Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0476067	10/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Hospital	1401 W Locust St, Stilwell, 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 10/19,20,21/2022. The laboratory was found out of compliance with the following CLIA Conditions of Participation: 493.801; D2000: Enrollment and Testing of Samples 493.1421; D6063: Laboratories Performing Moderate Complexity Testing; Testing Personnel The findings were reviewed with technical consultant #1 and the laboratory manager during an exit conference performed at the conclusion of the survey.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to enroll in a proficiency testing program for Free Thyroxine testing for five of five events reviewed. Findings include: (1) On 10/19/2021, a review proficiency testing records for 2021 (first, second and third events) and to date in 2022 (first and second events) identified no evidence the laboratory was enrolled in proficiency testing for Free Thyroxine testing for 5 of 5 events; (2) The records were reviewed with technical consultant #1 who stated on 10/19/2022 at 04:30 pm, the laboratory had not enrolled in proficiency testing for Free Thyroxine testing.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to evaluate the accuracy for six of six analytes at least twice annually. Findings include: (1) On 10/19/2021 at 01:30 pm, technical consultant #1 stated the following: (a) Procalcitonin testing was performed on the Roche Cobas e411 analyzer in the laboratory; (b) Salicylate testing was performed on the Roche Cobas Integra 400 analyzer in the laboratory; (c) Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, and Methemoglobin were performed on the Gem Premier 5000 analyzer in the respiratory therapy department. (2) A review of 2021 and 2022 proficiency testing records identified the laboratory had not enrolled and participated in proficiency testing for the six analytes, therefore, it was determined the laboratory must verify the accuracy of the testing at least twice annually; (3) Interview with technical consultant #1 on 10/19/2021 at 04:30 pm confirmed the laboratory did not have a method in place to verify the accuracy of Procalcitonin, Salicylate, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, and Methemoglobin testing twice annually and the accuracy of the testing had not been verified for accuracy during 2021 and to date in 2022.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures and interview with technical consultant #1, the laboratory failed to have a written procedure for Manual Differential testing using the Cellavision. Findings include: (1) On 10/21/2022 at 10: 00 am, technical consultant #1 stated the laboratory began performing Manual Differential testing using the Cellavision on 08/01/2022; (2) A review of the Hematology procedure manual identified no evidence of a written procedure for Manual Differential testing using the Cellavision; (3) The findings were reviewed with technical consultant #1 who stated on 10/21/2022 at 10:55 am, the laboratory did not have a written procedure for performing manual differentials using the Cellavision.
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 technical consultant #1, the laboratory failed to follow the manufacturer's implementation instructions for verifying the normal reference range for two of two new analytes. Findings include: (1) On 10/19/2022 at 01:35 pm, technical consultant #1 stated the laboratory began using the ACL Elite analyzer to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing in January 2022; (2) On 10/20/2022, a review of the manufacturer's implementation instructions under "Normal Reference Interval" stated to use a "minimum of 40 normal donors screened per lab policy". A review of the laboratory policy required using equal numbers of males and females and stated, "All samples should have patient age, sex, and medication history documented. Normal Samples are defined as patients with no major disease state who are not currently taking any anticoagulants (including HIGH dose aspirin low dose is acceptable), or hormone replacement (including birth control)"; (3) A review of the records for the normal reference range study for PT and PTT identified the laboratory had not followed the manufacturer's instructions as follows: (a) Although 40 donors had been used, there was no documentation of the donors age,gender, medication and health history. (4) The records were reviewed with technical consultant #1 who stated on 10/20/22 at 04: 30 pm, the laboratory had not followed the manufacturer's instructions for verifying the normal reference range.
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 a review of records and interview with technical consultant #1, the laboratory failed to ensure the demonstrated reportable ranges were utilized for one of one new test system introduced into the laboratory. Findings include: (1) On 10/19 /2022 at 01:35 pm, technical consultant #1 stated the laboratory began using the ACL Elite analyzer to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing in January 2022; (2) On 10/20/2022, a review of the performance specification records for the new test system identified the following: (a) PT - The laboratory had demonstrated a reportable range of 10.9-42.0; (b) PTT - The laboratory had demonstrated a reportable range of 25.6-50.6. (3) Interview with technical consultant #1 on 10/21/2022 at 01:05 pm confirmed the laboratory was not using the reportable ranges that had been demonstrated as follows: (a) PT - The laboratory was using the manufacturer's reportable range of 8.0-115; (a) PTT - The laboratory was using the manufacturer's reportable range of 5.5-113.
