Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2077631	10/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Rocky Mountain Infectious Diseases	1450 East A 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
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 lack of documentation and interview with staff, the laboratory failed to verify the reportable range for tests performed using the Au480 chemistry analyzer and the HMX complete cell counter (CBC) at least once every six months, twice in 2017 and once in 2018. The laboratory performed approximately 26 CBC's per week and 339 chemistry tests per week. Findings include: 1. The laboratory lacked documentation to verify Sodium, Potassium, Chloride, Creatinine, Glucose, Urea

	Nitrogen, Calcium, Carbon Dioxide, Total Protein, Albumin, Alanine transaminase, Alkaline Phosphatase, Aspartamine Transaminase, Creatine Kinase, C-Reactive Protein, and Vancomycin reportable ranges using at least a zero or minimal level value, a midlevel value, and a value at the upper level of the reportable range at least once every six months in 2017, and for the first six months of 2018. 2. The laboratory lacked documentation they followed Coulter HMX complete cell count instrument manufacturer's recommendations to verify calibration once every six months in 2017, and for the first six months of 2018. 3. In an interview with staff on 10/23/2018 at approximately 1:45 P.M., staff confirmed they did not verify the reportable ranges for tests performed on the Au480 instrument or perform calibration verification as recommended by the HMX manufacturer once every six months.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on humidity records review, lack of documentation, laboratory daily environmental logs review, and interview with staff, the laboratory failed to document they followed their policy to monitor and when indicated correct the failure to monitor laboratory humidity percent each day of testing in January, February, and April of 2018. Findings include: 1. Humidity records reviewed failed to include documentation the laboratory monitored Humidity in January 2018, failed to record humidity on 01, 05, 06, 07, 08, 09, 12, 13, 14, 15, 16, 19, 20, 21, 22, 23, 26, and 27 of February 2018, and in April of 2018 failed to record humidity only on 02, 03, 04, 06, 09, 10, 13, 16, 18, 19, 20, 25, and 27. 2. In an interview with staff on10/23/2018 at approximately 2: 20 P.M., staff stated they did not realize the forms were missing or incomplete.