Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475664	01/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Choctaw Memorial Hospital	1405 E Kirk, Hugo, 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 01/08/19 through 01/11/19. The findings were reviewed with the laboratory manager at the conclusion of the survey. The laboratory was found to be in compliance with standard-level deficiencies cited.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director or designee. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. The following was identified for 5 of 19 testing events: (a) Second 2017 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee. (b) Third 2017 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee. (c) First 2018 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee. (d)

	Second 2018 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee. (2) The findings were reviewed with the laboratory manager who stated the attestations had not been signed as indicated above.
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 a review of records and interview with the laboratory manager, the laboratory failed to perform a technical consultant and general supervisor competency based on the position responsibilities as listed in Subpart M. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records for competency assessments performed during 2017 and 2018. There was no evidence competencies had been performed for the technical consultant and general supervisor, based on their job responsibilities; (2) The surveyor asked the laboratory manager if competencies had been performed for the technical consultant and gneral supervisor, based on job responsibilities. The laboratory manager stated the competencies had not been performed.
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 laboratory manager, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Second 2017 Chemistry Core Event (i) Triglyceride - 3 of 5 results exhibited a positive bias (aa) Sample CH-07- SDI of 3.0 (bb) Sample CH-08 - SDI of 4.0 (cc) Sample CH-09 - SDI of 2.5 (b) Third 2017 Chemistry Core Event (i) Glycated Hemoglobin (%) - 2 of 2 results exhibited a positive bias (aa) Sample GLY-11- SDI of 4.3 (bb) Sample GLY-12 SDI of 3.0 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory manager who stated the biases had not been addressed. D5411 was cited on the recertification survey performed on 04/17,18,19/17
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 clinical laboratory manager, the laboratory failed to follow the manufacturer's instructions. Findings include: PT REAGENT (1) On the third day of the survey, the laboratory manager stated the following to the surveyor: (a) The Sysmex CA-660 analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing; (b) PT - Dade Innovin reagent, lot #549713C, was put into use on 03/28/18; (c) PTT - Siemens Actin FSL reagent, Lot# 556931A was put into use on 03/28/18. (2) The surveyor reviewed the manufacturer's instructions for implementing new lot numbers of reagents, which were as follows: (a) Section I titled "Verification of Reference Range," required 20 normal individuals using the following screening guidelines: (i) "10 males; 10 females representing reference population. 20 is the minimum requirement for a statistically valid study"; (ii) "Note medication history. After review of data, history may be used for excluding questionable results that can be contributed to medications"; (iii) "Assay samples on current and new lot number reagents simultaneously or within 1 hour of each other. This data can be used in Section II"; (iv) "Calculate mean and 2 SD range"; (v) "MNPT for INR calculation must be the geometric mean". (3) The implementation records were reviewed by the surveyor with the following identified: (a) There was no evidence the medication history had been documented (4) The surveyor review the manufacturer's instructions with the laboratory manager who stated the medication history had not been documented.
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 laboratory manager, the laboratory failed to ensure analyzers were stored as required by the manufacturer. Findings include: (1) On the first day of the survey, the laboratory manager stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed using the Sysmex XS 1000i analyzer; (b) Routine Chemistry testing was performed using the Siemens Dimension EXL 200 analyzer; (c) Arterial Blood Gas (pH, pCO2, pO2, O2 Saturation) testing was performed using Rapid Point 500. (d) Routine Coagulation (PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing was performed using the Sysmex CA 660 analyzer. (2) On the second day of the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzers. The manufacturer's required the relative humidity be maintained as follows: (a) Sysmex XS 1000i - range of 30-85%; (b) Siemen Dimension EXL 200 - range of 20-80% (c) Rapid Point 500 - range of 5-85% (d) Sysmex CA 660 - range 30-85% (3) The surveyor reviewed laboratory records from January 2018 through December 2018.

	There was no evidence that the humidity of the room, where the analyzers were maintained, had been monitored at an acceptable range of 30-80% to accommodate all analyzers; (4) The surveyor asked the laboratory manager if the humidity of the room, where the hematology, chemistry, arterial blood gas, and coagulation analyzers were maintained, was being monitored. The laboratory manager stated the humidity was not being monitored.
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 laboratory manager, 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 the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer; (b) Coagulation testing (PT/INR (Prothrombin Time/International Normalized Ratio and PTT (Partial Thromboplastin Time) was performed on the Sysmex CA 660 analyzer. (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs: (a) Sysmex 1000i Weekly Maintenance (i) Power Down IPU (b) Sysmex CA 660 Quarterly Maintenance (i) Perform LED Calibration (ii) Clean DI Water Rinse Bottle With Alcohol (3) The surveyor then reviewed maintenance records for 19 months (June 2017 through December 2018). There was no evidence the following maintenance had been performed: (a) Sysmex 1000i Weekly Maintenance (i) Between 06/26/17 and 07/17/17 (ii) Between 12/25/17 and 01/08/18 (iii) Between 02/05/18 and 02/19/18 (iv) Between 06/25/18 and 07/16/18 (b) Sysmex CA 660 Quarterly Maintenance (i) Between 12/03/17 and 05/20/18 (ii) Between 11/06/18 and the second day of the survey (01/09/19) (4) The surveyor reviewed the records with the laboratory manager, who stated the maintenance had not been documented as performed as required. D5411 was cited on the recertification survey performed on 04 /17,18,19/17
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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--Test control materials in the same manner as patient specimens. (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 laboratory manager, the laboratory failed to use control materials of a similar matrix to that of patient specimens. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor serum human chorionic gonadotropin (HCG) testing was performed using the Cardinal Health SP hCG Combo Kit; (2) Later during the

