Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656773	09/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mccurtain Memorial Hospital	1301 Lincoln Road, Idabel, 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 09/13,14,15,16/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer, chief financial officer, chief nursing officer, emergency room nursing director, technical consultant #2, laboratory manager, and chemistry lead during an exit conference performed at the conclusion of the survey.
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, written policy, and interview with technical consultant #2 and the laboratory manager, the laboratory failed to follow their policy for performing general supervisor, technical consultant, and technical supervisor competencies based on the position responsibilities as listed in Subpart M for one of one general supervisor and one of two technical consultant and technical supervisor. Findings include: (1) On 09/13/2022, a review of the competency assessment policy and interview with technical consultant #2 at 01:00 pm revealed that competencies for the general supervisor, technical consultant, and technical supervisor based on the position responsibilities were required to be performed annually; (2) A review of personnel records for competency assessments performed during 2021 and to date in 2022 revealed the following: (a) General Supervisor - There was no evidence of competencies performed during the review period; (b) Technical Consultant - Competencies had not been performed since 02/10/2020; (c) Technical Supervisor - Competencies had not been performed since 02/10/2020. (3) The findings were reviewed with the laboratory manager and technical consultant #2. Both stated on 09 /13/2022 at 02:14 pm, the competencies had not been documented as performed.

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, observation, manufacturer's instructions, and interview with the laboratory manager and coagulation lead, the laboratory failed to follow the manufacturer's instructions for implementing one of four coagulation reagents. Findings include: (1) On 09/13/2022 at 09:45 am, the laboratory manager stated PT /INR (Prothrombin Time/International Normalized Ratio) testing were performed on the Sysmex CA-660 analyzer; (2) On 9/15/2022, a review of the current reagents and implementation records revealed the PT reagent, Siemens Dade Innovin reagent lot #549770B, had been put into use on 10/25/2021 and was currently in use; (3) A review of the manufacturer's instructions for implementing new lot numbers of reagents stated: (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 abhorrent results"; (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". (b) Section under the heading,"To "go live" with the new lot numbers, follow these steps" stated, (i) "Input the new ISI and Mean Normal PT" (ii) "Use the mean normal PT obtained from a minimum of 20 normal samples tests on the new lot of reagent". (4) Review of the implementation records revealed the mean normal PT that had been calculated by the laboratory, using the instructions above, was 10.25; (5) On 09/15/2022 at 03:15 pm, observation of the mean normal PT that had been programmed into the Sysmex CA-660 analyzer, with the assistance of the coagulation lead, revealed that the mean normal PT that had been programmed into the analyzer was 10.0; (6) The findings were reviewed with the laboratory manager and coagulation lead. Both stated on 09/15/2022 at 03:45 pm, the mean normal PT that had been programmed into the analyzer did not correlate with the value the laboratory had calculated (10.25) and they could not explain how the laboratory had derived the 10.0 value. (NOTE: the ISI and normal patient mean are used to calculate patient INR results).
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 the laboratory manager and technical consultant #2, the laboratory failed to ensure the performance specifications had been reviewed and evaluated by the laboratory for one of one new test system. Findings include: (1) On 09/14/2022 at 11:10 am, technical consultant #2 stated the laboratory began using the Nova Biomedical Stat Sensor Creatine meter to perform fingerstick Creatinine testing on 01/15/2021; (2) A review of the performance specification (validation) records revealed no documentation the laboratory had reviewed and evaluated the validation data to approve the new test method prior to putting into use; (3) The findings were reviewed with the laboratory manager and technical consultant #2. Both stated on 09/14/22 at 11:20 am, there was no documentation to prove that the validation data had been reviewed and evaluated by the laboratory. (NOTE: The interpretive guidelines at 493.1253(b)(1) state, "The laboratory is responsible for verifying the performance specifications of each nonwaived unmodified FDA-cleared or approved test system that it introduces, prior to reporting patient test results." In addition, the interpretive guidelines state, "Prior to introducing a test for routine patient testing, the laboratory must review and evaluate the verification data.")
