Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0476067	09/19/2018
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 09/17,18,19/18. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant The findings were reviewed with chief operating officer, technical consultant, laboratory manager, and respiratory therapy department supervisor during an exit conference performed at the conclusion of the survey.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the laboratory manager, technical consultant, and testing person #3 the laboratory failed to maintain quality control records for at least 2 years. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyors Ammonia testing was performed using the Siemens Dimension EXL 200 analyzer; (2) On the second day of the survey, the laboratory manager stated to surveyor #1 three levels of Bio-Rad Liquichek Ammonia quality control (QC) materials were tested on the analyzer each day of patient testing: (3) Surveyor #1 then observed the following lot numbers of QC materials in the refrigerator, that were currently in use for Ammonia testing: (a) Bio-Rad Liquichek Ammonia controls level 1 lot #54191, level 2 lot #54192, and level 3 lot #54193. (4) Surveyor #1 asked the technical consultant and testing person # 3 for documentation verifying how the laboratory established their means and limits of acceptability for the QC materials, and the dates the materials were put into use for patient testing. Testing person #3 stated the materials were put into use on 04/01/17, however, there was no documentation verifying the establishment of the means and limits; (5) Surveyor #1 reviewed QC records from 04/01/17 through 08/31/17; 12/01

	/17 through 12/31/17; and 06/01/18 through 08/31/18. There was no evidence in the records to substantiate how the means and limits had been derived; (6) Surveyor #1 reviewed the findings with the technical consultant who stated documentation to substantiate how the means and limits had been established could not be located.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, surveyor #2 reviewed 2017 and 2018 proficiency testing records and identified the following failures, in which corrective action documentation could not be located: (a) Second 2017 Chemistry Miscellaneous Event (i) UDS (Urine Drug Screen) Phencyclidine- The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (b) Third 2017 Hematology Event (i) BCI (Blood Cell Identification) - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (2) Surveyor #2 asked the technical consultant if corrective action had been taken for the failures. After reviewing the records, the technical consultant stated corrective action had not been taken to determine the cause of the failures.
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 technical consultant, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyors the ACL Elite analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio), PTT (Partial Thromboplastin Time) and D-Dimer testing; (2) On the third day of the survey, surveyor #2 reviewed the manufacturer's instructions contained in the "Hemostasis Performance Verification Manual" for implementing new reagents, which stated, "When changing to a new lot number of reagent or a new reagent, it is important to establish a new normal reference interval, establish new assay control ranges, and perform a comparison study for all tests". In addition, the manufacturer required the following: (a) Section titled "Comparison Study" (i) "At least 50% of the samples should be outside of the laboratory normal reference interval, if possible" (ii) "At least 40 specimens should be analyzed. More samples will improve the confidence in the data" (3) The technical consultant stated to surveyor #2 the HemosIL Synthasil APTT lot number N0570095 was currently in use, and had initially been put into use on 05/01/18: (4) Surveyor #2 reviewed the implementation

