Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0520036	07/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Weston County Health Services	1124 Washington Blvd, Newcastle, 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
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. 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 document corrective actions taken for proficiency testing failures to prevent recurrence and ensure reviews were conducted with staff performing testing to resolve problems and revise policies and procedures to ensure patient testing was not similarly affected for 2 of 2 tests, urine microalbumin and Bacteriology susceptibility testing. Findings include: 1. Proficiency testing record review included documentation the laboratory failed susceptibility testing for the 3rd American Proficiency Institute (API) Bacteriology event of 2016 with a score of 75% and failed susceptibility testing the 2nd API event of 2017 with a score of 43% for urine cultures and failed urine microalbumin testing the 3rd event of 2016 and the 2nd event of 2017 with 0% scores. 2. The laboratory failed to document the quality assessment plan included review of corrective actions taken after the 1st failure for effectiveness and that patient test results were reviewed during the same timeframe as the failed susceptibility tests to ensure patient susceptibility tests were not similarly affected. 3. In an interview conducted on 07/31/2018 at approximately 6:00 P.M. staff confirmed the laboratory quality assessment plan did not include a process to review patient testing when corrective actions taken for proficiency testing failures did not correct problems and subsequent failures occurred.
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 the laboratory manager, the laboratory failed to include a quality control plan and quality assessment plan for 1 of 1 new IQCP reviewed for Clostridium difficile (C.difficile) testing using the Illumagene test system. Findings include: 1. The IQCP reviewed for C. difficile failed to include a quality control plan (QCP) stating the number of external controls to be tested for each new lot number of test kits and failed to include a quality assessment plan (QAP). 2. In an interview with the laboratory manager on 07/31/2018 at approximately 6:30 P.M. the laboratory manager stated the IQCP did not include a QCP or QAP for C. difficile testing. The lab tested approximately 12 to 20 specimens for C. difficile per year.
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 the Individualized Quality Control Plan (IQCP) review, quality control record review, lack of documentation, and confirmation by the laboratory director the laboratory failed to perform a positive and negative quality control each day of testing until the IQCP for reduced frequency of control performance for Clostridium difficile (C. difficile) was approved by the director on 07/30/2018. The laboratory performed approximately 20 tests per year. Findings include: 1. The IQCP review included the approval by the director's signature for the plan dated 07/30/2018. 2. Quality Control (QC) records failed to include documentation the laboratory performed external positive and negative quality control for C. difficile each day of testing. The practice was to perform QC for each new lot number of test kit, (approximately 2 per year). 3. In an interview with the laboratory manager on 07/31/2018 at approximately 11:30 A. M. the manager stated the IQCP was signed on 07/30/2018 by the director.