Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0476048	10/26/2018
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 10/23,24,25,26/18. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant The findings were reviewed with the administrator, vice-president of clinical systems, cardiopulmonary director, and laboratory manager during an exit conference performed at the conclusion of the survey.
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 and interview with the laboratory manager and technical consultant #1, the laboratory failed to perform a technical consultant competency based on the position responsibilities as listed in Subpart M. Findings include: (1) On the first day of the survey, the surveyor reviewed reviewed personnel records for competency assessments performed during 2017 and 2018. There was no evidence a technical consultant competency for technical consultant #2, based on their job responsibilities, had been performed; (2) The surveyor asked the laboratory manager and technical consultant #1 if a technical consultant competency based on job responsibilities had been performed for technical consultant #2. The laboratory manager and technical consultant #1 stated a technical consultant competency based on job responsibilities had not been performed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing

	performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant #1, the laboratory failed to review and evaluate proficiency testing results. Findings include: BIASES (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Third 2017 Chemistry Core Event (i) Potassium - 3 of 5 results exhibited a negative bias (aa) Sample CH-11 - SDI of -2.2 (bb) Sample CH-13 - SDI of -2.2 (cc) Sample CH-14 - SDI of -2.2 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory manager and technical consultant #1 who stated the biases had not been addressed. FAILURES (1) During the review of proficiency testing records, the surveyor identified the following failure in which there was no evidence of corrective action: (a) First Chemistry Core Event (i) Cholesterol - The laboratory failed the result for 1 of 5 samples and attained a score of 80%. The result for sample CH-08 had failed. (2) The surveyor reviewed the records with the laboratory manager and technical consultant #1 and asked if corrective action had been taken for the above failure. The laboratory manager and technical consultant #1 stated there was no documentation to prove corrective action had been taken for the failure.
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 laboratory manager and technical consultant #1, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017 and 2018 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) First 2017 Hematology Event (i) Blood Cell Identification - BCI-06 and BCI -07 (b) Second 2017 Hematology Event (i) Blood Cell Identification - BCI-08 (c) First 2018 Hematology Event (i) Blood Cell Identification - BCI-01 (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) The surveyor asked the laboratory manager and technical consultant #1 if the results had been documented as evaluated. They both reviewed the records and stated the non-graded results had not been documented as reviewed.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to

