

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D1049790	(X3) Date Survey Completed 10/21/2019
Name of Provider or Supplier Rocky Mountain Oncology	Street Address, City, State 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation, and confirmation by the laboratory manager/technical consultant, the laboratory director failed to sign two of six testing events reviewed from October 2017 to October 2019. Findings include: 1. Proficiency testing records review failed to include the director's signature, attesting proficiency testing samples were tested in the same manner as patient specimens the first and second Chemistry Core events of 2019. 2. In an interview conducted on 10/21/2019 at approximately 4:00 P.M., the laboratory manager /technical constant confirmed the attestation statements did not include the director's signature.</p>
D5211	<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>

This STANDARD is not met as evidenced by:
 Based on proficiency testing records review, lack of documentation, and interview with staff, the laboratory failed to review and evaluate the results obtained in 4 of 6 American Proficiency Institute (API) Chemistry and Hematology testing events. Findings include: 1. Proficiency test records review failed to include documentation the director reviewed the test results to identify problems that may require corrective actions for the Second and Third Chemistry core events of 2018, and the First and Second Hematology events of 2019. 2. In an interview conducted on 10/21/2019 and confirmation by the laboratory manager, the manager stated the director had not signed and dated as reviewed the four testing events stated above.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
 CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
 Based on calibration verification records review, lack of documentation, and interview with staff, the laboratory failed to perform reportable range verification on the Roche Integra at least once every six months for 1 of 4 six month periods reviewed between October 2017 and October 2019. Findings include: 1. The laboratory failed to perform reportable range verification for all tests reported at the zero or minimal level, mid level and at the upper level of the reportable range for tests performed on the Roche Integra for the first six month period of 2019. 2. In an interview with staff on 10/21 /2019 at approximately 4:10 P.M. the technical consultant six month verification was missed the first six months of 2019.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures

necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on proficiency testing reports review, corrective action documentation review, and interview with the technical consultant, the laboratory failed to ensure corrective actions taken for failed white blood cell (WBC) differential component Monocyte cell percentage was effective for four of six American Proficiency Institute (API) testing events reviewed. Findings include: 1. Proficiency testing records review included documentation the laboratory scored 60% for the 3rd API complete blood cell testing event of 2017; 40% for the 2nd and 60% for the 3rd API events of 2018 and 20% for the first event of 2019. 2. The laboratory corrective action records review included the corrective actions taken failed to resolve the differential calibration until the instrument manufacturer's representative corrected the WBC differential calibration following the 20% failure in 2019. 3. In an interview conducted on 10/21/2019 at approximately 4:10 P.M. the technical consultant stated the corrective actions taken by the laboratory did not correct the Monocyte cell percentage of the WBC differential until a differential calibration was performed by the instrument manufacturer after four API monocyte proficiency failures between October 2017 and October 2019.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on competency evaluations review and interview with the technical consultant, the laboratory director failed to ensure competency procedures for technical consultant included a review by personnel qualified to perform evaluations for 1 of 1 evaluations for the new technical consultant reviewed. Findings include: 1. Competency evaluations for the new technical consultant were performed by testing personnel who did not qualify to perform this task for competency evaluations on 02/28/2019 for Cobas Integra and Coulter AcT Diff (CP) instrument testing. 2. In an interview with the technical consultant on 10/21/2019 at approximately 4:10 P.M., the technical consultant stated the competency evaluation performed for the initial evaluation was not performed by the director.