

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D0475185	<b>(X3) Date Survey Completed</b>  03/05/2026
<b>Name of Provider or Supplier</b>  Northeastern Health System, Tahlequah	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 03/02,03,04,05/2026. Standard-level deficiencies were cited.
<b>D3025</b>	<p><b>REQUIREMENTS FOR TRANSFUSION SERVICES</b> CFR(s): 493.1103(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, nursing policy, and interview with technical supervisor #2, the facility failed to ensure written policies were followed for preventing transfusion reactions for three of eight units of packed red-blood cells transfused. Findings include: (1) On 03/03/2026 at 10:00 am, technical supervisor #2 stated blood transfusions were performed by nursing staff; (2) A review of the hospital policy titled, "Blood and Blood Products Transfusion and Reaction" stated: (a) "Vital signs are taken pre-infusion"; (b) "15 minutes after start of infusion "; (c) "Post infusion"; (d) "Indicate when transfusion was started, stopped, vital signs, and presence or absence of suspected reaction". (3) A review of transfusion records for eight units transfused, identified the policy had not been followed for three of eight units as follows: (a) Unit #W091025191838 - The transfusion started on 05/06/2025 at 04:39 pm and there was no stop time documented; (b) Unit #W091025201410 - The transfusion started on 05/06/2025 at 07:30 pm and documentation was missing as follows: (i) There was no stop time documented; (ii) The 15 minute vital signs were not documented until 8:00 pm. (c) Unit #W091025260529 - The transfusion started on 11/05/2025 at 02:15 pm. Vital signs had not been taken as follows: (i) The patient's</p>

temperature was not documented until 03:15 pm. (4) The records were reviewed with technical supervisor #2, who stated on 03/03/2026 at 11:00 am, the vital signs had not been documented according to policy.

**D5401**

PROCEDURE MANUAL  
CFR(s): 493.1251(a)

(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 records, written policies and procedures, and interview with technical supervisor #2, the laboratory failed to have a written policy for catalase and fecal leukocyte testing. Findings include: I. CATALASE (1) On 03/03/2026 at 11:00 am, technical supervisor #2 stated the laboratory performed catalase testing for presumptive determination of Streptococcal vs. Staphylococcal species; (2) A review of the laboratory's written procedure manual identified that there was no policy available for catalase testing; (3) Interview with technical supervisor #2 on 03/03/2026 at 11:00 am confirmed that the laboratory did not have a written procedure for catalase testing. II. FECAL LEUKOCYTES (1) On 03/03/2026 at 11:00 am, technical supervisor #2 stated the laboratory performed fecal leukocyte testing for presumptive determination of inflammation of the digestive tract; (2) A review of the laboratory's written procedure manual identified that there was no policy available for fecal leukocyte testing; (3) Interview with technical supervisor #2 on 03/03/2026 at 11:00 am confirmed that the laboratory did not have a written procedure for fecal leukocyte testing.

**D5409**

PROCEDURE MANUAL  
CFR(s): 493.1251(e)

(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

This STANDARD is not met as evidenced by:

Based on a review of the procedure manual and interview with technical consultant #2, the laboratory failed to ensure that two of two written procedures no longer in use had been discontinued. Findings include: I. CEFINASE (1) on 03/04/2026 at 11:30 am, technical consultant #2 stated that laboratory had discontinued cefinase testing on 02/19/2024. (2) A review of the manual titled, "Microbiology Procedures" identified the following procedure; (a) "Cefinase" (3) The procedure was reviewed with technical consultant #2, who stated on 03/04/2026 at 11:30 am, the laboratory discontinued the use of cefinase in February 2024 and the procedure should have been indicated as discontinued. II. CHROMAGER CANDIDA PLATES (1) On 03/04/2026 at 11:30 am, technical consultant #2 stated that laboratory had discontinued CHROMagar candida plate testing in December, 2025; (2) A review of the manual titled, "Microbiology Procedures" identified the following procedure; (a) "CHROMagar candida plate testing" (3) The procedure was reviewed with technical

