Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0471986	10/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Hospital Love County	300 Wanda Street, Marietta, 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 10/26,27,28/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the administrator, chief of staff, laboratory director, laboratory manager, technical consultant #3, and general supervisor #2 during an exit conference performed at the conclusion of the survey.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing 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 take corrective actions for unacceptable proficiency testing scores for one of five Hematology proficiency testing events reviewed. Findings include: (1) On 10/26/2022 at 09:50 am, the laboratory manager stated CBC (Complete Blood Count) testing was performed on the Sysmex XS 1000i analyzer; (2) A review of five Hematology proficiency testing events (First 2021, Second 2021, Third 2021, First 2022, and Second 2022) identified the following failure: (a) Second 2021 Event - The laboratory attained a score of 60% for the analyte platelet. There was no evidence that corrective action had been documented. (3) The records were reviewed with the laboratory manager who stated on 10/26/2022 at 11:54 am, corrective action had not been taken and documented for the failure.

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 policies and procedures, and interview with the laboratory manager, the laboratory failed to have a written policy to assess the competency of two of three technical consultants, three of three general supervisors, and two of three technical supervisors, based on the position responsibilities as listed in Subpart M. Findings include: (1) On 10/26/2022, a review of the competency assessment policy revealed there was no guidance, including the frequency, for assessing the competency of the technical consultants, general supervisors, and technical supervisors; (2) A review of personnel records for competency assessments performed during the review period of 2021 through the current date in 2022 identified competencies, based on job responsibilities had not been performed for the following positions: (a) Technical Consultant #2 (b) Technical Consultant #3 (c) General Supervisor #1 (d) General Supervisor #2 (e) General Supervisor #3 (f) Technical Supervisor #2 (g) Technical Supervisor #3 (3) The findings were reviewed with the laboratory manager who stated on 10/26/2022 at 03:32 pm, a policy had not been written and competencies had not been performed for the position responsibilities as shown above.
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 for one of five Hematology Proficiency testing events. Findings include: (1) On 10/26/2022, a review of Hematology Proficiency testing records for five events (First 2021, Second 2021, Third 2021, First 2022, and Second 2022) identified the following failures with no evidence that corrective actions had been documented as performed: (a) Second 2021 Event (i) Hematocrit - The laboratory attained a score of 80% (ii) MCV - The laboratory attained a score of 60% (iii) MCHC - The laboratory attained a score of 60% (2) The records were reviewed with the laboratory manager who stated on 10/26 /2022 at 11:54 am, corrective action had not been taken and documented for the failures.
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 during three of 21 months reviewed. Findings include: (1) On 10/26/2022 at 09:55 am, the laboratory manager stated CBC (Complete Blood Count) testing was performed using the Sysmex XS 1000i analyzer; (2) On 10/27/2022, 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 2021 through September 2022 revealed the weekly maintenance had not been documented as performed between: (a) 05/11/2022 and 05/25/2022 (b) 06/08/2022 and 06/22/2022 (c) 09/14/2022 and 09/28 /2022 (4) The records were reviewed with the laboratory manager who stated on 10/27 /2022 at 02:30 pm, the weekly maintenance had not been documented as performed as shown above.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. 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 perform function checks every six months as defined by the manufacturer for the iSTAT 1 analyer. Findings include: (1) On 10 /26/2022 at 09:55 am, the laboratory manager stated the laboratory performed the following on the iSTAT 1 analyzer: (a) Glucose, Creatinine, BUN, Chloride, Potassium, Sodium, CO2, and Ionized Calcium testing using the Chem 8+ cartridge as a backup method to the Siemens Dimension Xpand analyzer; (b) pH, pCO2, pO2, and Lactic Acid testing using the CG4+ cartridge; (c) Troponin I testing using the cTnI cartridge. (2) A review of the manufacturer's "Quality System Instructions" on page 2 stated, "Ensure thermal probe check is performed every six months on each handheld reader"; (3) A review of records from January 2021 through the current date identified no evidence the thermal probe checks had been performed during the review period; (4) The findings were reviewed with the laboratory manager who stated on 10/27 /2022 at 10:28 am, the thermal probe checks had not been performed every six months.
