Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0662194	05/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Hospital Of Converse County	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.

(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 209 Laboratory Personnel Report, lack of documentation, and staff interview, the technical supervisor failed to complete an initial competency assessment for 4 of 8 (TP #1, TP #4, TP #5, TP #6) new testing personnel prior to patient testing. In addition, an annual competency assessments had not been completed for 6 of 6 respiratory therapists (TP #7, TP #8, TP #9, TP #10, TP #11, TP #12) and the technical supervisor (TS) for 2 of 2 years reviewed (2020, 2021). The findings were: 1. Review of the personnel file for TP #1 showed she was hired in January of 2022. There was no evidence the technical supervisor had completed an initial competency assessment prior to TP #1 independently testing patient samples. Interview with the technical supervisor on 5/11 /22 at 10:30 AM revealed TP #1 worked the 3rd shift. 2. Review of the personnel file for TP #4 showed she was hired in April of 2022. There was no evidence the technical supervisor had completed an initial competency assessment prior to TP #4 independently testing patient samples. Interview with the technical supervisor on 5/11 /22 at 10:30 AM revealed TP #4 worked the 3rd shift. 3. Review of the personnel file for TP #5 and TP #6 showed no evidence the technical supervisor had completed an initial competency assessment prior to TP #5 and TP #6 independently testing patient samples. 4. Review of the personnel files for TP #7, TP #8, TP #9, TP #10, TP #11, and TP #12 showed no evidence an annual competency assessment was completed in 2020 or in 2021. 5. Review of the laboratory's records showed no evidence a competency assessment was completed for the TS in 2020 or in 2021. 5. Interview on 5/12/22 at 9:55 AM with the lead respiratory therapist revealed he was unable to