consultant #2, who stated on 03/04/2026 at 11:30 am, the laboratory discontinued the use of CHROMagar candida plate testing in December 2025 and the procedure should have been indicated as discontinued.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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, manufacturer's instructions, observation, and interview with testing person #49 and testing person #53, the laboratory failed to ensure the room temperature was being maintained as required for one of one analyzer; and failed to ensure refrigerator and room temperature records accurately defined acceptable limits and reflected what was being monitored for four of four months reviewed in 2025 and 2026. Findings include: I. STORAGE OF ABL 90 ANALYZER (1) On 03/04/2026 at 10:00 am, testing person #49 stated the laboratory performed Blood Gas (pH, pCO<sub>2</sub>, pO<sub>2</sub>), Co-oximetry (Carboxyhemoglobin, Methemoglobin, Oxyhemoglobin), Calcium, Chloride, Potassium, Sodium, Glucose, and Lactate testing using the Radiometer ABL90 analyzer (denoted by the laboratory as ABL90-15) at the point of care in the CVICU (Cardiovascular Intensive Care Unit) department; (2) A review of the manual titled "ABL 90 Flex Operator's Manual" on page 13-6, identified the operating temperature was defined as 15-32 degrees C (Celsius); (3) Interview with testing person #49 on 03/04/2026 at 12:05 pm confirmed the room temperature in CVICU was not being monitored. II. REFRIGERATOR TEMPERATURE RECORDS (1) On 03/04/2026 at 10:00 am, testing person #49 stated the laboratory performed Blood Gas (pH, pCO<sub>2</sub>, pO<sub>2</sub>), Co-oximetry (Carboxyhemoglobin, Methemoglobin, Oxyhemoglobin), Calcium, Chloride, Potassium, Sodium, Glucose, and Lactate testing as follows: (a) Using the Radiometer ABL90 analyzer (denoted by the laboratory as ABL90-15) at the point of care in the CVICU (Cardiovascular Intensive Care Unit) department; (b) Using the Radiometer ABL90 analyzer (denoted by the laboratory as ABL90-14) in the main hospital laboratory; (c) Using the Radiometer ABL800 Flex analyzer in the Cardiopulmonary department. (2) Observation of the contents of the Magic Chef refrigerator in the Cardiopulmonary department identified the following examples of materials with the manufacturer's storage requirement: (a) One box of Radiometer Cleaning Met II Solution, lot #ED51; storage requirement of 2-10 degrees C; (b) One box of ABL90 Flex Sensor Cassette Pack, lot #R3574; storage requirement of 2-8 degrees C; (c) One box of VK-R7 Verification kit, lot #680; storage requirement of 2-8 degrees C. (3) Review of temperature logs for November, December 2025; and January, February 2026 identified the following: (a) Four of four logs were titled, "ABL 800 Temperature Log"; (b) The acceptable range was documented as "Range 2-10 C Room Temp". (4) The findings were reviewed with testing person #49 and testing person #53. Both stated on 03/04/2026 at 11:30 am, the logs were not specific and could allow for unacceptable temperatures to be recorded. III. ROOM