	survey, the surveyor reviewed quality control and patient HCG serum records for 4 months (May 2017, December 2017, March 2018 and November 2018) which identified the following: (a) For 2 of 4 patients tested, a negative and a positive urine control had been performed instead of blood based (serum/plasma) controls: (i) Patient tested 11/15/18 at 08:05 pm (ii) Patient tested 12/09/17 at 04:30 am (3) The surveyor reviewed the findings with the laboratory manager who stated urine controls had been used as indicated above. NOTE: The interpretive guidelines at D5465 (493.1256) state "Control materials of a similar matrix to that of patient specimens should be utilized, if available, and the control materials must be treated in the same manner as patient specimens and go through all analytic test phases."
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) 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, the laboratory failed to perform two levels of quality control materials each eight hours of PT/INR (Prothrombin Time/International Normalized Ratio and PTT (Partial Thromboplastin Time) testing. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyors PT/INR and PTT testing were performed on the Sysmex CA 660 analyzer; (2) On the third day of the survey, the laboratory manager stated to the surveyor two levels of quality control (QC) materials were performed each eight hours of patient testing; (3) The surveyor reviewed QC and patient testing records for testing performed in January 2018 and identified that two levels of QC testing had not been performed each eight hours of patient testing for 1 of 3 days of patient testing reviewed: (a) QC testing had been performed on 01/02/18 at 04:45 pm and patient testing had been performed on 01/03/18 at 01:30 am. (4) The surveyor reviewed the records with the laboratory manager, who stated two levels of QC materials had not been performed each eight hours of patient testing.
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, the laboratory failed to ensure units of blood were stored under appropriate conditions. Findings include: (1) On the third day of the survey, the surveyor 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; (2) The surveyor reviewed 16 refrigerator charts dated from August 2018 through November 2018. The review indicated that 1 of 16 charts had not been changed by the 7th day of usage as follows: (a) Chart #6 - The chart was put into use on 10/11/18 and removed on 10/23/18 (13 days). (3) The surveyor reviewed the charts with the laboratory manager, who stated the chart had not been changed by the 7th day of usage as indicated 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, policies and procedures, and interview with the laboratory manager, the laboratory failed to evaluate the relationship of chemistry testing performed on two different analyzers at least twice a year. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory performed routine chemistry using two Siemens Dimension analyzers interchangeably: (a) Siemens Dimension EXL 200 (denoted by the laboratory as #1) (b) Siemens Dimension EXL 200 (denoted by the laboratory as #2) (2) The surveyor then reviewed 2018 records and identified that, although the laboratory had performed comparison testing between the two analyzers twice in 2018, using Proficiency Testing Verification samples, there was no evidence the results had been evaluated by the laboratory for acceptability; (3) The surveyor reviewed the laboratory's policy and procedure manual. A policy could not be located that explained how the test results obtained from both analyzers were to be compared and evaluated; (4) The findings were reviewed with the laboratory manager. who stated the following to the surveyor: (a) The data had not been evaluated using defined criteria; (b) A comparison testing policy had not been written.
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 laboratory manager, the laboratory failed to make appropriate reference ranges available. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the Sysmex CA 660 analyzer; (2) On the third day of the survey, the surveyor reviewed the implementation records for the current lot numbers of reagents. The following was identified for PT and PTT: (a) PT Reagent

	(i) Siemens Dade Innovin reagent, lot #549713C put into use on 03/28/18; (ii) The normal reference range that had been established was 9.0-11.0 seconds. (b) PTT Reagent (i) Siemens Actin FSL reagent, lot #556931 put into use on 03/28/18; (ii) The normal reference range that had been established was 22.9-31.7 seconds. (3) The surveyor then reviewed a patient PT and PTT report: (a) Patient #1 - Testing performed on 01/10/19 with the following reference range: (i) PT reference range of 9.9-11.80 seconds. (b) Patient #2 - Testing performed on 01/09/19 with the following reference range: (i) PTT reference range of 25.0-31.30 seconds. (4) The surveyor reviewed the findings with the laboratory manager who stated the established normal reference ranges for PT and PTT were not included on the patient reports. D5411 was cited on the recertification survey performed on 04/17,18,19/17