

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 53D0662194	<b>(X3) Date Survey Completed</b> 09/04/2020
<b>Name of Provider or Supplier</b> Memorial Hospital Of Converse County	<b>Street Address, City, State</b> 111 South 5th Street, Douglas, WY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5407</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on new instrument verification study review, lack of documentation, and interview with staff, the laboratory director failed to sign and date the procedure for EPOC blood gas analysis as approved. Findings include: 1. Verification studies reviewed included documentation he laboratory introduced a new EPOC test system for blood gas (venous and arterial) in June of 2020. 2. The laboratory used the EPOC operator's manual as the procedure. 3. The EPOC operator's manual failed to include the director's signature and date of approval. 4. In an interview conducted on 08/04 /2020 at approximately 2:15 P.M., the laboratory manager and lead technician in the blood gas lab confirmed the director had not approved the operator's manual.</p>
<b>D5411</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on patient test records review, quality control records review, and interview with staff, the laboratory failed to document they followed the BD Affirm VP manufacturer's instructions to record the temperature of the heat block and internal</p>

controls to ensure the incubation was within the 85 degrees plus or minus 5 degrees range for 1 of 1 patient test reviewed collected on 11/14/2019. The laboratory performed approximately 10 to 15 tests per month. Findings include: 1. Patient test records review included Affirm VP test report for the presence or absence of Gardnerella, Trichomonas, and Candida for patient specimen 19:MC0006358R on 11/14/2019. 2. Quality control records review and temperature documentation review failed to document the lab followed the BD Affirm VP instructions to evaluate the positive and negative internal controls and the temperature of the test heat block for each test performed. 3. In an interview conducted on 09/04/2020 at approximately 5:00 P.M., the laboratory manager confirmed the laboratory failed to record the heat block temperature and internal positive and negative controls as instructed by the manufacturer.

**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 EPOC blood gas instrument verification records review, lack of documentation, and interview with staff, the laboratory failed to verify 3 of 3 measured tests reported, pH, Partial Pressure Carbon Dioxide, (pCO<sub>2</sub>), and partial pressure Oxygen (pO<sub>2</sub>) for accuracy and precision. The laboratory performed approximately 950 blood gas tests per year. Findings include: 1. EPOC blood gas instrument verification failed to include the statistical evaluation of accuracy and precision for pH, pCO<sub>2</sub> and pO<sub>2</sub> tests for determination of how close the detected results are to the expected results and the ability of the instrument to report the same value for the same specimen. The laboratory failed to document the reportable range results were linear. 2. In an interview conducted on 09/04/2020 at approximately 2:00 P.M., the laboratory manager and blood gas lead technician confirmed the laboratory had not completed the verification study to determine the accuracy and precision of the instrument and that the instrument reporting of values at low normal and high values were linear.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:  
Based on personnel competency records review, lack of documentation, and interview with staff, 1 of 1 new testing person (P) failed to have the educational documentation to qualify as a moderate complexity testing person. (See D6065)

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on personnel qualification records review, lack of documentation, and confirmation by the laboratory manager, the laboratory failed to have documentation to qualify 1 of 1 new moderate complexity testing person (P). Findings include: 1. Personnel qualification records review failed to include educational documentation test person P qualified as a moderate complexity test person. 2. In an interview conducted on 09/04/2020 at approximately 6:45 P.M., the laboratory manager confirmed test person P did not have documentation to meet the educational benchmark to perform moderate complexity testing.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that 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 EPOC blood gas instrument verification studies review, lack of documentation, and interview with staff, the laboratory director failed to approve the verification study for the instrument in use since 06/23/2020. The laboratory performed approximately 80 tests per month. Findings include: 1. The laboratory verified the EPOC instrument on 06/23/2020. 2. The laboratory verification studies failed to include the approval of the director ensuring the verification procedure was adequate to determine the accuracy, precision and reportable range and that the normal range was consistent with the previous test method or if normal ranges were to be adjusted due to method variation.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on competency records review, lack of documentation, and confirmation by staff, the technical supervisor failed to evaluate competency for 3 of 17 testing personnel for 1 of 2 years reviewed (September 2018 to September 2020). Findings include: 1. Competency records review failed to include competency evaluations for testing persons D, G, and P for 2019. 2. In an interview conducted on 09/03/2020 at approximately 7:00 P.M., the technical supervisor for Chemistry, General Immunology, Microbiology, and Hematology confirmed the 2019 competency evaluation was incomplete for test person D and not available for tests persons G and P.