TEMPERATURE RECORDS (1) On 03/04/2026 at 10:00 am, testing person #49 stated the laboratory performed Blood Gas (pH, pCO<sub>2</sub>, pO<sub>2</sub>), Co-oximetry (Carboxyhemoglobin, Methemoglobin, Oxyhemoglobin), Calcium, Chloride, Potassium, Sodium, Glucose, and Lactate testing as follows: (a) Using the Radiometer ABL90 analyzer (denoted by the laboratory as ABL90-15) at the point of care in the CVICU (Cardiovascular Intensive Care Unit) department; (b) Using the Radiometer ABL90 analyzer (denoted by the laboratory as ABL90-14) in the main hospital laboratory; (c) Using the Radiometer ABL800 Flex analyzer in the Cardiopulmonary Department. (2) A review of the manual titled "ABL800 Flex Operator's Manual" on page 13-13, identified the operating temperature was defined as 15-32 degrees C; (3) In addition to the Radiometer ABL800 Flex analyzer being used for patient testing in the Cardiopulmonary department, observation of the department on 03/04/2026 at 10:10 am identified the following examples of materials being stored at room temperature with the manufacturer's storage requirement: (a) One box containing 27 vials of Qualicheck 5+ control materials, level 2 lot #R0252; storage requirement of 2-25 degrees C; (b) One box containing 25 vials of Qualicheck 5+ control materials, level 1 lot #R0242; storage requirement of 2-25 degrees C; (c) One box containing four D733 membranes for the Calcium electrode; storage requirement of 2-32 degrees C; (d) One box containing four D755 membranes for the Sodium electrode; storage requirement of 2-32 degrees C. (4) Review of temperature logs for November, December 2025; and January, February 2026 identified the following: (a) Three of four logs (November and December 2025, and January 2026) were titled, "RT Refrigerator Temperature Chart"; and one of four logs (February 2026) was titled, "ABL 90-7 Temperature Log"; (b) The acceptable range was documented as "Range 2-25 C Room Temp". (5) The findings were reviewed with testing person #49 and testing person #53. Both stated on 03/04/2026 at 11:30 am, the logs were not specific and could allow for unacceptable temperatures to be recorded.

**D5415**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on observation and interview with technical consultant #2, the laboratory failed to ensure three of three Coplin jars containing staining materials had been labeled with the lot numbers of the contents. Findings include: (1) On 03/02/2026 at 02:30 pm, technical consultant #2 stated the laboratory prepared frozen sections which were stained with H&E (Hematoxylin & Eosin), then reviewed microscopically by the pathologist; (2) Observation on 03/02/2026 at 03:12 pm identified three Coplin jars containing staining materials used to stain the slides. Although the containers had been labeled with the identity of the stains and the expiration dates, the labels did not include the lot numbers of the materials; (3) The findings were reviewed with technical consultant #2 who stated on 03/02/2026 at 03:15 pm, the containers had not been labeled with the lot numbers of the staining materials.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

(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 manufacturer's instructions, observation, and interview with testing person #49, the laboratory failed to ensure AutoCheck 6+ control materials had not exceeded the room temperature expiration date for three of three boxes of QC (quality control) materials observed. Findings include: (1) On 03/04/2026 at 10:00 am, testing person #49 stated the following: (a) The laboratory performed Blood Gas (pH, pCO<sub>2</sub>, pO<sub>2</sub>), Co-oximetry (Carboxyhemoglobin, Methemoglobin, Oxyhemoglobin), Calcium, Chloride, Potassium, Sodium, Glucose, and Lactate testing using the Radiometer ABL800 Flex analyzer in the Cardiopulmonary department; (b) AutoCheck 6+ control materials (Level 1, Level 2, Level 3) were loaded on the analyzer with one of the levels aspirated and analyzed each eight hours to include all three levels within a 24 hour timeframe. (2) Observation of the Cardiopulmonary department on 03/05/2026 at 09:15 am identified the following boxes of QC materials being stored in a drawer, which had not been dated: (a) One box containing eight vials of AutoCheck 6+ level 1, lot R0210 (b) One box containing four vials of AutoCheck 6+ level 2, lot R0208 (c) One box containing ten vials of AutoCheck 6+ level 3, lot R0209 (3) Review of the manufacturer's package insert for the materials under the title, "Storage & Stability" required the controls be stored up to 32 degrees C (Celsius) for a maximum of three weeks after removal from the refrigerator; (4) The findings were reviewed with testing person #49 who stated on 03/05/2026 at 09:30 am, the control materials had not been dated to ensure they would not be used beyond the room temperature storage expiration date.

