Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0520182	10/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Castle Rock Medical Center	1400 Uinta Drive, Green River, 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 calibration records review, lack of documentation, and interview with staff, the laboratory failed to verify the reportable range at least once every six months using testing materials with values at the zero or minimal level, at the mid-level, and at the upper level of the reportable range for 10 of 10 tests reported from the Vitros 350 instrument, Alkaline Phosphatase, Alanine Transaminase, Amylase, Aspartate Transaminase, Potassium, Chloride, Uric Acid, Triglycerides, Phosphorous, and

	Magnesium tests reviewed from October 2016 to October 2018. The laboratory performed approximately 12,000 of these tests per year. Findings include: 1. Calibration records review failed to include documentation the laboratory verified calibration at least once every six months in 2017 and 2018 for Alkaline Phosphatase, Amylase, Potassium, Chloride, Uric Acid, Triglycerides, Phosphorous, and Magnesium. 2. Calibration records review failed to include documentation they used a material with a zero or minimal value, midlevel value, and a value at the upper level of the reportable range for Potassium, Sodium, and Chloride once every six months of testing for 3 of 4 six month periods between October 2016 and October 2018. 3. In an interview conducted on 10/25/2018 at approximately 5:30 P.M., the laboratory technical consultant stated the laboratory did not have a process to verify the reportable range at least once every six months using at least 3 levels of assayed materials at the low, mid, and upper level of the testing reportable range. This is a repeat deficiency.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on Individualized Quality Control Plan (IQCP) review, lack of documentation, and interview with staff, the laboratory failed to include a risk assessment and a quality assessment plan for the IQCP for 6 of 6 tests performed using the Cepheid Gene Expert molecular detection system for Group A Strep, Flu A and B, Neisseria Gonorrhea, Chlamydia, and Respiratory Syncytial Virus. Findings include: 1. The IQCP failed to include a risk assessment and quality assessment plan for reducing the frequency of quality control to two levels of control for each new lot number of test kits from the standard frequency of two levels of controls each day of testing. 2. In an interview conducted on 10/25/2018 at approximately 3:45 P.M., the laboratory technical supervisor stated the approved laboratory IQCP failed to include the required risk assessment and quality assessment plan needed to monitor the reduction in quality control frequency.