Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656546	11/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Hospital Logan County,Inc	200 S Academy Road, Guthrie, 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 11/13,14,15,16/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant, director of operations, laboratory manager, laboratory support technician, and testing person #2 during an exit conference performed at the conclusion of the survey.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the Hematology policy and procedure manual, and interview with the technical consultant, the laboratory failed to have complete written

	procedures for one of one procedure reviewed. Findings include: (1) On 11/13/2023 at 10:40 am, the technical consultant stated manual CSF (Cerebrospinal Fluid) Cell Counts were performed using a Hemacytometer; (2) A review of the procedure titled, "MHLC LABCO Hematology - Cerebrospinal Fluid (CSF) Cell Counts" identified the following had not been included: (a) Step-by-step performance of the procedure, including test calculations and interpretation of results (to include limits of acceptability for duplicate counts of quality control and patient specimens); (b) Control Procedures to include type of control, identity, number and frequency of testing controls, and criteria to determine acceptable control results; (d) The laboratory's system for entering results in the patient record and reporting patient results. (3) The findings were reviewed with the technical consultant who stated on 11 /15/2023 at 11:15 am, the CSF procedure did not include all of the required information.
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 centrifuging urine specimens for microscopic examination using the UniSystem Urinalysis System. Findings include: (1) On 11/15/2023 at 01:40 pm, the technical consultant stated the following: (a) Microscopic Urinalysis testing was performed using the UniSystem Urinalysis system. (2) A review of the manufacturer's package insert stated; (a) "Centrifuge the tube for five minutes at 450 RCF." (3) Observation of the Drucker Horizon centrifuge, revealed that the centrifuge was set to spin at 402 RCF; (4) The findings were reviewed with the technical consultant, who stated on 11 /15/2023 at 1:40 pm that urines were being centrifuged at 402 RCF.
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, observation, and interview with the technical consultant, the laboratory failed to ensure quality control materials were stored as required by the manufacturer for two of seven months reviewed in 2023. Findings include: (1) On 11/16/2023 at 11:00 am, observation of the contents of the ABS (American Biotech Supply) freezer identified the following materials: (a) One box

	containing 20 vials of Bio-Rad Unassayed Chemistry Control level one, lot #92951 - the storage requirement as stated on the box was -70 to -20 degrees C (Centigrade); (b) One box containing 20 vials of Bio-Rad Unassayed Chemistry Control level two, lot #92952 - the storage requirement as stated on the box was -70 to -20 degrees C (Centigrade); (c) Seven boxes (containing six vials each) of Bio-Rad Cardiac Markers Plus Control LT level three, lot #67673 - the storage requirement as stated on the boxes were -70 to -20 degrees C (Centigrade). (2) A review of temperature records for seven months (May 2023 through November 2023) identified documented temperatures warmer than -20 degrees C for two of seven months as follows: (a) June 2023, two of 30 temperatures were documented as warmer than -20 degrees C (b) October 2023, two of 31 temperatures were documented as warmer than -20 degrees C (3) The records were reviewed with the technical consultant on 11/16/2023 at 11:05 am, who stated that the quality control materials had not been stored as required by the manufacturer. 48517 Based on observation and interview with the technical consultant (TC), the laboratory failed to ensure two of two Vacuette brand tubes were stored as required by the manufacturer in the laboratory freezer. Findings include: (1) Observation of the laboratory freezer and interview with the TC on 11/13/2023 at 10: 38 am, identified the following: (a) Two Vacuette LiHep tubes, lot # 454029, storage temperature of 4-25 degrees Celsius; (b) Four Vacuette K2, EDTA tubes, lot # 454209, storage temperature of 4-25 degrees Celsius. (2) Interview with the technical consultant on 11/13/2023 at 10:38 am confirmed the tubes were being stored below the manufacterer's stated temperature.
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 technical consultant (TC), the laboratory failed to utilize the demonstrated reportable ranges for Blood Gas testing using the i-STAT analyzer put into use on 11/07/2023. Findings include: (1) On 11/16 /2023 at 11:15 am, the technical consultant stated the laboratory began testing on the Abbott i-STAT for Blood Gas (pH, pCO2, pO2) testing using the EG6+ cartridge on 11/07/2023; (2) A review of the performance specification records for the analyzer identified the laboratory had demonstrated the following reportable ranges: (a) pCO2 - 10.6 - 91 mmHg (b) pO2 - 10 - 612 mmHg (c) pH - 6.53 - 7.915 (3) Interview with the technical consultant 11/16/2023 at 11:15 am confirmed the laboratory was using the following manufacturer's reportable ranges instead of the ranges that had been demonstrated by the laboratory: (a) pCO2 - 7.0 - 105 mmHg (b) pO2 - 10 - 758 mmHg (c) pH - 5.57 - 9.07
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control

