Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475185	04/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Northeastern Health System, Tahlequah	1400 E Downing St, Tahlequah, 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 04/15,16,17,18/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the senior director of ancillary services, technical consultant #1, technical consultant #2, and technical consultant #3 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; and the laboratory, blood bank, and general nursing policy and interview with general supervisor #1 the facility failed to ensure written policies were followed for preventing transfusion reactions for two of five units reviewed. Findings include: (1) On 04/17/2024 at 2:30 pm, general supervisor #1 stated that the laboratory performed Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit(s)); (2) The policy "Blood and Blood Products Transfusion and Reaction" defined the parameters of issuing blood products from the blood bank; (3) The surveyor reviewed the policy which stated: (a) "The blood transfusion will be documented in the Electronic Health Record (EHR). Protocol detailing nursing requirement prior and during infusion are listed in the Insusion section. Required documentation points of the transfusion include: (i) Person starting the transfusion (ii) Person verifiying the transfusion (iii) Blood band number (iv) Type of product (v) Transfusion start time (vi) Transfusion stop time (vii) Vital signs for pre-infusion, 15 minutes after start of infusion and post infusion (vii) The person stopping the

	transfusion (viii) Volume of product infused (b) "Transfusion of red blood cells will be completed within 4 hours" (c) "Transfusions must be started, or the blood returned to the Blood Bank, within 30 minutes from the time the blood is signed out of the blood bank." (4) A review of transfusion records for five units of blood transfused with general supervisor #1 identified for two or five units transfused, the policy was not followed by nursing personnel: (a) Unit #W091023413240 - The unit was checked out from the blood bank at 6:10 pm and was started at 6:57 pm, 47 minutes after leaving the bood bank (b) Unit #W091023 - The unit was checked out from the blood bank at 6:36 pm and there was no documentation of when the transfusion was completed; (5) Interview with general supervisor #1 on 04/17/2024 at 02:30 pm confirmed the facility failed to ensure the policy was being followed as written.
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 #1, the laboratory failed to have a written policy that included assessing the competency of the general supervisors, based on the position responsibilities as listed in Subpart M, for three of three persons. Findings include: (1) On 04/16/2023, a review of the policy titled, "Competency Assessment" identified no evidence it included assessing the competency of the general supervisors; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of 2022 through the current date identified competencies, based on job responsibilities, had not been performed for three of three persons listed as general supervisor after 01/25/2022; (3) The findings were reviewed with technical consultant #1 who stated on 04/16/2024 at 09:20 am, the policy did not include assessment of the general supervisors and competencies had not been performed after 01/25/2022.
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 general supervisor #1, the laboratory failed to ensure 13 of 13 boxes of ChemTrak Unassayed Chemistry quality control materials were stored as required by the manufacturer. Findings include: (1) On 04/15/2024 at 2:00 pm observation of the contents of the Helmer Blood Bank freezer identified the following materials: (a) Seven boxes of MAS

	ChemTRAK H Unassayed chemistry control materials level three, lot #CHU24083A (b) Six boxes of MAS ChemTRAK H Unassayed chemistry control materials level one, lot #CHU24081A (2) The storage requirement, as stated on the bottles for the materials was -15 to -25 degrees C (Celsius); (3) Observation of the freezer digital temperature display (which included a current temperature reading and minimum /maximum temperature readings) on 04/15/2024 at 02:34 pm identified the following: (a) The current temperature reading was -26.3 degrees C (b) The minimum temperature reading was -30.4 degrees C (c) The maximum temperature reading was -11.0 degrees C (4) The findings were reviewed with general supervisor #1 who stated on 04/15/2024 at 2:36 pm, the observed freezer temperature was not within the manufacturer's storage requirement.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's package insert, and interview with technical consultant #1 and technical consultant #2, the laboratory failed to ensure QC (quality control) materials were not used beyond the open vial expiration date for three of seven lot numbers reviewed from August 2023 through February 2024. Findings include: (1) On 04/15/2024 at 02:50 pm, technical consultant #1 stated the following: (a) The laboratory performed Body Fluid and Cerebrospinal Fluid Manual Cell Counts; (b) Two levels of Streck Cell-Chex controls were performed each eight hours of patient testing. (2) On 04/18/2024, a review of the Streck Cell-Chex package insert stated "Open vial stability 30 days"; (3) A review of "Hematology Body Fluid Control Logs" for seven lot numbers of QC materials used from August 2023 through February 2024 identified the materials had been used beyond the open vial expiration dates for three of seven lot numbers reviewed as follows: (a) Low control lot #30930411 and high control lot #30930413 used for patient testing from 08/03/2023 through 08/20/2023. The open vial expiration date as documented on the log was 08 /17/2023; (b) Normal control lot #30930412 and high control lot #30930413 used for patient testing from 10/02/2023 through 10/24/2023. The open vial expiration date as documented on the log was 10/03/2023. (3) A review of patient test logs confirmed results had been reported on 08/20/2023 and 10/24/2023 when expired QC materials had been utilized; (4) The records were reviewed with technical consultant #1 and technical consultant #2 who stated on 04/18/2024 at 10:04 am, the controls had been used beyond the open vial expiration dates.
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