	locate the competency assessments for the respiratory therapy staff that performed blood gas analyses. 6. Interview with the technical supervisor on 5/11/22 at 2:53 PM revealed the lead respiratory therapist was responsible for conducting the competency assessments for testing personnel in the respiratory therapy department. In an additional interview with the technical supervisor on 5/12/22 at 10:16 AM she confirmed the competency assessments had not been completed. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on procedure manual review, lack of documentation, and staff interview, the laboratory failed to ensure the procedure manual contained all the required elements for 1 of 6 procedure manuals reviewed (EPOC Blood Analysis). The findings were: 1. Review of the EPOC blood analysis procedure manual showed the manual was provided by the manufacturer and did not contain all of the required sections. The procedure manual failed to include the following: a. The requirements for patient preparation; specimen collection, labeling, and criteria for specimen acceptability and rejection. b. The reportable range for the test system as established by the method verification study and approved by the laboratory director. c. The normal values as established by the laboratory director. d. The panic or alert values. e. The laboratory's system for entering results in the patient record and reporting patient results. f. The protocol for reporting critical values. g. A description of the course of action to take if a test system became inoperable. 2. Interview with the laboratory manager on 5/12/22 at 10:16 AM confirmed the procedure manual did not contain all of the required elements. .
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: . Based on review of policy and procedure, review of laboratory records, and staff interview, the laboratory director failed to sign and date the procedure for the EPOC blood gas analysis system as approved. The findings were: 1. Review of the laboratory's records showed the EPOC test system for blood gas analysis (venous and arterial) was introduced in June of 2020. 2. The laboratory used the EPOC operator's manual as the procedure, however it failed to include the laboratory director's signature and date of approval. 3. Interview with the laboratory manager and lead technician of the respiratory therapy department on 5/12/22 at 10:16 AM confirmed the laboratory director had not approved the operator's manual. THIS IS A REPEAT DEFICIENCY, last cited on 9/4/20. .
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 review of the "Specimen Count Summary Report", review of quality control (QC) records, review of the laboratory's individualized quality control plan (IQCP), and staff interview, the laboratory failed to perform quality control as directed by the IQCP for 4 of 7 molecular panels reviewed (Cepheid CT/NG (Chlamydia trachomatis/Neisseria gonorrhoeae), GBS (Group B Streptococcus), MRSA (methicillin-resistant Staphylococcus aureus), C. diff (Clostridium difficile toxin)) for 2 of 2 years (2021, 2022). The laboratory performed approximately 399 CT /NG patient tests, 145 GBS tests, 409 MRSA tests, and 97 C. diff tests from 4/1/21 through 3/31/22. The findings were: 1. Review of the laboratory's IQCP, last reviewed 7/22/21, showed QC was to be performed on the CT/NG, GBS, MRSA, and C. diff panels with each new shipment, each new lot number, and monthly. The following concerns were identified: a. Review of the QC records for the CT/NG panel showed a positive and negative control was performed monthly from 3/8/21 through 7/16/21, however the next documented QC date was 2/18/22. b. Review of the QC records for the GBS panel showed a positive and negative control was performed on 5/6/21, 7/17 /21, 11/6/21, and 11/9/21. c. Review of the QC records for the MRSA panel showed a positive and negative control was performed on 1/17/21, 4/10/21, 6/9/21, 7/17/21, 9/7 /21, 11/6/21, 2/16/22, and 2/18/22. d. Review of the QC records for the C. diff panel showed a positive and negative control was performed on 1/17/21, 6/9/21, and 8/10 /21. 2. Interview with the laboratory manager on 5/12/22 at 9:45 AM confirmed QC had not been performed as directed by the IQCP. .
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 review of the quality control (QC) records, review of the laboratory's individualized quality control plan (IQCP), review of the "Specimen Count Summary Report", and staff interview, the laboratory failed to perform two levels of quality control each day of patient testing for the Cepheid Gene Xpert molecular respiratory panel (SARS-CoV-2, respiratory syncytial virus, influenza A, and influenza B), the BioFire pneumonia panel, and the BioFire blood culture identification 2 (BCID2) panel for 2 of 2 years (2021, 2022) of testing reviewed. The laboratory performed 49 pneumonia panels, and 98 BCID2 panels from 4/1/21 through 3/31/22 and 201 respiratory panels from 1/28/22 through 5/12/22. The findings were: 1. Review of the QC records showed the laboratory performed a positive and a negative control on the Cepheid Gene Xpert analyzer for the respiratory panel on 2/8/22, 2/18/22, 3/18/22, and 4/15/22. Review of the IQCP, last reviewed 7/22/21, for the Cepheid Gene Xpert instrument showed no evidence the IQCP had been updated to include the respiratory panel. Review of the "Specimen Review Report" showed 201 respiratory panels had been performed between 1/28/22 and 5/12/22. 2. Review of the QC records showed the laboratory performed a positive and negative control on the BioFire pneumonia panel on 2/25/22 and 3/5/22. There was no evidence QC had been performed in 2021. Review of the IQCP, last reviewed on 7/22/21, for the BioFire instrument showed no evidence the IQCP had been updated to include the pneumonia panel. Review of the "Specimen Count Summary Report" showed 49 pneumonia panels had been performed between 4/1/21 and 3/31/22. 3. Review of the laboratory's records showed the BioFire BCID1 (27 target areas) was upgraded to the BioFire BCID2 (43 target areas) on 2/5/21. Review of the QC records showed the laboratory performed a positive and negative control on the BioFire BCID2 panel on 4/1/21 and 9/11/21. Review of the IQCP, last reviewed on 7/22/21, for the BioFire instrument showed no evidence the IQCP had been updated to include the BCID2 panel. Review of the "Specimen Count Summary Report" showed 98 blood culture identification panels had been performed from 4/1/21 through 3/31/22. 4. Interview with the laboratory manager on 5/12/22 at 9:43 AM confirmed the IQCP for the tests performed on the Cepheid Gene Xpert and the BioFire had not been updated to include the respiratory panel, pneumonia panel, or the BCID2 panel. In addition the laboratory manager confirmed positive and negative control materials had not been performed each day of patient testing. .
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: . Based on review of the CMS-209 Laboratory Personnel Report, review of personnel files, lack of documentation, and staff interview, the laboratory failed to ensure 4 of 8 new testing personnel (TP #1, TP #2, TP #3, TP #4) were qualified to perform high complexity testing (D6171). .

D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet

	the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: . Based on review of the CMS-209 Laboratory Personnel Report, review of personnel files, lack of documentation, and staff interview, the laboratory failed to ensure 4 of 8 new testing personnel (TP #1, TP #2, TP #3, TP #4) were qualified to perform high complexity testing. The findings were: 1. Review of the CMS-209 Laboratory Personnel Report, showed TP #1, TP #2, TP #3, and TP #4 performed high complexity testing. 2. Review of the personnel files for TP #1, TP #2, TP #3, and TP #4 showed no evidence of the educational documentation required to qualify as high complexity testing personnel. 3. Interview with the laboratory manager on 5/11/22 at 11 AM confirmed the documentation to show the required qualifications was unavailable.