Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0520182	11/04/2020
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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. 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 proficiency test results for 8 of 18 American Association of Biocatalysts (AAB) and College of American Pathologists (CAP) proficiency testing events reviewed for testing performed from November 4, 2018 to November 4, 2020. Findings include: 1. Proficiency testing records review failed to include documentation of review of proficiency test results for: AAB Proficiency Agency Score/Analyte Event 2nd Chemistry 2019 80%/Carbon Dioxide 80%/ Iron 2nd Non-Chemistry 2019 100% 3rd Chemistry 2019 100% 3rd Non-Chemistry 2019 80% Cell ID Basophilic Stippling reported Acceptable = Giant Platelet 1st Chemistry 2020 80% Albumin 80% Cholesterol 80% Alanine Transaminase 1st Non-chem 2020 80% Influenza B 2nd Non-Chem 2020 100% CAP 3rd 2018 Hematology 80% Protime 2. In an interview conducted on 11/04/2020 at approximately 6:15 PM, the director confirmed the proficiency tests listed lacked documentation results were reviewed to identify problems that may need corrective actions. .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: . Based on laboratory test menu review, lack of documentation and interview with the director, the laboratory failed to verify post vasectomy semen analysis test accuracy at least twice annually in 2019. The laboratory performed from 0 to 3 post vasectomy tests per year. Findings include: 1. The laboratory test menu included post vasectomy semen analysis. 2. The laboratory failed to document twice annual accuracy verification of post vasectomy semen analysis test results twice annually in 2019. 3. In an interview conducted on 11/04/2020 at approximately 4:59 P.M. and 6:15 P.M., the director confirmed the lab lacked verification of post vasectomy test accuracy performance at least twice annually in 2019. The laboratory performed approximately 5-10 semen analysis per year. Based on patient test report review, lack of documentation, and interview with the director, the laboratory failed to verify preliminary, presumptive Gram Negative Bacilli growth and no growth for urine culture testing at least twice annually for 1 of 2 urine colony counts tests reviewed. The laboratory performs approximately 285 colony counts per week. Findings include: 1. Patient test report review for a urine colony count for patient 243517 on 07 /10/2019 included the colony count of 10,000 to 50,000 colonies. The report also included the statement preliminary results - Possible pathogen GNR (Gram Negative Rods). Sent for identification an susceptibility testing). 2. The laboratory failed to document they checked presumptive identification of growth on MacConkey Agar for accuracy at least twice annually in 2019. 3. In an interview conducted on 11/04/2020 at approximately 6:00 P.M., the director stated they believed the presumptive report did not require twice annual accuracy verification since they participated in Colony Count Proficiency testing and specimens were referred for confirmation. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on procedure manual review, lack of documentation, and interview with the director, the laboratory failed to revise the laboratory procedure manual to include the current step-by-step procedure for performing microscopic manual white blood cell differentials. The laboratory performed approximately 1 manual differential per day for results flagged by the automated cell counter for follow-up testing. Findings

	include: 1. Hematology procedure manual review failed to include the revised procedure to perform a manual differential to confirm results flagged by the automated complete blood cell count and five part differential and to refer the differential for abnormal findings to a reference laboratory. 2. In an interview conducted on 11/04/2020 at approximately 3:50 P.M., the director confirmed the laboratory failed to update the procedure manual to include the current step-by-step process for manual white blood cell differentials. .
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on procedure manuals review, lack of documentation, and interview with the laboratory director, the director failed to sign and date as approved the laboratory procedure manuals for the subspecialties of microbiology, parasitology, virology, general immunology, routine chemistry, urinalysis, endocrinology, and the specialty of hematology from April 2020 to November 04, 2020. The laboratory performed approximately 54,500 tests per year. Findings include: 1. Procedure manuals review failed to include the signature and date of approval by the current laboratory director. 2. Procedure manuals for testing in the subspecialties of microbiology, parasitology, virology, general immunology, routine chemistry, urinalysis, endocrinology, and the specialty of hematology . 3. In an interview conducted on 11/04/2020 at approximately 11:30 A.M. and 6:30 P.M., the director confirmed the previous director resigned by telephone in April 2020. The laboratory discontinued the one high complexity test performed (manual differential including abnormal cells and RBC morphology review) for the technical supervisor to move into the director's position. The new director did not sign and date the procedure manuals as approved. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on quality control records review, direct observation, lack of documentation, and interview with staff and the laboratory director, the laboratory failed to perform two levels of quality control each day of testing for two of two years of test records reviewed for one of one urine quantitative test reviewed, (urine microalbumin). The laboratory performed approximately 4 tests per week. Findings include: 1. Quality control records review failed to include documentation the laboratory performed two control material of different concentrations each day of urine microalbumin patient testing performed for DCA Vantage. 2. Direct observation of DCA microalbumin testing on 11/04/2020 at approximately 10:45 A.M. failed to include performance of control materials prior to testing patient samples. 3. Patient test log record review

	failed to include documentation of control materials of different concentrations performance each day of patient testing. 4. In an interview conducted on 11/04/2020 at approximately 6:10 P.M., the laboratory director confirmed control materials of different concentrations were not performed each day of urine microalbumin testing. THIS IS A REPEAT DEFICIENCY .
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on quality control records review, patient test records review, lack of documentation, and interview with staff and the laboratory director, the laboratory failed to perform two levels of quality control each day of testing for two of two years of test records review for three of eight qualitative tests reviewed, Crytosporidium, Giardia, and Clostridium difficile (C.diff). The laboratory performed approximately 130 tests performed. Findings include: 1. Quality control records review failed to include documentation the laboratory performed two levels (a positive and a negative) of quality control each day of patient testing performed for Alere Quick Vue C. difficile and the Combination Kit for Giardia and Cryptosporidium presence or absence. 2. Patient test log record review failed to include documentation of a positive and negative control material performed each day of patient testing. 3, In an interview conducted on 11/04/2020 at approximately 6:10 P.M., staff and the laboratory director confirmed the laboratoary failed to perform positive and negative control materials each day of C.diff, Giardia, and Cryptosporidium testing. THIS IS A REPEAT DEFICIENCY. .
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation, and interview with staff, the laboratory director failed to ensure proficiency test results were reviewed to identify sources of error that may requrie corrective actions to prevent recurrence or affect patient test results for 5 of 6 American Association of Bioanalysts (AAB) and College of American Pathologists proficiency testing events reviewed. Findings include: 1. Proficiency testing records review failed to include the director reviewed proficiency test results to identify tests that may need corrective actions

	taken to correct test problems for testing events: AAB 2nd chemistry event of 2019 for a score of 80% for carbon dioxide and 80% for Iron; AAB 3rd non-chemistry event of 2019 for a score of 80% for Red Blood Cell morphology; AAB 1st chemistry event of 2020 for a score of 60% for microalbumin; AAB 1st non-chemistry event of of 2020 for a score of 80% for influenza; and CAP 3rd event of 2018 for a score of 80% for protime. 2. In an interview with staff on 11/04/2020 at approximately 6:15 P. M., the director confirmed 80% scores were not routinely investigated for the cause of the less than 100% test score to ensure patient testing was not similarly affected. .