material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (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, written procedure, and interview with the technical consultant, the laboratory failed to ensure quality control results were within the manufacturer's acceptable limits and duplicate testing within defined acceptability for five of five days reviewed; and failed to ensure duplicate testing of patient results were within defined acceptability for three of five days reviewed when performing manual Cerebrospinal Fluid (CSF) cell counts using a hemacytometer. Findings include: (1) On 11/13/2023 at 10:40 am, the technical consultant stated the following: (a) Manual CSF Cell Counts were performed using a Hemacytometer; (b) Two levels of Streck Cell-Chex Body Fluid Cell Count QC (Quality Control) materials were tested in duplicate, with an average of the two counts calculated, when patient specimens were tested. The manufacturer's provided package insert ranges were used to determine acceptability of quality control results; (c) Patient specimens were tested in duplicate with the average of the two counts reported; (d) The verbal policy for the correlation of the QC and Patient results from the duplicate testing was 10%. (2) On 11 /15/2023 a review of QC and patient testing performed in April 2023, May 2023, July 2023, and August 2023 identified the following for five of five days of patient testing reviewed: (a) QC Testing - The QC results for the counts in one or both chambers were not within the acceptable limits of the commercial QC materials or the correlation of the counts from the duplicate testing for WBC and/or RBC were beyond 10% for five of five days of patient testing as follows: (i) 04/29/2023 (aa) WBC (White Blood Cell) Count Level 2 (lot #30370413) - The acceptable range for the QC was 86-136. The count from the first chamber was 77 and the count from the second chamber was 66. In addition, the correlation of the counts was beyond 10%; (bb) RBC (Red Blood Cell) Count Level 2 (lot #30370413) - The acceptable range for the QC was 77-127. The count from the second chamber was 65. (ii) 05/31/2023 (aa) WBC Count Level 2 (lot #30370413) - The acceptable range for the QC was 86-136. The count from the first chamber was 60. In addition, the correlation of the counts was beyond 10% (count from the second chamber was 109); (bb) RBC Count Level 2 (lot #30370413) - The acceptable range for the QC was 77-127. The count from the second chamber was 75. (iii) 07/27/2023 (aa) WBC Count Level 2 (lot #30370413) - The acceptable range for the QC was 86-136. The count from the first chamber was 81. In addition, the correlation of the counts was beyond 10% (count from the second chamber was 125); (iv) 08/10/2023 (aa) RBC Count Level 2 (lot #31490413) - The acceptable range for the QC was 78-128. The count from the first chamber was 77. (v) 08/25/2023 (aa) WBC Count Level 2 (lot #31490413) - The acceptable range for the QC was 83-133. The count from the first chamber was 80 and the count from the second chamber was 74; (bb) RBC Count Level 2 (lot #31490413) - The acceptable range for the QC was 78-128. The count from the second chamber was 76. (b) Patient Testing - The correlation of the counts from the duplicate testing for WBC and/or RBC were beyond 10% for three of five days of patient testing as follows: (i) 05/31 /2023 (aa) RBC Count - The count from the first chamber was 729 and the count from the second chamber was 921, with an average of 825 reported. (ii) 08/10/2023 (aa) WBC Count - The count from the first chamber was 50 and the count from the second chamber was 36, with an average of 43 reported. (iii) 08/25/2023 (aa) RBC Count - The count from the first chamber was 33 and the count from the second chamber was 61, with an average of 47 reported. (3) A review of the procedure titled, "MHLC LABCO Hematology - Cerebrospinal Fluid (CSF) Cell Counts" identified no

	guidance for evaluating QC results and patient results, including correlation of the results from the duplicate testing (refer to D5403); (4) The findings were reviewed with the technical consultant who stated on 11/25/2023 at 02:50 pm, QC and/or patient results were not reported as required 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 a written policy and interview with the technical consultant, the facility failed to ensure that written policies provided safety for individuals being transfused for one of four patients reviewed. Findings include: (1) On 11/14/2023 at 02:00 pm, the technical consultant 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) A review of the hospital policy titled, "MW NUR Administration Transfusion of Blood or Blood Products" stated the following: (a) "Assess, obtain vital signs, and monitor for signs and symptoms of transfusion reaction"; (i) "Within 30 minutes before transfusion begins"; (ii) "Within 10-15 minutes after the transfusion begins"; (iii) "At the end of the transfusion, but not more than 60 minutes after the transfusion has been discontinued". (3) A review of records for four patients receiving transfusions in December 2022, July 2023, Spetember 2023, and October 2023, identified no evidence the policy had been followed for one of four patients transfused as follows: (a) Patient #E1401900418 - Transfused with one unit of PRBC's on 12/15/2022 (unit #W091022392726). There was no evidence a temperature had been obtained within 30 minutes prior to transfusion. (4) The records were reviewed with the technical consultant, who stated on 11/14/2023 at 02:50 pm, the policy had not been followed as stated above.