Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472824	04/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Hospital Of Texas County Authority	520 Medical Drive, Guymon, OK	

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
D0000	The recertification survey was performed on 04/10,11,12,13/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the vice president of operations and provider services, vice president of patient care, technical consultant, and general supervisor during an exit conference performed at the conclusion of the survey.
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 a review of policies and interview with the general supervisor the laboratory failed to ensure one of three policies had been approved, signed, and dated by the laboratory director. Findings include: (1) On 04/10/2023 at 02:55 pm, the general supervisor stated the following: (a) Urine drug screen testing was performed using the Med Tox Scan test system; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system effective 10/19/2021. (2) On 04/12/2023 a review of the IQCP identified the QCP (Quality Control Plan) for the test system had not been approved, signed, and dated by the laboratory director until 04/11/2023; (3) The records were reviewed with the general supervisor who stated on 04/12/2023 at 09:00 am, the QCP for the above test system had not been approved, signed, and dated by the laboratory director until 04/11/2023.
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 a review of records, manufacturer's instructions, and interview with the general supervisor, the laboratory failed to follow the manufacturer's implementation instructions to ensure the mean of the normal range was accurately entered into the analyzer for one of one PT reagent lot change. Findings include: (1) On 04/10/2023 at 03:00 pm, the general supervisor stated PT/INR (Prothrombin Time/International Normalized Ratio) testing was performed using the Sysmex CA-600 analyzer; (2) On 04/12/2023 at 02:57 pm, the general supervisor stated the PT reagent, Innovin lot #549775, was put into use on 06/23/2022; (3) A review of the manufacturer's instructions in section XIV "Reagent Lot Roll-Over Studies" provided instructions for calculating the geometric mean and stated, "The MNPT for INR calculation must be the geometric mean". In addition the instructions stated, "Refer to the Instrument Operator's Manual for the procedure of entering the reagent lot specific ISI value and the PT Geomean to allow INR calculation"; (4) A review of the implementation records for the reagent lot change identified the geometric mean that had been calculated by the laboratory was 9.4; (5) Observation of the geometric mean that had been programmed into the analyzer, with the assistance of the general supervisor on 04 /12/2023 at 03:15 pm, identified the value had been entered as 10.1; (6) The findings were reviewed with the laboratory manager who stated on 04/12/2023 at 03:30 pm, the geometric mean that was programmed into the analyzer was not correct and should have been entered as 9.4.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the general supervisor, the laboratory failed to ensure the humidity was maintained as required by the manufacturer of the Sysmex CA-660 analyzer for five of eight months reviewed. Findings include: (1) On 04/10/2023 at 03:00 pm, the general supervisor stated PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the Sysmex CA-600 analyzer; (2) On 04/12/2023, a review of the manual for the analyzer titled, "Instructions for Use" in Section 4.2 "Installation Environment" stated "Use the instrument at a relative humidity range of 30-85%"; (3) A review of the laboratory humidity records from August 2022 through March 2023 identified the humidity readings were less than 30% for five of eight months as follows: (a) November 2022 - 15 of 30 humidity readings were documented as less than 30%; (b) December 2022 - 22 of 29 humidity readings were documented as less than 30%; (c) January 2023 - 31 of 31 humidity readings were documented as less than 30%; (d) February 2023 - 23 of 28 humidity readings

