Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0476048	10/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Northeastern Health System-Sequoyah	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 10/17,18,19/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the administrator, laboratory director, cardiopulmonary director, technical consultant, and chief medical technologist during an exit conference performed at the conclusion of the survey.
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, the laboratory failed to have a written procedure for Manual Differential testing. Findings include: (1) On 10/17/2022 at at 09:40 am, the technical consultant stated Manual Differential testing was performed in the laboratory; (2) On 10/18 /2022, a review of the Hematology procedure manual identified no evidence of a written procedure for Manual Differential testing; (3) The manual was reviewed with the technical consultant who stated on 10/19/2022 at 09:55 am, the laboratory did not have a written procedure for performing manual differentials.
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 verifying automated differential flags for two of 20 records; and failed to follow the manufacturer's implementation instructions for verifying the normal reference range for one of one new analyte reviewed. Findings include: AUTOMATED DIFFERENTIAL FLAGS (1) On 10/17/2022 at 09:40 am, the technical consultant stated CBC (Complete Blood Count) testing was performed on the Sysmex XS 1000i analyzer; (2) On 10/18/2022, a review of the manufacturer's instructions for verifying automated differential flags stated: (a) Immature Gran? - "Perform smear review send for further testing if present" (3) The surveyor randomly reviewed 20 patient CBC records, containing flags for testing performed during March and August 2022. For two of the records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flag as follows: (a) Record #1 - Testing was performed on 03/29/2022 at 03:50 pm, with an Immature Gran? flag obtained. The result of the smear review stated "4 seen" next to the flag. There was no documentation the sample had been sent for further testing; (b) Record #2 - Testing was performed on 8/21/22 at 06:39 am, with an Immature Gran? flag obtained. The result of the smear review stated "4 seen" next to the flag. There was no documentation the sample had been sent for further testing. (4) The records were reviewed with the technical consultant who stated on 10/19/2022 at 09:40 am the patient samples had not been sent for further testing as shown above. IMPLEMENTING COAGULATION ANALYZER (1) On 10/17/2022 at 09:45 am, the technical consultant stated the laboratory began using the ACL Elite analyzer to perform PT (Prothrombin Time) testing in May 2022; (2) On 10/18/2022, a review of the manufacturer's implementation instructions under "Normal Reference Interval" stated to use a "minimum of 20 normal donors screened per lab policy". A review of the laboratory policy required using equal numbers of males and females of varying ages and include diseases/treatments; (3) A review of the records for the verification of the normal reference range identified the laboratory had not followed the manufacturer's instructions as follows: (a) 38 donors had been used which included 21 males, five females, and 12 did not specify whether the donor was male or female; (b) There was no documentation of the donor's medication or health history. (4) The records were reviewed with the technical consultant who stated on 1018/2022 at 02:54 pm the laboratory had not followed the manufacturer's instructions for verifying the normal reference range.
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, the

	laboratory failed to ensure the reportable range had been demonstrated for one of two new test methods. Findings include: (1) On 10/18/2022 at 10:50 am, the technical consultant stated the laboratory began performing PT/INR (Prothrombin Time /International Normalized Ratio) testing using the iSTAT 1 analyzer and the PT/INR cartridge on 03/12/2022; (2) A review of performance specification records identified no documentation to prove the laboratory had demonstrated the reportable range; (3) The findings were reviewed with the technical consultant who stated on 10/18/22 at 10:52 am, the laboratory had not demonstrated the reportable range.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different test methods for one of one analyte. Findings include: (1) On 10/17/2022 at at 09:47 am, the technical consultant stated Troponin I testing was performed using two methods: (a) Ortho Vitros 5600 analyzer as the primary method; (b) iSTAT 1 analyzer and the cTnIas the back-up method. (2) On 10/19/2021, a review of records from June 2022 through the current date identified the relationship between the different test methods had been evaluated on 07/09/2021; (3) Interview with the technical consultant on 10/19/2022 at 11:07 am confirmed the relationship between the test methods had not been evaluated since 07/09/2021.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to follow their policy for monitoring the effectiveness of their QCP for one of one test system. Findings include: (1) On 10/17/22 at 11:50 am, the technical consultanat stated the following: (a) Troponin I testing was performed using the iSTAT 1 analyzer and the cTnI cartridge as a backup method to the Ortho Vitros 5600 analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) A review of the IQCP identified that QA (Quality Assessment) reviews of the QCP (Quality Control Plan) were to be performed on an annual basis; (3) A review of records for the test systems for 2021 and to date in 2022 revealed the IQCP had been approved on 10/16/2018. There was no documentation

	QA reviews had been performed during 2021 and to date in 2022; (4) The records were reviewed with the technical consultant who stated on 10/18/2022 at 10:36 am annual QA reviews had not been documented as performed as stated above.