Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0520036	09/03/2020
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
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 records review, lack of documentation and interview with staff, the laboratory director failed to attest to the routine integration of proficiency test (PT) samples into the patient workload using the laboratory's routine methods for 9 of 17 testing events reviewed. Findings include: 1. Proficiency testing attestation statements reviewed from: a. The 1st, and 3rd of 2019, and the 1st and 2nd core chemistry events of 2020 reviewed failed to include the director's signature attesting to the routine integration of PT samples. b. The 1st miscellaneous chemistry event of 2020 failed to include the director's signature attesting to the routine integration of PT samples. c. The 2nd and 3rd Hematology events of 2019 and the 1st event of 2020 failed to include the director's signature attesting to the routine integration of PT samples. d. The 3rd immunohematology events of 2019 failed to include the director's signature attesting to the routine integration of PT samples. 2. In an interview with the laboratory director on 09/03/2020 at approximately 5:30 P.M., the laboratory manager confirmed the 9 attestation statements did not include the signature of the laboratory director
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.

	This STANDARD is not met as evidenced by: Based on lack of documentation and confirmation by staff, the laboratory failed to document the date microbiology testing was discontinued for organism identification, susceptibility testing, blood culture testing, and Methicillin Resistant Staphylococcus A testing. Findings include: 1. The laboratory procedure manuals failed to include the date testing was discontinued for bacteriology tests. 2. In an interview conducted on 09 /03/2020 at approximately 4:45 P.M., the laboratory manager stated bacteriology culture testing was discontinued in April 2019 and confirmed the laboratory failed to document the date the bacteriology procedure was no longer in use.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency testing record review, lack of corrective action documentation, and interview with staff, the laboratory general system quality assessment failed to prevent recurrence for 3 of 5 neonatal bilirubin event failures (1st and 2nd events of 2019 and the 2nd event of 2020) and for 3 of 3 direct bilirubin event failures (3rd event of 2018, 1st and 2nd events of 2019. Findings include: 1. Proficiency testing records review failed to include a review of the corrective actions taken to prevent recurrence of the errors resulting in failures for 3 of 5 neonatal bilirubin events: the 1st event of 2019 for a score of 0% was no results from the analyzer. The 2nd events of 2019 for a score of 50% was wrong results were recorded. The 2nd event of 2020 for a score of 50% was no corrective actions recorded. For specimen NB-07 results of 2.1 the acceptable range was 0.0 to 0.6 mg /dl. 2. Proficiency testing records review failed to include a review of the corrective actions taken to prevent recurrence of the errors resulting in failures for 3 of 5 direct bilirubin events: 3rd event of 2018 for a score of 50% was clerical error. 1st event of 2019 for a score of 50% was clerical error. 2nd event of 2019 for a score of 50% was no corrective action recorded for: a. Specimen CH-07 reported as 1.6 the acceptable range was 0.0-0.9 mg/dl; b. Specimen CH-08 reported as 1.1 the acceptable range was 0.0-0.7 mg/dl. 3. In an interview conducted on 09/03/2020 at approximately 5:50 P. M., the laboratory manager confirmed the laboratory quality assessment program previously failed to review proficiency testing corrective actions effectiveness in preventing recurrence of neonatal and direct bilirubin testing.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1)

	Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Illumagene C. Difficile Individualized Quality Control Plan (IQCP) review, lack of documentation, patient test report review, and confirmation by staff, the laboratory failed to include a quality control plan (QCP) stating the number and frequency of liquid controls performance and approved by the director from 02/07 /2019 to 09/03/2020. The laboratory performed approximately 1 C. difficile test every 2 months. Findings include: 1. IQCP review included the director's approval of the risk assessment portion of the C. Difficile IQCP on 02/07/2019. 2. IQCP review failed to include a Quality Control Plan stating the number and frequency of qualify control performance. 3. In an interview conducted with the laboratory manager on 09/08/2020 at approximately 5:00 P.M., the laboratory manager confirmed the IQCP lacked a QCP.
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 patient test records review, lack of documentation, and confirmation by the laboratory manager, the laboratory failed to perform 2 levels of controls each day of testing for 1 of 1 day of parathyroid hormone testing. The laboratory performed approximately 2000 hormone tests per year. Findings include: 1. Patient test records review included documentation the laboratory performed a parathyroid test for patient 20C-07C0006 collected on 03/10/2020 and reported as 70.3pg/ml. 2. The laboratory lacked documentation 2 levels of quality control was performed on 03/10/2020 or the date the specimen was tested. 3. In an interview conducted on 09/03/2020 at approximately 6:40 P.M., the lab manager confirmed the control values could not be located on the instrument or in the quality control records. The number of parathyroid specific hormone tests was not determined.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for

	acceptability. This STANDARD is not met as evidenced by: Based on patient test reports review, manufacturer's package instructions review, lack of documentation and confirmation by staff, the laboratory report for Prostate Specific Antigen (PSA) tests failed to include the information for interpretation required by the manufacturer. The laboratory performed approximately 50 PSA tests per year. Findings include: 1. Patient test reports review included a PSA result of 9.48 ng/ml for patient #20WC-008C0041 collected on 01/08/2020. 2. Vitros 5600 manufacturer's instructions included instructions for reporting PSA test results the laboratory must include as: "The concentration of total PSA varies with different assay methods. Values obtained with different assay methods cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used is changed additional testing should be carried out and new baselines confirmed. (Name of facility) method for testing PSA is Vitro's Immunoassay." 3. In an interview conducted on 09/03/2020 at approximately 5:00 P.M., the laboratory manager confirmed the test report failed to include the manufacturer's instructions for reporting PSA results.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on Sysmex LN-10 verification studies review, lack of documentation, and interview with staff, the laboratory director failed to document verification procedures used were adequate for the LN-10 instrument prior to reporting patient test results in August 2018 (Studies were completed on 08/08/2018). Findings include: 1. Verification studies review failed to include the approval of the verification of the LN-10 accuracy, precision, reportable range, and normal range verification prior to reporting patient results. 2. In an interview conducted on 08/03/2020 at approximately 4:50 P.M., staff confirmed the LN-10 studies lacked the director's signature and date of approval.