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 technical consultant #1, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures on one of four analyzers. Findings include: (1) On 10/19/2022 at 01:30 pm, technical consultant #1 stated CBC (Complete Blood Count) testing was performed using the Sysmex XS 1000i analyzer; (2) On 10/20 /2022, a review of the manufacturer's maintenance log showed the following manufacturer required weekly maintenance procedure: (a) "Power Down IPU" (3) A review of maintenance logs from January 2022 through August 2022 revealed the weekly maintenance had not been documented as performed between: (a) 03/23/2022 and 04/06/2022 (b) 08/10/2022 and 08/24/2022 (4) The records were reviewed with technical consultant #1 who stated on 10/20/2022 at 03:24 pm, the weekly maintenance had not been documented as performed as shown above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to perform calibration verification procedures at least once every 6 months for two of two chemistry analyzers. Findings include: ROCHE COBAS INTEGRA 400 (1) On 10/19/2021 at 01:30 pm, technical consultant #1 stated the laboratory performed Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Ammonia, Amylase, AST (Aspartate Aminotransferase), Total Bilirubin, Direct Bilirubin, BUN (Blood, Urea, Nitrogen), Calcium, Chloride, Cholesterol, CO2, CK (Creatine Kinase), Creatinine, Direct LDL (Low Density Lipoprotein), Glucose, HDL (High Density Lipoprotein), Lactic Acid, Lipase,

	Magnesium, Phosphorus, Potassium, Total Protein, Sodium, and Triglycerides using the Roche Cobas Integra 400 analyzer; (2) On 10/21/2022 a review of 2022 calibration records identified the calibration procedures for the above analytes had been performed with less than three levels of calibrators therefore, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) A review of analyzer records from January 2021 through the current date in 2022 identified no evidence calibration verification procedures had been performed; (4) Interview with technical consultant #1 on 10/21/2022 at 11:57 am confirmed calibration verification had not been performed at least once every six months for the above analytes during 2021 and to date in 2022. ROCHE COBAS E411 (1) On 10/19/2021 at 01:30 pm, technical consultant #1 stated the laboratory performed CKMB (Creatine Kinase Isoenzyme), Troponin I, Troponin T, Vitamin B12, Vitamin D, Procalcitonin, TSH (Thyroid Stimulating Hormone), Free T4 (Thyroxine), and HCG (Human Chorionic Gonadotropin) testing using the Roche Cobas e411 analyzer; (2) On 10/21/2022 a review of 2022 calibration records identified the calibration procedures for the above analytes had been performed with less than three levels of calibrators therefore, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) A review of analyzer records from January 2021 through the current date in 2022 identified calibration verification had not been performed as follows during the review period: (a) Prior to or after 10/18/2021 for CKMB, HCG, TSH, Troponin I, and Troponin T; (b) Not performed during the review period for Vitamin B12, Vitamin D, Procalcitonin, and Free T4. (4) Interview with technical consultant #1 on 10/21/2022 at 11:57 am confirmed calibration verification had not been performed at least once every six months for the above analytes during 2021 and to date in 2022 as shown 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 written policies and interview with technical consultant #1, the laboratory failed to ensure that written policies provided safety for individuals being transfused for one of three patients reviewed. Findings include: (1) On 10/19/2022 at 01:40 pm technical consultant #1 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 10/21/2022, a review of the hospital policy titled, "Blood and Blood Product Administration" stated "Vital signs should be monitored throughout the transfusion: every 15 minutes for 30 minutes than every 30 minutes thereafter until completion of the transfusion"; (3) A review of records for three patients receiving

	transfusions in October 2021, February 2022, and August 2022 identified no evidence the policy had been followed for one patient for two of three units transfused as follows: (a) Patient #105927 (i) Unit #W091021331075 - The transfusion began on 10 /01/2021 at 10:30 pm and ended on 10/02/2021 at 12:40 am. Vital signs had been documented in a space designated for 15 minutes after the beginning of the transfusion, but the time had not been documented, and there was no documentation of additional vitals as required by policy; (ii) Unit #W091021315658 - The transfusion began on 10/02/2021 at 12:50 am and ended on 10/02/2021 at 03:15 am. Vital signs had been documented in a space designated for 15 minutes after the beginning of the transfusion, but the time had not been documented and there was no documentation of additional vitals as required by policy. (4) The records were reviewed with technical consultant #1 who stated on 10/21/2022 at 11:55 am, the documentation of the vitals for the above units were not available because they had not been scanned into the computer system.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the technical consultant failed to evaluate personnel performing moderate complexity testing in the respiratory therapy department at least annually for one of one person. Findings include: (1) On 10/20/2022, a review of personnel records for persons performing moderate complexity testing in the respiratory therapy department during 2020, 2021, and to date in 2022 identified no evidence of an annual evaluation during 2021 for one of one person (testing person #14): (a) The semi-annual competency had been performed on 07/22/2020 and an annual competency had been performed on 08/17 /2022. (2) The findings were reviewed with technical consultant #1 who stated on 10 /20/2022 at 10:10 am, an annual competency evaluation had not been performed during 2021.
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 a review of records and interview with technical consultant #1, the laboratory failed to ensure an individual who performed moderate complexity testing met the educational qualifications for one of eight persons peforming testing in the respiratory therapy department. Findings include: (1) The laboratory failed to a ensure testing person met the educational qualifications. Refer to 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 a review of records and interview with technical consultant #1, the laboratory failed to ensure a testing person met the educational qualifications to perform moderate complexity testing for one of eight testing persons performing testing in the respiratory therapy department. Findings include: (1) On 10/20/2022 at 09:30 am, technical consultant #1 stated Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, and Methemoglobin testing were performed on the Gem Premier 5000 analyzer in the respiratory therapy department by eight testing persons as listed on the CMS-209, Laboratory Personnel Report: (2) A review of personnel records for testing person #14 revealed no evidence of an education document to ensure the individual met the moderate complexity personnel requirements; (3) The findings were reviewed with technical consultant #1, who stated on 10/20/2022 at 10:10 am, the education document was not available.