

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2176125	(X3) Date Survey Completed 11/22/2021
Name of Provider or Supplier Rocky Mountain Oncology Lander	Street Address, City, State 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	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Casper 155 report, review of the American Proficiency Institute (API) evaluation reports, and staff interview, the laboratory failed to successfully participate in two consecutive API chemistry core proficiency testing events for chloride (2021 event #2, 2021 event #3). Refer to D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid (CMS) Casper 155 report, review of the American Proficiency Institute (API) evaluation reports, and staff interview, the laboratory failed to successfully participate in two consecutive API chemistry core proficiency testing (PT) events for chloride (2021 event #2, 2021 event #3). The findings were: 1. Review of the CMS Casper 155 report and the API chemistry core PT evaluations showed the laboratory failed to successfully obtain a passing score for the analyte of chloride on the following API testing events: a. 2021 event #2 showed the laboratory scored a 40%. b. 2021 event #3 showed the laboratory scored a 20%. 2. Telephone interview on 11/22/21 at 3:28 PM with the technical consultant verified the laboratory had failed to achieve a passing score for chloride on the API 2021 PT event #2 and event #3.

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 155 report, review of the American Proficiency Institute (API) evaluation reports, and staff interview, the laboratory director failed to ensure an effective corrective action plan was developed to prevent reoccurrence of the failed analyte of chloride for 2 consecutive API chemistry core proficiency testing events (2021 event #2, 2021 event #3). Refer to D6019.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Casper 155 report, review of the American Proficiency Institute (API) evaluation reports, and staff interview, the laboratory director failed to ensure an effective corrective action plan was developed to prevent reoccurrence of the failed analyte of chloride for 2 consecutive API chemistry core proficiency testing events (2021 event #2, 2021 event #3). Refer to D2096.