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 and chemistry lead, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for two of two Dimension EXL analyzers. Findings include: DIMENSION EXL DENOTED AS "B" (1) On 09/13/2022 at 10:30 am, the laboratory manager stated the following: (a) Acetaminophen, Albumin, Alcohol, Ammonia, Amylase, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), BUN, Calcium, Carbamezapine, Chloride, Cholesterol, CK (Creatine Kinase), CKMB (CK isoenzyme), CO2, Creatinine, CRP (C-Reactive Protein), Digoxin, Dilantin, Direct Bilirubin, Ferritin, Gentamicin, Glucose, HDL Cholesterol, Hemoglobin A1c, Iron, Lactic Acid, Lipase, Magnesium, Myoglobin, Phenobarbital, Phosphorus, Potassium, Prealbumin, PSA (Prostate Specific Antigen), Quantitative HCG (Human Chorionic Gonadotropin), Sodium, TIBC (Total Iron Binding Capacity), Tobramycin, Total Bilirubin, T4, Total Protein, Triglycerides, Troponin I, TSH (Thyroid Stimulating Hormone), T-uptake, Uric Acid, Valproic Acid, and Vancomycin testing were performed on the Siemens Dimension EXL, denoted by the laboratory as "B", as the primary analyzer; (2) On 09/16/2022, a review of the manufacturer's maintenance instructions, as stated on the manufacturer's maintenance logs revealed the following requirements: (a) Weekly (i) Clean Outside of R2 Probe (ii) Clean Outside of HM Wash Probe (b) Monthly (i) Clean Clot Check Drain on IMT Port (ii) Replace IMT Pump Tubing (iii) Clean IMT System (iv) Replace/Clean Air Filters (v) Stylette HM Wash Probes (vi) Replace HM Pump Heads (vii) Clean R1/R2 Drain (viii) Clean R3 Drain (3) A review of maintenance records for eight months (01/01/2022 through 08 /31/2022) revealed the following for the weekly and/or monthly maintenance: (a) Weekly - Not documented as performed between: (i) 03/08/2022 and 03/23/2022 (ii) 04/18/2022 and 05/09/2022 (iii) 05/09/2022 and 06/28/2022 (iv) 06/08/2022 and 07/19

	/2022 (v) 07/27/2022 and 08/11/2022 (b) Monthly (i) Clean Clot Check Drain on IMT Port, Replace IMT Pump Tubing, Replace/Clean Air Filters, Stylette HM Wash Probes, Replace HM Pump Heads, Clean R1/R2 Drain, and Clean R3 Drain not documented as performed between 07/17/2022 and 08/29/2022. (4) The records were reviewed with the laboratory manager and chemistry lead. Both stated on 09/16/2022 at 10:20 am, the maintenance had not been documented as performed as stated above. DIMENSION EXL DENOTED AS "D" (1) On 09/13/2022 at 10:30 am, the laboratory manager stated the following: (a) Acetaminophen, Albumin, Alcohol, Ammonia, Amylase, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), BUN, Calcium, Carbamezapine, Chloride, Cholesterol, CK (Creatine Kinase), CKMB (CK isoenzyme), CO2, Creatinine, CRP (C-Reactive Protein), Digoxin, Dilantin, Direct Bilirubin, Ferritin, Gentamicin, Glucose, HDL Cholesterol, Hemoglobin A1c, Iron, Lactic Acid, Lipase, Magnesium, Myoglobin, Phenobarbital, Phosphorus, Potassium, Prealbumin, PSA (Prostate Specific Antigen), Quantitative HCG (Human Chorionic Gonadotropin), Sodium, TIBC (Total Iron Binding Capacity), Tobramycin, Total Bilirubin, T4, Total Protein, Triglycerides, Troponin I, TSH (Thyroid Stimulating Hormone), T-uptake, Uric Acid, Valproic Acid, and Vancomycin testing were performed on the Siemens Dimension EXL, denoted by the laboratory as "D", as the backup analyzer; (b) The analytes Urine Microalbumin, Cerebral Spinal Fluid Protein, and Cerebral Spinal Fluid Glucose were performed solely on this analyzer. (2) On 09/16/2022, a review of the manufacturer's maintenance instructions, as stated on the manufacturer's maintenance logs revealed the following requirements: (a) Weekly (i) Clean Outside of R2 Probe (ii) Clean Outside of HM Wash Probe (b) Monthly (i) Clean Clot Check Drain on IMT Port (ii) Replace IMT Pump Tubing (iii) Clean IMT System (iv) Replace/Clean Air Filters (v) Stylette HM Wash Probes (vi) Replace HM Pump Heads (vii) Clean R1/R2 Drain (viii) Clean R3 Drain (3) A review of maintenance records for eight months (01/01 /2022 through 08/31/2022) revealed the following for the weekly and/or monthly maintenance: (a) Weekly - Not documented as performed between: (i) 04/12/2022 and 04/20/2022 (ii) 05/10/2022 and 07/03/2022 (iii) 07/03/2022 and 07/29/2022 (b) Monthly (i) Clean Clot Check Drain on IMT Port, Replace IMT Pump Tubing, Replace/Clean Air Filters, Stylette HM Wash Probes, Replace HM Pump Heads, Clean R1/R2 Drain, and Clean R3 Drain not documented as performed during February 2022; (ii) Replace IMT Pump Tubing not documented as performed between 03/27/2022 and 07/29/2022. (4) The records were reviewed with the laboratory manager and chemistry lead. Both stated on 09/16/2022 at 10:20 am, the maintenance had not been documented as performed as stated 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 laboratory manager the

