Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0471956	06/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Hospital Healdton, Inc	3462 Hospital Rd, Healdton, 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 06/26,27,28/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, technical consultant, administrator, and testing person #4 during an exit conference performed at the conclusion of the survey.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on a review of records, policy and interview with the technical consultant, the facility failed to ensure written policies were followed for preventing transfusion reactions for three of seven units reviewed. Findings include: (1) On 06/27/2024 at 11: 00 am, the technical consultant stated the laboratory performed transfusion services for emergency release blood and blood products that have been tested by Mercy Hospital Ardmore; (2) The policy "Administration Transfusion of Blood or Blood Products" defined the parameters for ensuring safe administration of blood or blood products for transfusion therapy; (3) The surveyor reviewed the policy which stated, "Assess, obtain vital signs, and monitor for signs and symptoms of transfusion reaction": (a) "Within 30 minutes before transfusion begins"; (b) "Within 10-15 minutes after the start of transfusion" (c) "At the end of the transfusion, but not more than 60 minutes after the transfusion has been discontinued"; (d) "Continue to assess and monitor the patient for signs and symptoms of a delayed transfusion reaction for 4-6 hours after the transfusion. If outpatient, provide patient teaching about signs and symptoms of a delayed transfusion reaction". (4) A review of transfusion records for seven units of blood transfused identified for three of seven units transfused, the

	policy was not followed by nursing personnel: (a) Unit #W09102322015 - The unit was started at 2:12 pm and ended at 4:17 pm. There were no vitals documented for the 4-6 hour post transfusion assessment; (b) Unit #W091024129278 - The unit was started at 6:23 pm and ended at 8:55 pm. There were no vitals documented for the 4-6 hour post transfusion assessment; (c) Unit #W091024242316 - The unit was started at 1:32 pm and ended at 4:06 pm, there were no vitals documented for the 4-6 hour post transfusion assessment. (5) Interview with the technical consultant on 06/27/2024 at 11:00 am confirmed the facility failed to ensure the policy was being followed as written.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to evaluate the accuracy of testing when a proficiency result had not been graded by the proficiency testing program for two of seven Hematology /Coagulation events reviewed from August 2022 through the current date. Findings include: (1) A review of Hematology/Coagulation proficiency testing records for the period of 2022 through 2024 identified the following for two of seven events: (a) Third 2022 Event - four of four results had not been graded by the proficiency testing program for Educational Blood Cell Identification (samples DIF-03). There was no documentation to prove the laboratory performed a self-evaluation of the non-graded results. (b) Second 2023 Event - 11 of 11 results had not been graded by the proficiency testing program for Educational Blood Cell Identification (samples DIF-02) and (samples ECI-06, ECI-07, ECI-08, ECI-09, and ECI-10). There was no documentation to prove the laboratory performed a self-evaluation of the non-graded results. (2) The records were reviewed with the technical consultant who stated on 06 /26/2024 at 2:23 pm, the laboratory had not performed a self-evaluation to evaluate the non-graded results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures and interview with the technical consultant and testing person #4, the laboratory failed to have a written procedure for two of two i-STAT1 test systems. Findings include: (1) On 06/26/2024 at 10:45 am, the technical consultant and testing person #4 stated the laboratory performed arterial and venous blood gases (pH, pO2 and pCO2) on i-STAT1 analyzer (SN373548) using

	the EG6+, and Troponin I testing using the cTnI cartridges; (2) A review of the test volume list completed for the survey identified the laboratory performed approximately 546 blood gas and 781 troponin I tests annually; (3) A review of the laboratory policies and procedures identified no evidence of a written procedure for i-STAT EG6+ and cTNI test systems; (4) The findings were reviewed with technical consultant #1 who stated on 06/27/2024 at 3:00 pm, the laboratory did not have a written procedure for performing the test. 48517 Based on a review of policies and procedures and interview with the technical consultant, the laboratory failed to have a written procedure that explained the current practices and procedures for two of three procedures reviewed. Findings include: URINALYSIS (1) On 06/26/2024 at 02:57 pm, the technical consultant stated the laboratory performed urine microscopic testing by spinning them at 1500 revolutions per minute (RPM) for five minutes and examining the sediment using the Kova system; (2) A review of the policy titled, "Urinalysis - Microscopic Exam policy and procedure" stated to centrifuge the sample for five minutes at 2500 RPM; (3) A review of the Kova system package insert stated to centrifuge at a relative centrifugal force (RCF) of 400 for five minutes (approximately 1500 RPM); (4) The findings were reviewed with the technical consultant, who stated on 06/26/2024 at 03:00 pm, the urine microscopic procedure did not reflect their current practice. BLOOD BANK (1) On 06/27/2024 at 03:30 pm, the technical consultant stated the laboratory performed blood bank alarm checks electronically for the Cardinal blood bank refrigerator; (2) A review of the policy titled, "Blood Bank Refrigerator Temperature Check" stated to place the thermocouple into a salt/ice solution to check the low alarm and into a pan with 12-15 degree Celsius water to check the high alarm; (3) The findings were reviewed with the technical consultant, who stated on 06/27/2024 at 03:30 pm, the blood bank refrigerator temperature check procedure did not reflect their current practice.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing

	person #4, the laboratory failed to perform calibration verification procedures at least once every six months for two of two i-STAT1 test systems during the review period of 05/11/2022 through the current date. Findings include: (1) On 06/26/2024 at 10:45 am, the technical consultant and testing person #4 stated the laboratory performed arterial and venous blood gas (pH, pO2 and pCO2) on i-STAT1 analyzer (SN373548) using the EG6+, and Troponin I testing using the cTnI cartridges; (2) A review of records from 05/11/2022 through the current date identified no evidence the calibration verification procedures had been performed for the EG6+ and cTnI test systems; (3) The findings were reviewed with the technical consultant and testing person #4, who stated on 06/27/2024 at 01:13 pm, the calibration verification procedures had not been performed every six months as stated above.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for one of nine persons during the review period of May 10, 2022 through the current date. Findings include: (1) A review of personnel records for nine persons performing moderate complexity testing from May 2022 through the current date identified no evidence annual competency evaluations had been performed for one of nine persons and follows: (a) Testing person #7 - not performed in 2022 (2) The records were reviewed with the technical consultant who stated on 06/26/2024 at 10:00 am, the competency for testing person #7 had not been performed as stated above.