	technical consultant #1 and technical consultant #2, the laboratory failed to ensure the manufacturer's instructions were followed for performing quarterly maintenance procedures on two of two Roche Cobas 6000 analyzers during the review period of September 2023 through February 2024. Findings include: (1) On 04/15/2024 at 02:57 pm, technical consultant #1 stated the following: (a) Routine chemistry and immunoassay tests were performed using two Roche Cobas 6000 analyzers denoted by the laboratory as "Sam" and "Dean"; (b) The analyzers consisted of two modules each (Cobas e 601 and Cobas c 501). (2) On 04/16/2024, a review of the manufacturer's maintenance logs identified the following required quarterly maintenance procedures: (a) Cobas e 601 Module (i) "Replace e 601 pinch valve tubing" (b) Cobas c 501 Module (i) "Replace ISE pinch valve tubing" (ii) "Replace ISE sipper tubing" (iii) "Clean ultrasonic mixers" (3) A review of maintenance logs from September 2023 through February 2024 for "Sam" and "Dean" identified no documentation quarterly maintenance had been performed between: (a) 09/07/2023 and 02/28/2024 (4) The records were reviewed with technical consultant #1 and technical consultant #2 who stated on 04/16/2024 at 12:28 pm, the quarterly maintenance had not been documented as performed as shown above.
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 technical consultant #1, the laboratory failed to perform calibration verification procedures at least once every six months for one of three blood gas analyzers during the review period of February 2023 through the current date. Findings include: (1) On 04/16/2024 at 10:30 am, technical consultant #1 stated the following was performed in the Respiratory Therapy department: (a) Blood Gas (pH, pCO2, pO2), Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Lactate, Creatinine, Oxyhemoglobin, Carboxyhemoglobin, and Methemoglobin testing using the ABL 800 analyzer; (b) Blood Gas (pH, pCO2, pO2), Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Lactate, Creatinine, Oxyhemoglobin, Carboxyhemoglobin, and Methemoglobin testing using the ABL 90

	analyzer (denoted by the laboratory as ABL 90-15) stored and utilized at the point of care in ICU (Intensive Care Unit); (c) Blood Gas (pH, pCO2, pO2), Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Lactate, Creatinine, Oxyhemoglobin, Carboxyhemoglobin, and Methemoglobin testing using the ABL 90 analyzer (denoted by the laboratory as ABL 90-14) stored in the main laboratory. (2) A review of records from February 2023 through the current date identified no evidence calibration verification had been performed at least once every six months for one of three analyzers as follows: (a) ABL 90-14 - Not performed between 02/07/2023 and 10 /19/2023 (3) The records were reviewed with technical consultant #1 who stated on 04 /16/2024 at 12:20 pm, calibration verification procedures had not been performed every six months as shown above. 47979 Based on a review of records and interview with technical consultant #1, the laboratory failed to perform calibration verification procedures at least once every six months for one of 15 analytes requiring calibration verification using the Roche Cobas 6000 analyzer during the review period of January 2023 through the current date. Findings include: (1) On 04/15/2024 at 02:57 pm, technical consultant #1 stated Testosterone testing was performed using the Roche Cobas 6000 analyzer (denoted by the laboratory as "Dean"); (2) A review of calibration records for 2023 identified the calibration procedures for the above analyte was performed with less than three levels of calibrators. Therefore, calibration verification procedures using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) A review of records from January 2023 through the current date identified calibration verification had not been performed for Testosterone between 02/04/2023 and 10/26/2023; (4) The records were reviewed with technical consultant #1 who stated on 04/16/2024 at 02:52 pm, calibration verification procedures had not been performed every six months as shown above.