	laboratory failed to follow their written protocol for ensuring the urine and coagulation centrifuges were functioning properly. Finding include: URINE CENTRIFUGE (1) On 09/13/2022 at 09:30 am, the laboratory manager stated the following: (a) Urine sediment examinations were performed in the laboratory; (b) The specimens were processed in the Cardinal Health Horizon 6 flex FA centrifuge at a speed of 1900 rpm (revolutions per minute) for 5 minutes; (c) It was the policy of the laboratory to perform centrifuge speed and timer checks on an annual basis. (2) A review of centrifuge records for 2021 and 2022 revealed that although the centrifuge had been checked annually, the following was identified: (a) 11/2021 - The speed had been checked at 2210 rpm, instead of the speed the laboratory processed specimens and the timer check had been documented with checkmark and not the actual time that had been obtained; (b) 05/2022 - The speed had been checked at 2230 rpm, instead of the speed the laboratory processed specimens and the timer check had been documented with checkmark and not the actual time that had been obtained. (3) The records were reviewed with the laboratory manager who stated on 09/13/2022 at 04: 36 pm, the speed had not been checked at the speed urine specimens were processed and the timer checks had not been documented. COAGULATION CENTRIFUGE (1) On 09/13/2022 at 09:30 am, the laboratory manager stated the following: (a) PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed in the laboratory using the Sysmex CA 660 analyzer; (b) The specimens were processed in the Beckman Coulter Allegrax-30 centrifuge at a speed of 3500 rpm (revolutions per minute) for 10 minutes; (c) It was the policy of the laboratory to perform centrifuge speed and timer checks on an annual basis. (2) A review of centrifuge records for 2021 and 2022 revealed that although the centrifuge had been checked annually, the following was identified: (a) 11/2021 - The timer check had been documented with checkmark and not the actual time that had been obtained; (b) 5/2022 - The timer check had been documented with checkmark and not the actual time that had been obtained. (3) The records were reviewed with the laboratory manager who stated on 09/13/2022 at 04:36 pm, the timer checks had not been documented.
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 a review of records and interview with the laboratory manager, the laboratory failed to perform a negative and positive control material each day of Fetal Screen testing for one of three days of patient testing and Clostridium difficile testing for two of 14 days of patient testing. Findings include: FETAL SCREEN (1) On 09/14 /2022 at 01:30 pm, the laboratory manager stated the following: (a) Fetal Screen testing was performed in the blood bank department using the Immucor FMH Rapid Screen test kit; (b) Negative and positive QC (Quality Control) materials were performed each day of patient testing. (2) A review of QC and patient records revealed that negative and positive QC materials had not been performed one of three days of patient testing. The specific day was 03/18/2022; (3) The records were reviewed with the laboratory manager who stated on 09/14/22 at 04:37 pm, negative

	and positive QC had not been performed each day of patient testing. CLOSTRIDIUM DIFFICILE (1) On 09/14/2022 at 04:00 pm, the laboratory manager stated the following: (a) Clostridium difficile testing was performed using the Meridian C. diff Toxin A/B test kit; (b) Negative and positive QC materials were performed each day of patient testing. (2) A review of QC and patient records revealed that negative and positive QC materials had not been performed two of 14 days of patient testing. The specific days were 05/21,24/2022; (3) The records were reviewed with the laboratory manager who stated on 09/14/22 at 05:00 pm, negative and positive QC had not been performed each day 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 for three of 19 blood bank refrigerator temperature charts and three of 19 plasma freezer temperature charts. Findings include: (1) On 09/13/2022 at 09:20 am, the laboratory manager stated units of packed red blood cells were stored in the blood bank refrigerator and units of FFP (fresh frozen plasma) were stored in the Migali plasma freezer. The units were to be used for patient transfusions; (2) On 09/14/2022 at 11:30 am, the surveyor observed the thermograph temperature recorder for the