

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 53D2176125	<b>(X3) Date Survey Completed</b> 10/07/2024
<b>Name of Provider or Supplier</b> Rocky Mountain Oncology Lander	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, and staff interview, the laboratory failed to rotate the testing personnel performing 12 out of 12 API (American Proficiency Institute) chemistry core and hematology PT events reviewed from October 2022 through September 2024. The findings were: 1. Review of the CMS 209 Laboratory Personnel Report, dated 10/4/24, showed 5 testing personnel (TP #1, TP #2, TP #3, TP #4, TP #5) were listed as performing moderate complexity testing. 2. Review of the laboratory's PT records from October 2022 through September 2024 showed each of the 12 PT events were performed by TP #1. 3. Interview with the technical consultant on 10/7/24 at 1:33 PM confirmed the PT events had not been rotated between testing personnel.</p>
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>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 evaluate proficiency testing (PT) results for 2 of 12</p>

PT events reviewed from October 2022 through September 2024. The findings were: 1. Review of the American Proficiency Institute (API) 2023 Chemistry Core Event #3 proficiency testing evaluation showed the laboratory scored a 40% on glucose. Review of the corrective action form completed following the event showed the root cause for the failure had not been determined and a corrective action plan was not developed. 2. Review of the API 2023 Hematology Event #2 proficiency testing evaluation showed the laboratory scored an 80% on the monocyte cell count. There was no evidence the laboratory had investigated the cause of the failure of sample PNT-08. 3. Interview with the technical consultant on 10/7/24 at 1:50 PM confirmed the unsatisfactory PT scores had not been thoroughly investigated.

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

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 have a system in place for reviewing proficiency testing results that received an artificial score of 100% for 1 of 12 American Proficiency Institute (API) proficiency testing events reviewed from October 2022 through September 2024. The findings were: 1. Review of the 2024 API Chemistry Core Event #1 proficiency testing evaluation showed sample CH-02, CH-03, and CH-05 (total bilirubin) were not graded due to "result variance". There was no evidence the non-graded proficiency testing samples had been evaluated. 2. Interview with the technical consultant on 10/7/24 at 1:42 PM confirmed the non-graded proficiency testing samples had not been evaluated.