

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0476048	(X3) Date Survey Completed 10/16/2024
Name of Provider or Supplier Northeastern Health System-Sequoyah	Street Address, City, State 213 East Redwood Ave, Sallisaw, 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 10/14,15,16/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer, technical consultant, chief medical technologist, and director of respiratory during an exit conference performed at the conclusion of the survey.
D3025	<p>REQUIREMENTS FOR TRANSFUSION SERVICES 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 the technical consultant, the facility failed to ensure written policies were followed for preventing transfusion reactions for four of five units of packed red-blood cells transfused. Findings include: (1) On 10/15/2024 at 03:30 pm, the technical consultant stated blood transfusions were performed by nursing staff; (2) On 10/16/2024, a review of the hospital policy titled, "Blood/Blood Components - Transfusions" stated, "Vital signs (blood pressure, pulse, and temperature) shall be obtained and documented on the Transfusion Record": (a) "Prior to transfusion" (b) "Every 5 minutes x 3 upon initiation of the transfusion, every 30 x 2 after infusion begins, then hourly thereafter" (c) "Upon completion of the transfusion" (3) A review of transfusion records for five units transfused, identified the policy had not been followed for four of the five units as follows: (a) Unit #W091023261828 - The transfusion started at 04:52 pm. Vital signs had not been taken as follows: (i) Five Minute Vital Signs - Not taken between 04:57 pm and 05:07 pm (ii) 15 Minute Vital signs - Not taken between 05:07 pm and 05:22 pm (b) Unit #W091023259475 - The transfusion started at 06:32 pm. Vital</p>

signs had not been taken as follows: (i) Five Minute Vital Signs - Not taken between 06:34 pm and 06:44 pm (ii) 15 Minute Vital Signs - Not taken between 06:44 pm and 06:59 pm (c) Unit #W091024316685 - The transfusion started at 10:40 am. Vital signs had not been taken as follows: (i) Five minute vital Signs - not taken between 10:45 am and 10:55 am (ii) 15 Minute Vital Signs -not taken between 10:55 am and 11:10 am (iii) 30 Minute Vital Signs -not taken between 11:40 am and 12:40 pm (d) Unit #W091024288851 - The transfusion started at 12:25 pm. Vital signs had not been taken as follows: (i) Five Minute Vital Signs - Not taken between 12:30 pm and 12:40 pm (ii) 15 Minute Vital Signs - Not taken between 12:40 pm and 12:55 pm (iii) 30 minute Vital Signs - Not taken between 01:25 pm and 02:25 pm (4) The records were reviewed with the technical consultant who stated on 10/16/2024 at 09:55 am , the vital signs had not been documented according to policy.

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 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 one of six procedures reviewed. Findings include: (1) On 10/14/2024 at 12:35 pm, the technical consultant and chief medical technologist stated the laboratory began using the Sysmex XN-550 analyzer to perform CBC (Complete Blood Count) testing on 01/12/2024; (2) A review of the Hematology procedure titled "General Hematology", identified the procedure was for the Sysmex XS-1000i analyzer instead of the Sysmex XN-550 analyzer; (3) The findings were reviewed with the technical consultant, who stated on 10/16/2024 at 10:00 am, the CBC procedure had not been revised to include the Sysmex XN-550.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on a review of written procedures and interview with the technical consultant, the laboratory failed to ensure one of six procedures had been approved, signed, and dated by the current laboratory director. Findings include: (1) On 10/14/2024 at 12:45 pm, the technical consultant stated the laboratory performed Troponin I testing using the iSTAT-1 analyzer (SN 316043) and the cTnI cartridge; (2) A review of the Troponin procedure identified no evidence it had been approved, signed, and dated by the current laboratory director; (3) The findings were reviewed with the technical consultant who stated on 10/14/2024 at 2:35 pm, the procedure had not been signed and dated by the current laboratory director.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

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

This STANDARD is not met as evidenced by:

Based on observation and interview with the technical consultant and chief medical technologist, the laboratory failed to label three of three containers with the identity, expiration date, and lot number of the contents. Findings include: (1) On 10/14/2024 at 12:35 pm, the technical consultant and chief medical technologist stated the laboratory stained peripheral blood smears to perform manual differential testing; (2) Observation on 10/14/2024 at 12:35 pm identified three unlabeled Copeland jars, appearing to contain materials used to stain peripheral blood smears; (3) The findings were reviewed with the technical consultant and chief medical technologist who on 10/14/2024 at 12:40 pm stated the Copeland jars contained staining materials had not been labeled with the identity, expiration date, and lot numbers.

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 technical consultant, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for two of two analyzers. Findings include: ACL ELITE (1) On 10/14/2024 at 12:35 pm, the technical consultant stated PT/INR, PTT, and D-Dimer testing were performed using the ACL Elite coagulation analyzer; (2) A review of the "ACL Elite Pro System Operator Manual", Section 5.2 - Maintenance Procedures, showed the following required maintenances: (a) Biweekly - Reboot analyzer, Rotor Holder and Optical Path Cleaning Procedure (b) Monthly - Checking and cleaning the air filter (3) A review of maintenance logs from January 2024 through September 2024 identified maintenance had not been documented as performed as follows: (a) Biweekly: (i) Between 04/16/2024 and 05/14/2024 (b) Monthly: (i) Between 05/22/2024 and 07/17/2024 (ii) Between 07/17/2024 and 09/11/2024 (4) The records were reviewed with the technical consultant who stated on 10/15/2024 at 04:00 pm, maintenance procedures had not been documented as performed as stated above. ROCHE COBAS 6000 Findings include: (1) On 10/14/2024 at 10:40 am, the technical consultant stated the following: (a) Routine chemistry and immunoassay testing were performed using Roche Cobas 6000 modular analyzer; (b) The Cobas 6000 analyzer consisted of the sampling unit, c 501 (performed the routine chemistry testing), and e 601 (performed the immunoassay testing) modules. (2) On 10/15/2024, a review of the manufacturer's maintenance logs identified the following required maintenance procedures: (a) 6000 Sampling Unit: (i) Weekly: Perform system power off, and performed system power on (ii) Monthly: Clean rack sampler unit filter, Clean/Inspect DI water tank (b) c 501

Module: (i) Weekly: Clean cell covers, Rinse stations, IS bath, and perform weekly pipe (ii) Monthly: Clean incubation water bath, KCl aspiration filter, Detergent aspiration filters, Circuit board rack filter, Power supply filter, Radiator filter, and replace Reaction cells (iii) Two months: Replace ISE measuring cartridges (c) e 601 Module (i) Weekly: Clean PC/CC reservoir fill nozzles, PC/CC reservoir positions, PreClean mixer, Preclean separation stations, incubator, AssayCup vortex mixer, Rinse stations, Replace PCC reservoirs, and Perform Monday Pipe (3) A review of maintenance logs from March 2024 through August 2024 identified maintenance had not been documented as performed for the following: (a) 6000 Sampling Unit (i) Weekly: Between 05/26/2024 and 06/09/2024 (ii) Monthly: Between 05/21/2024 and 07/29/2024 (b) c 501 Module (i) Weekly: Between 05/26/2024 and 06/09/2024 (ii) Monthly: Between 05/31/2024 and 07/29/2024 (iii) Every two months: Between 05/21/2024 and 08/11/2024 (c) e 601 Module (i) Weekly: Between 05/26/2024 and 06/09/2024 (4) The records were reviewed with the technical consultant who stated on 10/16/2024 at 11:18 am, the required maintenance had not been documented as performed as shown above.