blood bank refrigerator and the plasma freezer. Both had recorders connected to them for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees Centigrade and units of FFP must be stored at -18 degrees Centigrade or colder). Each chart monitored the temperature for a 7 day period; (3) A review of 19 refrigerator and freezer charts dated from 04/11/2022 through 08/22/2022 revealed that three of 19 refrigerator charts and three of 19 plasma freezer charts had not been changed by the 7th day of as follows: (a) Refrigerator (i) Chart #1 - The chart had been put into use on 06/20/2022 and removed on 06/28/2022 (8 days); (ii) Chart #2 - The chart had been put into use on 06 /28/2022 and removed on 07/12/2022 (14 days); (iii) Chart #3 - The chart had been put into use on 07/31/2022 and removed on 08/08/2022(8 days). (b) Freezer (i) Chart #1 - The chart had been put into use on 06/20/2022 and removed on 06/28/2022 (8 days); (ii) Chart #2 - The chart had been put into use on 06/28/2022 and removed on 07/12/2022 (14 days); (iii) Chart #3 - The chart had been put into use on 07/31/2022 and removed on 08/08/2022(8 days). (4) The charts were reviewed with the laboratory manager who stated on 09/14/2022 at 01:10 pm, the charts had not been changed by the 7th day, 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 written policies and interview with the laboratory manager, the laboratory failed to ensure that written policies provided safety for individuals being transfused for one of three patients reviewed. Findings include: (1) On 09/13/2022 at 09:20 am, the laboratory manager stated units of packed red blood cells were stored in the blood bank refrigerator. The units were to be used for patient transfusions; (2) A review of the hospital policy titled, "Blood/Blood Components, Transfusion" stated, "A consent form shall be signed prior to infusion"; (3) A review of three patient records for six units of packed red blood cells that had been transfused in December 2021, May 2022, and July 2022 revealed the following: (a) Patient Record #2 - Unit #W091022213397 transfused on 05/17/2022 from 08:54 pm-11:54 pm and unit #W091022125122 transfused on 05/18/2022 from 08:55 am-11:50 am; (b) There was no evidence of a signed consent. (4) The records were reviewed with the laboratory manager who stated on 09/14/2022 at 02:15 pm, the signed consent was not available.
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, patient report, written procedure, and interview with the laboratory manager and technical consultant #2, the laboratory failed to ensure reference intervals were available to the authorized person who ordered tests. Findings include: (1) On 09/14/2022 at 11:10 am, technical consultant #2 stated the following: (a) The laboratory began using the Nova Biomedical Stat Sensor Creatinine meter to perform fingerstick Creatinine testing on 01/15/2021; (b) The primary method of performing Creatinine testing was using plasma specimens on the Siemens Dimension EXL analyzer. (2) A review of the procedure titled, "StatSensor Creatinine Testing" revealed the following normal reference intervals: (a) Female 0.5-1.2 mg/dl (b) Male 0.7-1.3 mg/dl (3) A review of a patient fingerstick Creatinine report for a female tested on 08/15/2022 at 02:09 pm revealed a reference range of 0.6-1.3, which did not correlate to the female reference range in the procedure. In addition, there was no documentation to differentiate the Creatinine result performed using a fingerstick specimen and the StatSensor and a plasma specimen using the Siemens Dimension EXL analyzer; (4) The records were reviewed with the laboratory manager who stated on 09/14/2022 at 12:25 pm, the reference range on the patient report did not match the reference range in the procedure and the reports did not differentiate between the different methods.

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 laboratory manager and technical consultant #2, the technical consultant failed to ensure that a person performing moderate complexity testing had been evaluated semiannually during the first year of testing for one of two testing persons. Findings include: (1) On 09/13/2022, a review of personnel records revealed no evidence a semiannual evaluation had been performed as follows: (a) Testing Person #6 - The initial training for this person was completed on 11/02/2020. There was no evidence an evaluation had been performed between 11/02/2020 and 12/24/2021; (2) The records were reviewed with the laboratory manager and technical consultant #2. Both stated on 09/13/2022 at 02:14 pm there were no records to prove the above person had been evaluated semiannually.