Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2176125	05/19/2022
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: . Based on review of the Centers for Medicare and Medicaid Casper Report 155, review of the American Proficiency Institute (API) evaluation reports, and staff interview, the laboratory failed to participate in two out of three API Hematology proficiency testing events for the regulated analytes; erythrocytes, hematocrit, hemoglobin, leukocytes, and the white blood cell differential (2021 Event #2, 2022 Event #1). Refer to D2121. .
D2121	HEMATOLOGY CFR(s): 493.851(a)

	Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: . Based on review of the Centers for Medicare and Medicaid (CMS) Report Casper 155, review of the American Proficiency Institute (API) evaluation reports, and staff interview, the laboratory failed to participate in 2 out of 3 API Hematology proficiency testing (PT) events for the regulated analytes; erythrocytes, hematocrit, hemoglobin, leukocytes, and the white blood cell differential (2021 Event #2, 2022 Event #1). The findings were: 1. Review of the CMS Casper Report 155 and the API Hematology PT evaluations showed the laboratory failed to participate in the API Hematology 2021 Event #2 and the API Hematology 2022 Event #1. The laboratory received a score of 0% for each PT event. 2. Telephone interview on 5/19/22 at 9:04 AM with the technical consultant revealed he was unaware of the reason the API Hematology 2021 Event #2 was not completed and confirmed the API Hematology Event #1 was not completed due to an "oversight". .
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on review of the Centers for Medicare and Medicaid Casper Report 155, review of the American Proficiency Institute (API) evaluation reports, and staff interview, the laboratory director failed to ensure proficiency testing events were returned within the specified timeframe established by the proficiency testing program (D6017). .
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: . Based on review of the CMS (Centers of Medicaid and Medicare) CASPER Report 155D and staff interview, the laboratory director failed to ensure the results of 2 of 3 API (American Proficiency Institute) proficiency testing events (API Hematology 2021 Event #2, API Hematology 2022 Event #1) were returned within the specified timeframe established by the proficiency testing program. The findings were: 1. Review of CMS Casper Report 155D showed the laboratory scored a 0% on the API 2021 Hematology Event #2 and the API 2022 Hematology Event #1 for lack of

	participation. 2. Telephone interview on 5/19/22 at 9:04 AM with the technical consultant revealed he was unaware of the reason the API Hematology 2021 Event #2 was not completed and confirmed the API Hematology Event #1 was not completed due to an "oversight".