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 laboratory manager and technical consultant #3, the laboratory failed to ensure the blood bank centrifuge timer was functioning properly for one of two years reviewed. Findings include: (1) On 10/26/2022 at 11:00 am, the laboratory manager stated the laboratory used the Ortho MTS workstation centrifuge to process specimens for ABO Group, D (Rh) Typing and Antibody Screen testing at a speed of 1022-1042 rpm (revolutions per minute) for 15 minutes; (2) The "Centrifuge Function Check" policy required twice annual centrifuge speed checks and quarterly timer checks; (3) A review of centrifuge speed and timer check records for 2021 through the current date identified that, although the centrifuge speed had been checked twice annually during the review period, the timer had not been checked quarterly as follows: (a) The timer had not been checked after 3/15/22 (4) The records were reviewed with technical consultant #3 who stated on 10/28/2022 at 12:00 pm, the centrifuge timer had not been checked quarterly.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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 and technical consultant #3, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process for Chemistry testing for four of nine months reviewed. Findings include: (1) On 10/26/2022 at 09:47 am, the laboratory manager stated the following: (a) The laboratory performed Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Alcohol, Amylase, AST (Aspartate Aminotransferase), BUN (Blood, Urea, Nitrogen), Calcium, CK (Creatine Kinase), CKMB (Creatine Kinase Isoenzyme), Creatinine, Chloride, Cholesterol, Hemoglobin A1c, HDL, LDL, LDH (Lactate Dehydrogenase), Triglyceride, CO2, Direct Bilirubin, Glucose, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Bilirubin, Total Protein, Uric Acid, PSA (Prostate Specific Antigen), Digoxin, Acetaminophen, TSH (Thyroid Stimulating Hormone), and Free T4 (Thyroxine) testing using the Siemens Dimension Xpand analyzer; (b) Two levels of QC (quality control) materials were performed each day of patient testing. (2) On 10/28/2022, QC records (i.e., Levey-Jennings data) were requested for the above testing performed from January 2022 through September 2022 to ensure QC had been monitored for variances (shifts, trends, biases). Technical consultant #3 stated on 10/28/2022 at 10:10 am, there were no records (i.e., Levey-Jennings and cumulative data) proving the control results had been monitored for variances during the review period.

D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (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 and general supervisor #2, the laboratory failed to perform two levels of quality control materials each day of patient testing for two of five days reviewed. Findings include: (1) On 10 /26/2022 at 10:00 am, the laboratory manger stated the following: (a) Glucose, Creatinine, BUN, Chloride, Potassium, Sodium, CO2, and Ionized Calcium testing were performed using the Chem 8+ cartridge and the iSTAT 1 analyzer as the backup method to the Siemens Dimension Xpand analyzer; (b) An IQCP (Individualized Quality Control Program had not been developed for the test system). (2) A review of QC (Quality Control) and patient testing records from January 2022 through the current date identified at least two levels of QC testing had not been performed each day of patient testing reviewed for two of five days (06/18/2022 and 07/13/2022). (3) The records were reviewed with general supervisor #2 who stated on 10/27/2022 at 09: 55 am, the laboratory had not performed two levels of QC testing each day of patient testing as stated above.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different test methods for seven of seven analytes. Findings include: (1) On 10/26/2022 at at 09:47 am, the laboratory manager stated Glucose, Creatinine, BUN, Chloride, Potassium, Sodium, and CO2 testing were performed using two methods: (a) Siemens Dimension Expand analyzer as the primary method; (b) iSTAT 1 analyzer and the Chem 8+ cartridge as the back-up method. (2) Records were requested to prove the relationship between the testing performed using the different test methods had been evaluated twice annually during the review period of January 2021 through the current date; (3) The laboratory manager stated on 10/26/2022 at 03:45 pm, there was no documentation to show the relationship between the testing using the two methods had been evaluated twice annually during the review period.
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 ensure reference intervals were determined as appropriate for the laboratory's patient population for two of two patient reports reviewed. Findings include: (1) On 10/26/2022 at 09:55 am, the laboratory manager stated CBC (Complete Blood Count) testing was performed using the Sysmex XS 1000i analyzer; (2) On 10/27/2022, two patient CBC reports were reviewed - the first report was for an adult female patient with the testing performed on 10/26/2022 at 08:50 am; the second report was for an adult male patient with the testing performed on 10/27/2022 at 11:19 am. Both reports included the same reference intervals for the following CBC parameters: (a) RBC (red blood cell) count - 4.20-10.9 K/ul (b) Hemoglobin - 12.0-18.0 g/dl (c) Hematocrit - 37.0-51.0% (3) The reports were reviewed with the laboratory manger who stated on 10/27/2022 at 02:30 pm, the patient reports did not include gender specific reference ranges for RBC, Hemoglobin, and Hematocrit.