIA 360 analyzer showed the QC lot number 40430 used for the analytes TSH, CEA, ferritin, and PSA was put into use on 3/10/23. QC lot number 74620 used for the analytes CA 125 and CA 27.29 was put into use on 1/26/23. There was no documentation the laboratory had verified the new lot numbers of quality control material prior to being used on the immunoassay analyzer. 3. Interview with the technical consultant on 8/21/23 at 3:11 PM confirmed the statistical parameters of the quality control materials had not been verified before use.