Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0520182	11/16/2022
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency testing record review and staff interview, the laboratory failed to ensure all of the proficiency testing specimens within a specialty or subspecialty received in a "quarter" were analyzed by one analyst for 4 of 14 College of American Pathologist (CAP) and American Association of Bioanalysts (AAB) testing events reviewed from November 2020 to November 2022. The findings were: 1. Review of the CAP and AAB attestation statements showed the following concerns: a. Review of the 2021 first quarter AAB chemistry proficiency testing event showed basic chemistry samples #1 and #2 were performed by testing personnel (TP) #1 and samples #3, #4, and #5 were performed by TP #2. Special chemistry and bilirubin sample #1 was performed by TP #2 and sample #2 was performed by TP #1. b. Review of the 2021 first quarter CAP Chlamydia/Neisseria gonorrhoeae proficiency testing event showed the samples were split between TP #1 and TP #2. c. Review of the 2021 second quarter AAB special chemistry proficiency testing event showed the samples were split between TP #3 and TP #4. d. Review of the 2022 second quarter AAB chemistry proficiency testing event showed the bilirubin, microalbumin, lipids, basic chemistry, and immunochemistry samples were split between TP #1 and TP #2. In addition, non-chemistry proficiency testing samples for infectious mononucleosis, Cryptosporidium/Giardia, and Clostridium difficile testing samples were split between TP #2 and TP #5. 2. Interview with the laboratory director on 11/15/22 at 3 PM revealed she was unaware of the regulation and split the proficiency samples between testing personnel to evaluate competency.

D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation and staff interview, the laboratory failed to report 586 SARS-CoV-2 negative test results from 5/1/22 through 11/16/22. The findings were: 1. Observation of the laboratory showed testing for SARS-CoV-2 was performed using a molecular platform on the Cepheid Gene Xpert Xpress and the Abbott ID Now test systems 2. Interview with the laboratory director on 11/16/22 at 10:39 AM revealed the laboratory had reported 257 positive SARS-Co-V-2 test results to the State Public Health Laboratory, however the laboratory had not reported the 586 negative test results. Further, the laboratory director stated she was unaware of the regulation.
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 test results that received an artificial score of 100% due to lack of peer group data for 2 of 6 American Association of Bioanalysts (AAB) proficiency testing events reviewed from November 2020 to November 2022. The laboratory performed approximately 378 prostate specific antigen (PSA) tests annually. The findings were: 1. Review of the AAB proficiency testing evaluation forms showed the laboratory received an artificial score of 100% on the analyte of PSA on the first and second events of 2022 due to lack of peer group data. There was no documentation the results of the proficiency testing events had been evaluated for accuracy. 2. Interview with the laboratory director on 11/15/22 at 4:47 PM confirmed an evaluation of the proficiency testing results had not been evaluated for accuracy.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks

	may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the CMS (Centers for Medicare and Medicaid Services) 116 form, lack of documentation, and staff interview, the laboratory failed to have a written procedure for reporting SARS-CoV-2 test results to the appropriate agencies. The findings were: 1. Review of the CMS-116 form showed the laboratory performed SARS-Co-V-2 testing using the Abbott ID Now and the Cepheid Gene Xpert Xpress test systems. 2. Review of the laboratory's procedure manuals showed no evidence the laboratory had developed a policy and procedure for reporting SARS-Co-V-2 test results to the appropriate agencies. 3. Interview with the laboratory director on 11/16 /22 at 10:39 AM confirmed the laboratory did not have a written procedure for reporting SARS-Co-V-2 patient test results.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's environmental records, review of manufacturer's instructions, and staff interview, the laboratory failed to monitor humidity in the testing and reagent storage areas. The laboratory performed approximately 70,000 patient tests annually. The findings were: 1. Review of the daily environmental log sheets showed the humidity level in the laboratory was not monitored. 2. Review of the manufacturer's instructions for the Sysmex SN-L 430 hematology instrument showed the relative humidity must be maintained between 10 and 95%. The Diagnostica Stago Start 4 instrument required the relative humidity to be maintained between 20 and 80%. 3. Interview with the laboratory director on 11/16/22 at 10:32 AM confirmed the humidity of the laboratory had not been monitored.