Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0662176	11/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Hospital Of Carbon County	2221 W Elm St, Rawlins, 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
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 direct observation on 11/10/2020 at approximately 8:10 A.M., procedure manual review and interview with staff, the laboratory failed to follow the laboratory procedure to positively identify blood product recipients. See D3023. .
D3023	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient. This STANDARD is not met as evidenced by: . Based on direct observation, procedure manual review, and interview with staff, the laboratory failed to follow their procedure to ensure positive identification of a blood product recipient for 1 of 1- 3 unit crossmatch awaiting transfusion on 11/10/2020. Findings include: 1. During direct observation at approximately 8:00 A.M. on 11/10

	/2020, segregated units of blood were observed to be crossmatched and awaiting possible transfusion for patient MR130018/ accession number 3405749. The 3 units of packed red blood cells included a blood bank arm band bracelet attached to the unit of packed red blood cells. 2. The patient's specimen for cross match observed did not include the green sticker labeled from the armband; rather the laboratory printer generated label. 3. Blood Bank procedure manual review included instructions for the blood bank arm band bracelet to be attached to the patient and for removing the top sticker to be placed on the specimen collected from the patient at the time of collection. The removable sticker from the armband contained the identical information as was pressure copied on to the arm band bracelet to ensure the specimen undoubtedly belonged to the banded patient and to the specimen used for crossmatching. 4. In an interview with staff conducted on 11/10/2020 at approximately 8:10 A.M., staff stated the procedure was not followed due to the patient being an outpatient and outpatient's could not be trusted to keep the arm band bracelet on when outside of the hospital. Without the positive and continuous identification of the patient to the specimen and units crossmatched the chain of the identification process could not be maintained. .
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 proficiency testing records review, lack of documentation, and interview with staff, the laboratory failed to document proficiency testing results were evaluated for potential and/or actual patient outcome for tests the laboratory received failing scores and the corrective actions included actions that may have affected patient test results. Findings include: 1. Proficiency test record review included: A. For the 1st American Proficiency Institute (API) miscellaneous chemistry event of 2019 the laboratory scored 67% for Vitamin D. The corrective action was to recalibrate the test. B. For the 1st API Core chemistry event of 2019 the laboratory scored 60% for Thyroid Stimulating Hormone (TSH); scored 20%, for Phosphous; scored 80% for Acetaminophen and Quantitative human chorionic gonadotrophin (hCG); and a vancomycin score of 60% . Corrective actions were to retest the samples and watch trends. For phosphorous, the corrective action included the failure was due to a calibration issue. C. For the 2nd API core event of 2019 the laboratory scored 80% for hCG and 80% for Phosphorous. Corrective actions after recalibration of hCG were to monitor QC. D. For the 2nd API Myobacteriology Acid Fast Stain the laboratory scored 60% due to specimen mix-up of specimens D8 the laboratory reported negative. The correct response was positive and for specimen D9 the laboratory reported positive. The correct response was negative. E. For the 3rd API Microbiology event of 2019 the laboratory failed the sputum culture organism identification with 0% score. The corrective action was to use the API system to identify organism when indicated for suspected Niesseria and Moraxella organisms. F. For the 3rd API Chemistry core event the laboratory scored a 60% for Troponin T and 40% for Phosphorous. The corrective action was to recalibrate and retest the proficiency test's samples. (See also "B" above). G. For the 3rd API Hematology

	event of 2019 the laboratory scored 50% for red blood cell manual cell count, 50% for Cerebral Spinal Fluid (CSF), and 50% for CSF differential; for body fluid analysis the laboratory scored 50% for CYS-03 reporting Talc. Correct results were Calcium Pyrophosphate DiHy. Corrective action was to retrain testing personnel. H. For the 2nd API Hematology event of 2020 the laboratory scored 60% for prothrombin time. Specimen COA-07 was reported as 22.6 - acceptable range was 16.4 to 22.3 seconds; Specimen COA-09 was reported as 43.0 - acceptable range was 25.2 to 34.7 seconds). Corrective actions were tech error. I. For the 2nd API Chemistry event of 2020 the laboratory scored 0% for Calcium. (Specimen CH-06 reported as 9.4mg/dl (acceptable = 10.2.12.2); CH-07 reported as 8.5mg/dl (acceptable = 8.9-11.0); CH-08 reported as 10.6mg/dl (acceptable = 11.5-13.6); CH-09 reported as 7.8mg/dl (acceptable = 8.0-10.0); and CH-10 reported as 9.0mg/dl (acceptable = 9.5-11.6). Corrective action was stated as reagent problem - resolved with new lot number. J. For the 3rd API Chemistry event of 2020 the laboratory scored 0% for Vitamin B12, PSA, Testosterone, and Gamma Glutaryl Transaminase; 50% for Folate; and 60% for Sodium. Corrective actions were to retrain staff on sample identification for testing multiple samples at once. 2. The laboratory proficiency testing corrective actions failed to include documentation patient tests from the same timeframe as proficiency tests were performed were reviewed to identity patient samples that may have been similarly affected by the same circumstances that affected the proficiency test results. 3. In an interview conducted on 11/10/2020 at approximately 5:30 P.M., staff confirmed the corrective actions failed to include documentation the laboratory investigated patient outcome for similarly affected test results as caused the failed proficiency tests. THIS IS A REPEAT DEFICIENCY. .
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 manufacturer's instructions review, quality control records review, lack of documentation, and interview with staff, the laboratory failed to follow Becton Dickson (BD) Phoenix microbiology identification and susceptibility testing instrument instruction to perform Gram's Stain on each culture specimen prior to entering the specimen into the test system. The laboratory performed approximately 1772 culture identifications per year. Findings include: 1. Page 3 of the procedure stated the specimens that required performance of a Gram's Stain prior to selecting the specimen test cartridge for use. 2. Quality control records and patient test records review failed to include documentation the laboratory performed a Gram's stain prior to testing patient samples from November 2018 to November 2020. 3. In an interview with staff on 11/10/2020 at approximately 3:00 P.M., staff confirmed a Gram's Stain was not performed for each patient specimen prior to selecting the BD Phoenix test system cartridge. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on direct observation and interview with staff, the Acid Fast Stain available for use on 11/10/2020 exceeded the expiration date of 09/20/2020. Findings include: 1. Direct observation of the Mycobacteriology Acid Fast Stain on 11/10/2020 at approximately 1:45 P.M. included an expiration date of 2020-09-30. 2. In an interview with staff on 11/10/2020 at approximately 5:00 P.M., staff confirmed the stain was expired and an in-date stain kit was not available for patient acid fast stain performance. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on laboratory test menu review, lack of documentation, and interview with staff, the laboratory failed to verify one of one new tests systems, VIDAS Clostridium difficile (C. diff) test for C. diff presence or absence. The laboratory failed to verify manufacturer's performance specifications for accuracy, precision, detectable limits and normal range. The laboratory performed approximately 45 tests per year. Findings include: 1. The laboratory test menu included C. difficile presence or absence. 2. The laboratory failed to document they verified the test's accuracy, precision, and the lowest detectable amount C. diff could be detected. 3. In an interview with staff on 11/10/2020 at approximately 6:30 P.M., staff confirmed they did not have documentation to verify the Vidas test system performance verification prior to reporting patient test results. The instrument was installed in 09/23/2020. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on preventive maintenance records review, patient test records review, lack of documentation, and interview with staff, the laboratory failed to follow the Triage and Cobas manufacturer's instructions to perform weekly maintenance for the Cobas 501 and 601 instruments for 2 of 2 weeks reviewed. The laboratory tested approximately 82,000 tests per year on the Cobas system and 1288 on the Triage instrument. Findings include: 1. Patient test records review included evidence of: A. A Troponin I

