Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0520182	11/05/2024
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel files, review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, policy and procedure review, and staff interview, the laboratory failed to ensure an annual competency assessment had been completed for 1 of 3 testing personnel (LD/TC/TP #1) for 2 of 2 years (2022, 2023) reviewed. The findings were: 1. Review of the CMS 209 Laboratory Personnel Report showed LD/TC/TP #1 performed the duties of the laboratory director (LD), the technical consultant (TC), and testing personnel (TP). Review of the personnel file for LD/TC/TP #1 showed no competency assessments had been completed to evaluate her testing personnel responsibilities in 2022 or 2023. 2. Interview with LD/TC/TP #1 on 11/5/24 at 12 PM confirmed the competency assessments for her testing personnel responsibilities had not been completed. 3. Review of the "Policy and Procedure for Laboratory Staff Competency Assessment", last revised 6/19/24, showed "Every lab employee shall regularly be assessed for competency for the tasks defined by their position's job description..." The policy stated a competency assessment would be conducted upon hire, at 6-months, and annually thereafter.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results

	within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of patient test reports, the VITROS XT 7600 analyzer manufacturer's instructions for use, and staff interview, the laboratory failed to follow the manufacturer's instructions to include the prostate specific antigen (PSA) test assay method on 1 of 1 PSA patient test reports (patient #1) reviewed. The laboratory performs approximately 527 patient PSA tests annually. The findings were: 1. Review of the VITROS XT 7600 analyzer manufacturer's instructions stated "Different test methods cannot be used interchangeably. PSA results in a given patient sample determined with different tests and from different manufacturers can vary due to differences in test methods and reagent specificity. A change to a different method during serial monitoring of a patient should be accompanied by additional sequential testing to confirm baseline values. The results reported by the laboratory to the physician must include the identity of the PSA test used." Review of the VITROS XT 7600 new instrument verification study showed the study was approved by the laboratory director on 4/28/23. The following concerns were identified: a. Review of the PSA test report for patient #1, dated 10/30/24, failed to include the test method used. 2. Interview with the laboratory director on 11/5/24 at 4:30 PM confirmed the PSA test method was not included on the patient test reports.