	were documented as less than 30%; (e) March 2023 - 28 of 31 humidity readings were documented as less than 30%. (4) The records were reviewed with the general supervisor who stated on 04/13/2023 at 02:02 pm the laboratory humidity had not been maintained as required by the manufacturer as shown above.
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 a review of records, manufacturer's instructions, and interview with the general supervisor, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for three of seven analyzers. Findings include: CEPHEID GENEXPERT DX (1) On 04/10/2023 at 02:50 pm, the general supervisor stated the laboratory performed SARS CoV-2, RSV (Respiratory Syncytial Virus), Influenza A&B, and MRSA (Methicillin Resistant Staphylococcus aureus) testing using the Cepheid GeneXpert DX system; (2) On 04/11/2023 a review of the manufacturer's maintenance log showed the following required maintenance procedures: (a) Weekly (i) "Power down the GeneXpert instrument" (ii) "Power down the GeneXpert computer" (b) Monthly (i) "Archive tests" (ii) "Purge tests" (c) Quarterly (i) Clean plunger rod and cartridge bays" (ii) Clean instrument surfaces" (3) A review of maintenance logs from March 2022 through March 2023 identified the maintenance had not been documented as performed as follows: (a) Weekly (i) Between 12/02/2022 and 12/16/2022 (b) Monthly (i) Prior to 04/01/2022 (ii) Between 04/01/2022 and 07/01/2022 (iii) Between 07/22/2022 and 09/02/2022 (iv) After 09/02/2022 (c) Quarterly (i) After 10/12/2022 (4) The records were reviewed with the general supervisor who stated on 04/11/2023 at 01:55 pm the maintenance had not been documented as performed as shown above. BECKMAN COULTER DXH 600 (1) On 04/10/2023 at 02:55 pm, the general supervisor stated CBC (Complete Blood Count) testing was performed using the Beckman Coulter DXH 600 analyzer as the primary method; (2) On 04/12/2023 a review of the manufacturer's maintenance log showed the following required maintenance procedures: (a) Each Six Months (i) "Clean the STM" (3) A review of maintenance logs from January 2022 through March 2023 identified the maintenance had not been documented as performed as follows: (a) Prior to or after 09/30/2022 (4) The records were reviewed with the general supervisor who stated on 04/12/2023 at 02:05 pm the maintenance had not been documented as performed as shown above. SYSMEX CA-600 (1) On 04/10/2023 at 03:00 pm, the general supervisor stated PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the Sysmex CA-600 analyzer; (2) On 04/12/2023 a review of the manufacturer's maintenance log showed the following required maintenance procedures: (a) Quarterly (i) "Clean DI H2O Rinse Bottle w/alcohol" (ii) "Perform LED Calibration" (iii) Clean filters under front of analyzer" (b) Yearly (i) "Replace Rinse Filter" (3) A review of maintenance logs from January 2022 through March 2023 identified the maintenance had not been documented as performed as follows: (a) Quarterly (i) Between 02/14/2022 and 07/08/2022 (b) Yearly (i) Not documented as performed during the review period (4) The records were reviewed with the general supervisor who stated on 04/12/2023 at 03:22 pm the maintenance had not been documented as performed as shown above.

D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory failed to follow their written protocol for ensuring the Blood Bank pipette was functioning properly during the review period of 11/23/2021 through the current date. Finding include: (1) On 04/10/2023 at 02:35 pm, the general supervisor stated the laboratory began performing ABO/Rh, Antibody Screen, and Compatibility testing using the Ortho ID-MTS gel system on 11/23/2021; (2) On 04/12/2023 at 09:30 am, the general supervisor stated the ID Tipmaster pipette (a multiple delivery pipette) was used for the testing as follows: (i) The 12.5 ul (microliter) setting was used to dispense patient plasma for forward ABO/Rh typing; (ii) The 25 ul setting was used to dispense commercial A1 and B cells for reverse typing and dispense patient plasma for Antibody Screen and Compatibility testing; (iii) The 50 ul setting was used to dispense commercial screen cells for Antibody Screens and donor cell suspensions for Compatibility testing. (3) A review of the policy titled, "Equipment Function Checks" included requirements for checking the pipettes used for testing and stated "The Laboratory and/or Maintenance Department will contract and/or notify the Bio-Medical service when they should perform the annual function checks"; (4) A review of records from 11/23/2021 through the current date identified the ID Tipmaster pipette had not been checked for accuracy since the laboratory began testing on 11/23 /2021; (5) The findings were reviewed with the general supervisor who stated on 04/12 /2023 at 10:35 am, the pipette had not been checked for accuracy as stated above.
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 a review of records and interview with the general supervisor, the laboratory failed to perform QC (Quality Control) as stated in the IQCP (Individualized Quality Control Plan) for one of three test systems during the review period of September 2022 through the current date. Findings include: (1) On 04/10/2023 at 02:50 pm, the

	general supervisor stated the the following: (a) SARS CoV-2 was performed using the Cepheid Gene Xpert DX system and the CoV-2 plus test cartridge; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) On 04/11/2023 a review of the QCP (Quality Control Plan) identified positive and negative quality control materials were to be tested on a monthly basis; (3) A review of QC records from September 2022 through the current date identified QC testing had not been performed as stated in the QCP as follows: (a) Prior to 01/23/2023 (b) Between 01/23/2023 and 03/11/2023 (4) The records were reviewed with the general supervisor who stated on 04/11/2023 at 03:24 pm, QC had not been performed as stated above.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of a written policy and interview with the general supervisor and director of nursing, the facility failed to ensure that written policies provided safety for individuals being transfused for two of three patients reviewed. Findings include: (1) On 03/10/2023 at 03:40 pm, the general supervisor stated the laboratory stored units of PRBC's (packed red blood cells) in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On 03/12/2023, a review of the hospital policy titled, "Blood Component Administration" stated the following: (a) "Ensure a Blood Consent is signed. One signed consent form is acceptable for the hospital stay"; (b) "Check vitals every 5 minutes x3, every 15 minutes for one hour then, every 30 minutes throughout the transfusion". (3) A review of records for three patients receiving transfusions in April 2022, October 2022, and March 2023 identified no evidence the policy had been followed for two patients for three of five units transfused as follows: (a) Patient #772302 - Transfused with two units of PRBC's on 04/11/2022 (unit #W091022174003 and unit #W091022173855). There was no evidence a signed consent had been obtained; (b) Patient #784461 - Transfused with one unit of PRBC's on 03/20/2023 (unit #W091022180845). There was no evidence the vitals had been taken as required by policy as follows: (i) Not taken every five minutes for the first 15 minutes. The vitals had not been documented between 02:35 pm and 02:50 pm; (ii) Not taken every 15 minutes for one hour. The vitals had not been documented between 02:50 pm and 03:50 pm. (iii) Not taken every 30 minutes throughout the transfusion. The vitals had not been documented between 03:50 pm and 04:55 pm. (4) The records were reviewed with the general supervisor and director of nursing. Both stated on 04/12/2023 at 12:00 pm, the policy had not been followed as stated above.
D5775	COMPARISON OF TEST RESULTS

	CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results for Routine Chemistry testing performed using two test methods during the review period of January 2022 through March 2023. Findings include: (1) On 04/10/2023 at 03:18 pm, the general supervisor stated the laboratory performed Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), BUN, Calcium, Chloride, CK (Creatine Kinase), Creatinine, CO2, Glucose, Sodium, Potassium, Total Bilirubin, and Total Protein testing using the Beckman Coulter DXC 600 analyzer, denoted by the laboratory as "Bonnie", as the primary method and the Beckman Coulter DXC 600 analyzer, denoted by the laboratory as "Clyde", as the backup method; (2) On 04/12/2023, a review of records from January 2022 through March 2023 identified the relationship between the two test methods had not been evaluated prior to 10/24/2022; (3) The records were reviewed with the general supervisor who stated on 04/12/2023 at 02:39 pm, the relationship between the above test methods had not been evaluated at least twice annually as stated above.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor and respiratory therapy supervisor, the laboratory failed to make appropriate reference ranges available for two of two reagent lot numbers implemented for PT (Prothrombin Time) and PTT (Partial Thromboplastin Time) testing; and failed to make appropriate reference ranges available for one of one patient venous Blood Gas report. Findings include: PT AND PTT TESTING (1) On 04/10/2023 at 03:00 pm, the general supervisor stated PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the Sysmex CA-600 analyzer; (1) On 04/12/2023 at 02:57 pm, the general supervisor stated the following reagent lot numbers were put into use on 06/23/2022: (a) Dade Innovin lot #549775 (b) Dade Actin FSL - #562693 (3) A review of the implementation records identified the following: (a) PT - The normal reference interval had been verified as 8.6-10.3 (b) PTT - The normal reference interval had been verified as 22.2-30.2 (4) A review of a patient report with PT and PTT testing performed on 04/11/2023 showed the following normal ranges: (a) PT - 9.6-12.5 (b) PTT - 22.5-38.0 (5) The reports and implementation records were reviewed with the general supervisor who stated on 04 /12/2023 at 04:07 pm, the laboratory had not updated the normal reference ranges into

	the laboratory's computer information system. VENOUS BLOOD GAS TESTING (1) On 04/10/2023 at 03:18 pm, the general supervisor stated venous and arterial Blood Gas (pH, pO2, pCO2) testing were performed using the GEM 5000 analyzer; (2) On 04/13/2023, a review of two patient reports identified identical reference ranges for venous blood gas testing as follows: (a) A patient venous blood gas tested on 01/28 /2023 with the following reference intervals: (i) pH - 7.35-7.45 (ii) pO2 - 83.0-108.0 (iii) pCO2 - 35.0-45.0 (b) A patient arterial blood gas tested on 04/05/2023 with the following reference intervals: (i) pH - 7.35-7.45 (ii) pO2 - 83.0-108.0 (iii) pCO2 - 35.0-45.0 (3) The reports were reviewed with the general supervisor and respiratory therapy supervisor. Both stated on 04/13/2023 at 01:45 pm, the patient report tested on 01/28/2023 did not include reference intervals for venous Blood Gas testing.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for one of eight testing persons performing testing from June 2021 through the current date. Findings include: (1) On 04/11/2023 a review of personnel records for eight persons hired to perform moderate complexity testing after the previous recertification survey identified the following for one of eight persons: (a) Testing Person #8 - The initial training was complete on 06/21/2021. There was no evidence a competency evaluation had been performed through the current date. (2) The records were reviewed with the general supervisor who stated on 04/11/2023 at 11:01 am, a semiannual competency evaluation had not been performed.
D6127	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the technical supervisor failed to ensure competency evaluations for high complexity testing had been performed semiannually during the first year of testing for one of one testing person. Findings include: (1) On 04/11/2023 a review of personnel records for one person hired to perform high complexity testing after the previous recertification survey identified the following for one of one person: (a) Testing Person #7 - The initial training was complete on 01/10/2022. There was no evidence a competency evaluation had been performed between 01/10/2022 and 01/18/2023. (2) The records were reviewed with the general supervisor who stated on 04/11/2023 at 11:01 am, a semiannual competency evaluation had not been performed.