	records for HemosIL Synthasil APTT reagent lot #N0570095 with the following identified: (i) There was no evidence the comparison study had been performed using 20 samples outside of the laboratory normal reference interval (they had only used 20 normal samples). (5) The findings were reviewed with the technical consultant who stated the manufacturer's instructions had not been followed for the reagent lot change as specified 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 technical consultant, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyors CBC (Complete Blood Count) testing was performed on the Sysmex XS 1000i analyzer; (2) On the second day of the survey, surveyor #1 reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for weekly maintenance were as follows: (a) Weekly (i) Power Down IPU (3) Surveyor #1 then reviewed maintenance records for the analyzer for 20 months (January 2017 through August 2018). The weekly maintenance had not been documented as performed between: (a) 01/05/17 and 01/20/17 (b) 01/20/17 and 01/31/17 (c) 02/24/17 and 03/07/17 (d) 04/26 /17 and 03/07/17 (e) 04/26/17 and 05/09/17 (f) 06/30/17 and 07/10/17 (g) 12/01/17 and 12/12/17 (h) 01/05/18 and 01/14/18 (i) 05/05/18 and 05/16/18 (j) 08/18/18 and 08 /28/18 (4) Surveyor #1 reviewed the records with the laboratory manager and technical consultant. Both stated the maintenance had not been performed as indicated above. 39088 Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to perform maintenance procedures as required by the manufacturers. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyors PT/INR (Prothrombin Time /International Normalized Ratio), PTT (Partial Thromboplastin Time) and D-Dimer testing were performed on the ACL Elite analyzer; (2) On the third day of the survey, surveyor #2 reviewed the manufacturer's maintenance instructions for the analyzer which were: (a) Weekly (i) Clean External Surfaces (ii) Clean/Align Probe (3) Maintenance records were reviewed by surveyor #2 for 7 months (January 2018 through July 2018). The weekly maintenance had not been documented as performed: (a) between 06/22/18 and 07/06/18 (4) Surveyor #2 reviewed the records with the technical consultant who stated there was no evidence the above maintenance had been performed as required. NOTE: This deficiency was cited on the previous recertification survey performed 10/10,11,12/2016.
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, policies and procedures, and interview with the technical consultant and laboratory manager, the laboratory failed to follow their written protocol for ensuring the urine centrifuge and MTS dispensers were functioning properly. Findings include: URINE CENTRIFUGE (1) On the first day of the survey, the laboratory manager stated to the surveyors urine sediment examinations were performed in the laboratory. The specimens were processed in the LW Scientific Ultra 8S centrifuge at a speed of 1500 rpm for 5 minutes; (2) Surveyor #1 reviewed the policy titled "Centrifuge and Timer Verification". It stated "The hospital contracts with Commercial Medical Electronics (CME) to come every six months to perform verification checks of all centrifuges and timers associated with them"; (3) Surveyor #1 reviewed the centrifuge maintenance records for 2017 and 2018. There was no evidence the centrifuge speed and timer had been checked between 07/12/17 and 07/05/18; (4) Surveyor #1 reviewed the findings with the technical consultant and laboratory manager. Both stated the centrifuge speed and timer had not been checked between 07/12/17 and 07/05/18. MTS DISPENSERS(1) On the first day of the survey, the laboratory manager stated to the surveyor blood bank testing (ABO, Rh, Antibody Screen, Compatibility Testing) was performed using the Ortho ID-MTS gel system; (2) On the third day of the survey, surveyor #1 asked the laboratory manager to explain the use of the following dispensers (stored in the blood bank refrigerator): (a) Ortho MTS Diluent 2 Plus 0.5 mL dispenser (b) Ortho MTS Diluent 2 1 mL dispenser (3) The laboratory manager explained the following to surveyor #1: (a) The MTS Diluent 2 Plus 0.5 mL dispenser was used to dispense 0.5 mL of diluent for performing ABO, Rh, and Compatibility testing on patient specimens and quality control materials; (b) The MTS Diluent 2 1.0 mL dispenser was used to dispense 1.0 mL of diluent for performing ABO and Rh typing on cord blood specimens. (4) Surveyor #1 reviewed the policy titled, "Blood Bank Equipment Maintenance". It stated, "A calibration check will be performed as part of a routine laboratory quality control schedule each six (6) months. Dispense 10 times into a clean, dry graduated cylinder and record the volume. Acceptable limits after 10 deliveries: 4.75-5.25 mL for the 0.5 mL dispenser, 9.50-10.50 mL for the 1.0 mL dispenser"; (5) Surveyor #1 reviewed records for 2017 and 2018 with the following identified: (a) Dispenser checks had not been performed between 04/05/17 and 01/17 /18; (b) Although the records indicated dispenser checks had been performed on both dispensers on 04/05/17, 01/17/18, and 07/13/18, there was no documentation of the results obtained to ensure the volumes were within the acceptable limits as defined in (4) above. The checks were documented as follows: (i) 04/05/17 - "All mechanical pipettes were manually checked for proper volume dispensing and all were found to be within proper ranges"; (ii) 01/17/18 - "MTS Dispensers calibration check performed as required every six (6) months"; (iii) 07/13/18 - "MTS Dispensers calibration checked". (6) Surveyor #1 reviewed the records with the laboratory manager and technical consultant. Both agreed the dispensers had not been checked between 04/05/17 and 01/17/18, and since the volumes obtained had not been documented in the records, it could not be determined if the dispenser checks that had been performed were acceptable.
D5555	IMMUNOHEMATOLOGY

	CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 records and interview with the laboratory manager and technical consultant, the laboratory failed to ensure units of blood were stored under appropriate conditions. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyors that units of packed red blood cells were stored in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On the third day of the survey, surveyor #1 observed the thermograph temperature recorder for the blood bank refrigerator. The refrigerator had a recorder connected to it for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees Centigrade). Each chart monitored the temperature for a 7 day period; (3) Surveyor #1 reviewed 26 refrigerator charts dated from 12/26 /17 through 08/14/18. The review indicated that 4 of 26 charts had not been changed by the 7th day of as follows: (a) Chart #1 - The chart was put into use on 12/26/17 and removed on 01/09/18 (14 days); (b) Chart #2 - The chart was put into use on 01/09/18 and removed on 01/17/18 (8 days); (c) Chart #3 - The chart was put into use on 05/01 /18 and removed on 05/15/18 (14 days); (d) Chart #4 - The chart was put into use on 05/22/18 and removed on 06/05/18 (14 days). (4) Surveyor #1 reviewed the charts with the technical consultant who stated the 4 charts had not been changed by the 7th day, as indicated above. NOTE: This deficiency was cited on the previous recertification survey performed 10/10,11,12/2016.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant, the laboratory failed to ensure corrective actions were taken to resolve problems with automated differential flags. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyors CBC (Complete Blood Count) testing was performed on the Sysmex XS 1000i analyzer; (2) On the second day of the survey, the laboratory manager stated to surveyor #1 the laboratory performed manual differentials or slide reviews as required by the manufacturer to verify flags obtained on the analyzer for the CBC analytes WBC (White Blood Cell), RBC (Red Blood Cell), and Platelet; (3) The laboratory manager and technical consultant then explained to surveyor #1 the laboratory performed a monthly QA (Quality Assessment) review to ensure testing personnel were addressing the flags as