	assay was run on 4/3/19 on patient #3377187 on the Triage instrument. B. An Hepatic panel was run on 6/13/19 on patient #3380543 on the Cobas 601instrument. 2. Preventive maintenance record review for: A. The Triage instrument maintenance log sheet failed to include documentation of weekly or monthly maintenance requirements. B. The cobas 601maintenance log sheet for July 2019 failed to show the instrument was powered- off and powered-on weekly on 6/3/19 and 6/14/19. 3. In an interview conducted on 11/10/2020 at approximately 5:15 P.M., staff confirmed the maintenance records failed to document performance of manufacturer's required maintenance was performed. .
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 lack of documentation and interview with staff, the laboratory failed to document they monitored, over time, accuracy and precision of test performance that may be influenced by changes in the test system performance and environmental conditions and variance in operator performance for tests performed on the Epoc blood gas analyzer, the Cobas 501, and 311 instruments for routine chemistry and immunoassay tests, Stago Compact Max coagulation instrument, Sysmex XT 2000i and XP300 complete blood count instruments, and Vidas immunoassay instrument for D Dimer and Clostridium difficile tests. The laboratory performed approximately 90,000 tests per year using assayed quality controls that provided control means and acceptable performance ranges. Findings include: 1. The laboratory lacked documentation they monitored quality control performance for assayed materials used to infer the test systems were performing within the stated performance specifications as stated by the instrument manufacturer and approved by the laboratory director. 2. In an interview conducted on 11/10/2020 at approximately 5:15 P.M., staff confirmed they did not monitor assayed quality control materials to proactively identity problems in testing precision and accuracy and to identify when changes in reagents caused shifts in test results or results displayed trends that may require calibration.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: . Based on patient test record review, lack of documentation, and interview with staff, the laboratory failed to perform blood gas controls once every 8 hours of testing for partial pressure Carbon Dioxide (pCO2), Oxygen (pO2), and for pH. Findings include: 1. Patient test record review for patient 3405552 on 11/04/2020 for arterial blood gas testing reporting pH as 7.37, pCO2 as 49.1mmHg, and pO2 as 88.3mmHg. Patient test record review for patient 3375247 collected on 02/20/2019 at 1:20 A.M. reporting pH as 7.445, pCO2mmHg as 31.52, and pO2 as 89.1 mmHg. 2. The laboratory lacked documentation of quality control performance within 8 hours of test performance for 11/04/2020 and 02/20/2019. 3. In an interview conducted on 11/10 /2020 at approximately 5:15 P.M., staff confirmed they did not perform arterial blood gas testing every 8 hours or have an Individualized Quality Control Plan to verify a reduced frequency of quality control performance for arterial blood gas performance on the EPOC test system. .
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: . Based on bacteriology blood culture procedure review, patient test records review, and interview with staff, high complexity testing personnel failed to follow the laboratory's approved procedure to report 7 days of culture incubation prior to reporting the culture as, No Growth at 7 days. The laboratory performed approximately one blood culture per day. Findings include: 1. Microbiology procedure manual review included instructions to incubate blood culture specimens 7 days prior to reporting the final result as No Growth at 7 Days. 2. Patient tests review included patient 3376343 collected on 03/17/2019. The test report included No Growth at 24 hours, 48 hours, 3 days, 4 days, and 5 days. 3. In an interview conducted on 11/10/2020 at approximately 3:10 P.M., staff confirmed the procedure had not been updated to include the current test procedure to report final results as No Growth after 5 days of incubation.