**D5555**

**IMMUNOHEMATOLOGY**

CFR(s): 493.1271(c)(f)

(c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (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.

This STANDARD is not met as evidenced by:

Based on a review of records, and interview with technical supervisor #2 and technical supervisor #3, the laboratory failed to ensure that blood products were stored under appropriate conditions for four of four alarm checks reviewed between January through December 2025. Findings include: (1) On 03/02/2026 at 12:50 pm, technical supervisor #2 and technical supervisor #3 stated PRBC (Packed Red Blood Cells) were stored in the blood bank refrigerator for patient transfusions; (2) A review of the Quarterly Maintenance record identified documentation of low and high refrigerator alarm checks with an acceptable range defined as 1.1 C to 5.9 C (Centigrade); (3) A review of the alarm check records from January through December 2025 identified the following: (a) 03/11/2025 - The high temperature sounded at 6.0 degrees C, the low temperature sounded at 1.0 degrees C; (b) 06/27/2025 - The low temperature sounded at 1.0 degrees C; (c) 09/26/2025 - The high temperature sounded at 6.1 degrees C, the low temperature sounded at 1.0 degrees C; (d) 12/17/2025 - The high temperature

sounded at 6.0 degrees C, the low temperature sounded at 1.0 degrees C. (4) The findings were reviewed with technical supervisor #2 and technical supervisor #3, who stated on 03/03/2026 at 01:30 pm, the high and low alarm checks had sounded at temperatures that were beyond the acceptable limits.

**D5807**

TEST REPORT  
CFR(s): 493.1291(d)

(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 technical consultant #2, technical consultant #3, and testing person #49, the laboratory failed to make appropriate reference ranges available for two of two analytes and failed to include a normal reference range for one of one report reviewed. Findings include: I. PT/INR TESTING (1) On 03/03/2026 at 01:30 pm, technical consultant #2 and technical consultant #3 stated the following: (a) PT/INR (Prothrombin Time/International Normalized Ratio) testing was performed using the IL ACL Top 300 coagulation analyzer; (b) The following lot number was currently in use: (i) PT Reagent - Hemosil Recombiplastin 2G lot #N0855833 (2) A review of the implementation records for the reagent identified the lot number was put into use on 01/26/2026 and the normal reference range had been verified as 10.19 -13.03 seconds; (3) A review of a patient report with testing performed on 03/02/2026 showed the normal reference range as 10.08-12.75 seconds; (4) The records were reviewed with technical consultant #2 and technical consultant #3 who stated on 03/04/2026 at 12:45 pm, the laboratory had not updated the normal reference range in the LIS (laboratory information system). II. PTT TESTING (1) On 03/03/2026 at 01:30 pm, technical consultant #2 and technical consultant #3 stated the following: (a) PTT (Partial Thromboplastin Time) testing was performed using the IL ACL Top 300 coagulation analyzer; (b) The following lot number was currently in use: (i) APTT Reagent - Hemosil Synthasil Lot #N0956949. (2) A review of the implementation records for the reagent identified the lot number was put into use on 01/26/2026 and the normal reference range had been verified as 27.70-36.13; (3) A review of a patient report with testing performed on 03/02/2026 showed the normal reference range as 23.44-37.88 seconds; (4) The records were reviewed with technical consultant #2 and technical consultant #3 who stated on 03/04/2026 at 12:45 pm, the laboratory had not updated the normal reference range in the LIS (laboratory information system). III. BLOOD GAS PO2 (1) On 03/04/2026 at 10:00 am, testing person #49 stated the laboratory performed venous blood gas (pH, pCO2, pO2) testing using the Radiometer ABL Flex 800 and Radiometer ABL Flex 90 analyzers; (2) On 03/05/2026, a review of a patient report with testing performed on 02/28/2026 identified the normal reference range was not included for the analyte venous pO2; (3) The report was reviewed with technical consultant #3 who stated on 03/05/2026 at 11:29 am the patient report did not include normal reference interval as stated above.