	required. The QA review consisted of the following: (a) The laboratory manager reviewed patient printouts for flags and determined the total number of flags obtained for the month; (b) The records were then reviewed to determine the number of patient reports containing flags that had not been addressed as required by the manufacturer; (c) For the flags that were not addressed, corrective action was to be performed, which consisted of completing an "Incident Report Form" and "Patient Remediation Worksheet" for each patient to determine if patient outcome had been affected. (4) Surveyor #1 reviewed the QA documentation from January 2018 through July 2018 and identified that, although the laboratory had identified when flags had not been addressed, there was no documentation of the corrective action (including discussion with staff) and patient remediation taken to help prevent a recurrence for 5 of 7 months as follows: (a) January 2018 - The laboratory identified that 15 of 181 flags had not been addressed (b) March 2018 - The laboratory identified that 4 of 102 flags had not been addressed (c) May 2018 - The laboratory identified that 7 of 120 flags had not been addressed (d) June 2018 - The laboratory identified that 1 of 104 flags had not been addressed (e) July 2018 - The laboratory identified that 2 of 116 flags had not been addressed (5) Surveyor #1 reviewed the records with the technical consultant and laboratory manager and asked if there was documentation to prove corrective action and patient remediation had been performed for the above patients. Both stated corrective action and patient remediation had not been performed and documented.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with the respiratory therapy department supervisor, the laboratory failed to follow written policies when critical values were obtained. Findings include: (1) On the second day of the survey, the respiratory therapy department supervisor stated to surveyor #2 Arterial Blood Gas testing was performed on the Nova Stat Profile Prime analyzer; (2) Later on the second day of the survey, surveyor #2 reviewed a policy titled "REPORTING OF CRITICAL VALUES" which stated: (a) "When a critical value is obtained on any blood gas analyte, it is to be reported immediately to the attending physician, if available, and also to the patient's charge RN. Documentation is to be made on the report as to whom the result was reported to, the time of notification and the initials of the technician doing the reporting."; (3) The policy (Reporting of Critical Values) was then reviewed by surveyor #2 which defined the following critical values: (a) pO2 critical value as 50 mmHG (panic low); (b) pH critical value as 7.30 (panic high) and 7.5 (panic high); (c) pCO2 critical value as 20 mmHG (panic low) and 60 mmHG (panic high); (d) O2 Saturation value as 60% (panic low). (4) Surveyor #2 then chose 9 patient test reports containing Arterial Blood Gas results that met the critical value criteria. It was determined the laboratory had not followed their critical value policy for the 9 reports reviewed as follows: (a) Report #1 - Testing performed on 05/26/18 at 5.26 pm. The result obtained on 05/26/18 was pO2 25.6 mmHG. There was no evidence the result had been reported as required; (b) Report #2 -Testing performed on 06/09/18 at 01:49 pm. The result obtained on 06/09/18 was pO2 21.4 mmHG. There was no evidence the result had been reported as required; (c) Report #3 -

	Testing performed on 06/12/18 at 08:32 am. The result obtained on 06/12/18 was pO2 121.0 mmHG and pH 7.117. There was no evidence the result had been reported as required; (d) Report #4 - Testing performed on 06/21/18 at 06:20 pm. The result obtained on 06/20/18 was pCO2 84.8 mmHG. There was no evidence the results had been reported as required; (e) Report #5 - Testing performed on 06/23/18 at 01:22 am. The result obtained on 06/23/18 was pCO2 83.1 mmHG. There was no evidence the result had been reported as required; (f) Report #6 - Testing performed on 06/23/18 at 05:11 pm. The result obtained on 06/23/18 was pCO2 67.5 mmHG. There was no evidence the result had been reported as required; (g) Report #7 - Testing performed on 07/10/18 at 02:01 pm. The result obtained on 07/10/18 was pCO2 62.5 mmHG. There was no evidence the result had been reported as required; (h) Report #8 - Testing performed on 08/01/18 at 10:23 08:20 pm. The result obtained on 08/01/18 was pO2 16.3 mmHG. There was no evidence the result had been reported as required; (i) Report #9 - Testing performed on 08/03/18 at 10:23 am. The result obtained on 08/03/18 was pO2 27.8 mmHG. There was no evidence the result had been reported as required; (6) Surveyor #2 reviewed the findings with the respiratory therapy department supervisor, who stated the "REPORTING OF CRITICAL VALUES" policy had not been followed for the 9 results.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant and respiratory therapy department supervisor, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) 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; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical

	technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and respiratory therapy department supervisor, the technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings include: (1) On the first day of the survey, surveyor #2 reviewed records for 2 persons performing moderate complexity testing in 2017 and 2018. The records verified the evaluations for 1 of 9 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #11 (i) The 05/30/18 evaluation had been performed by testing person #10 (this person had earned a high school diploma). (2) Surveyor #2 explained to the technical consultant and respiratory therapy department supervisor, that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service).