	the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant #1, the laboratory failed to provide written instructions to clients collecting and referring hematology and chemistry specimens. Findings include: (1) On the first day of the survey, the laboratory manager and technical consultant #1 stated the following to the surveyor: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XS 1000i analyzer; (i) Hematology specimens were transported to the laboratory from outside home health agencies and long term care facilities. (b) The laboratory performed routine chemistry testing using the Ortho Vitros 5600 analyzer; (i) Routine chemistry specimens were transported to the laboratory from outside home health agencies and long term care facilities. (2) The surveyor asked the laboratory manager and technical consultant #1 if instructions (e. g., client service manual) had been written and provided to the home health agencies and long term care facilities which would explain the laboratory's specimen handling policies (e.g., collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances). The laboratory manager and technical consultant #1 stated specimen handling instructions had not been written and provided to the clients.
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 laboratory manager and technical consultant #1, the laboratory failed to failed to follow a written policy. Findings include: (1) On the first day of the survey, the laboratory manager and technical consultant #1 stated the following to the surveyor: (a) PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed on the ACL Elite analyzer; (b) The laboratory had a policy to ensure the specimens tested on the analyzer were platelet poor. (2) On the third day of the survey, the surveyor reviewed the policy titled, "Platelet Poor Plasma Procedure" which stated, "Twice annually the lab will validate that platelet poor plasma is being achieved. Routine patient samples will be collected and processed as described above. The processed plasma sample will be tested on the hematology instrument to determine the platelet count. At least 10 samples will be tested for each validation period. Platelet counts should be less than 10,000."; (3) The surveyor then reviewed records for 2017 and 2018 and identified the platelet-poor plasma checks had not been performed twice annually as required by policy (the checks had not been performed during the review period); (4) The surveyor reviewed the records and policy with the laboratory manager who stated the laboratory had not followed their written policy for ensuring platelet-poor plasma twice annually.
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 laboratory manager and technical consultant #1, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On the first day of the survey, the laboratory manager and technical consultant #1 stated to the surveyor that CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirement for weekly maintenance was as follows: (a) Power Down IPU (3) The surveyor then reviewed maintenance records for 9 months (January 2018 through September 2018). There was no evidence the weekly maintenance had been performed: (a) Between 07/31/18 and 08/14/18 (b) Between 09 /04/18 and 09/18/18 (4) The surveyor reviewed the records with the laboratory manager and technical consultant #1, who stated the maintenance had not been performed as required.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant #1, the laboratory failed to have control procedures that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for chemistry testing. Findings include: (1) On the third day of the survey, the laboratory manager and technical consultant #1 stated CK-MB and FT4 (Thyroxine) testing were performed using the Ortho Vitros 5600 analyzer. In addition, the laboratory manager and technical consultant #1 stated the following: (a) Bio-Rad Liquichek Cardiac Markers Plus Control LT control materials (Level 1c and Level 3) were performed each day of patient CKMB testing; (b) Bio-Rad Liquichek Immunoassay Plus Control control materials (Level 1, Level 2 and Level 3) were performed each day of patient FT4 testing; (2) The surveyor reviewed the package inserts for the control materials which stated the following: (a) Bio-Rad Liquichek Cardiac Markers Plus Control LT , "The mean values provided in the Assignment of Values Data Charts (available separately) were derived from replicate

	analyses and are specific for each lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and representative sampling of this lot of control. Individual laboratory means should fall within the corresponding acceptable range; however, laboratory means may vary from the listed values during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides." (b) Bio-Rad Liquichek Immunoassay Plus Controls , "The mean values and corresponding +/- 3 SD ranges in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides"; (3) The surveyor then reviewed QC (Quality Control) records for testing performed July 2018 and August 2018. It was identified the laboratory was using ranges wider than the package insert ranges as follows: (a) Bio-Rad Liquichek Cardiac Markers Plus Control LT (i) CKMB level 1c (lot# 23680 - put into use on 04/23/18) - The package insert range was 1.84 - 3.32. A range of 1.131 - 5.195 had been used to evaluate QC results, (from lower to upper limit, the insert difference was 1.48; from lower to upper limit, the difference used by the laboratory was 4.064). (b) Bio-Rad Liquichek Immunoassay Plus Controls (i) FT4 level 1 (lot# 40940 - put into use 02/03/18) - The package insert range was 0.468 - 0.746. A range of -1.835 - 4.749 had been used to evaluate QC results, (from lower to upper limit, the insert difference was 0.278; from lower to upper limit, the difference used by the laboratory was 6.584). (4) The surveyor reviewed the records with the laboratory manager and technical consultant #1, who stated that ranges which were wider than the package insert ranges, had been used to evaluate QC results.
D5807	TEST REPORT CFR(s): 493.1291(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 the laboratory manager and technical consultant #1, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) On the first day of the survey, the laboratory manager and technical consultant #1 stated to the surveyor CBC (Complete Blood Count) testing was performed using the Sysmex 1000i analyzer; (2) On the second day of the survey, the surveyor reviewed two patient CBC reports - the first report was for an adult female patient with the testing performed on 01/27/18 at 02:00 pm; the second report was for an adult male patient with the testing performed on 04/20/18 at 11:35 am. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell) and Hematocrit which were: (a) RBC - 3.76 - 5.44 uL (b) Hematocrit - 34 - 46 % (3) The surveyor reviewed the findings with the laboratory manager and technical consultant #1 who stated the patient reports did not include gender specific reference ranges. NOTE:

	Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the cardiopulmonary director/testing person #12 and technical consultant #1, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the cardiopulmonary director/testing person #12 and technical consultant #1, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings include: (1) On the second day of the survey, the surveyor reviewed records for 5 persons in the cardiopulmonary department performing moderate complexity testing in 2017 and 2018. The records indicated the evaluations for 5 of 5 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #13 (i) The 10/30/17 evaluation had been performed by a previous testing person #12 (this person had earned a high school diploma); (b) Testing Person #14 (i) The 11/04 /17 evaluation had been performed by testing person #12; (c) Testing Person # 15 (i) The 10/30/17 evaluation had been performed by testing person #12; (d) Testing Person #16 (i) The 11/04/17 evaluation had been performed by testing person #12; (e) Testing Person #17 (i) The 10/31/17 evaluation had been performed by testing person #12. (2) The surveyor explained to cardiopulmonary director and technical consultant #1 that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service).
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant #1, the technical consultant failed to ensure that a person performing moderate complexity testing had been evaluated semiannually during the first year of testing. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records. The following was identified: (a) Testing Person #9 - The initial training for this person was completed on 12/17/16. There was no evidence that a semiannual evaluation had been performed (due 06/17). (2) The surveyor reviewed the records with the laboratory manager and technical consultant #1 who both stated there were no records to prove the above person had been evaluated semiannually.
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 laboratory manager and technical consultant #1, the laboratory failed to ensure evaluations included all moderate

	complexity testing performed; and failed to ensure testing persons performing moderate complexity testing had been evaluated at least annually during 2017 and 2018. Findings include: ANNUAL EVALUATIONS NOT PERFORMED (1) On the first day of the survey, the laboratory manager and technical consultant #1 stated the following to the surveyor: (a) CBC (Complete Blood Count) was performed on the Sysmex XS 1000i analyzer; (b) PT (Prothrombin Time)/INR (International Normalized Ratio and PTT (Partial Thromboplastin Time) were performed on the ACL Elite analyzer; (c) Albumin, Total Bilirubin, Calcium, CO2, Chloride, Creatinine, Glucose, ALP (Alkaline Phosphatase), Potassium, Total Protein, Sodium, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Triglycerides and BUN (Blood Urea Nitrogen), Cholesterol and HDL (High Density Lipoprotein) testing were performed on the Vitros 5600 analyzer; (d) Microscopic Urinalysis, Manual Differentials, Post Vasectomy and Wet Prep procedures were performed in the laboratory; (e) Routine Urinalysis was performed on the Clinitek Advantus analyzer; (f) Immunohematology testing (ABO/Rh, Antibody Screening and Compatibility) was performed using the MTS Gel system; (g) D-Dimer testing was performed on the Biosite Triage Meter. (2) The surveyor reviewed personnel records for 9 persons who performed testing in 2017 and 2018 and identified the following for 1 of 9 persons: (a) Testing Person #8 (i) Although evaluations had been performed on 02/05/17, there was no evidence an annual evaluation had been documented as performed in 2018 (due 02/2018); (3) The surveyor reviewed the findings with laboratory manager and technical consultant #1, who stated the annual evaluation had not been documented as performed by the technical consultant in 2018 for testing person #8. ALL TESTING NOT INCLUDED IN EVALUATIONS (1) At the beginning of the survey, the laboratory manager verified to the surveyor Wet Prep and Post Vasectomy testing were performed in the laboratory; (2) The surveyor then reviewed personnel records for 9 persons performing Wet Prep and Post Vasectomy testing in the laboratory. The records verified that evaluations had been performed as follows: (a) Laboratory Manager/Testing Person #1 - Performed on 07/14/17 and 01 /10/18 (b) Testing Person #2 - Performed on 12/02/17 (c) Testing Person #3 - Performed on 12/10/17 (d) Testing Person #5 - Performed on 12/18/17 (f) Testing Person #6 - Performed on 05/22/18 (g) Testing Person #7 - Performed on 09/10/17 and 03/07/18 (h) Testing Person #8 - Performed on 02/15/17 and 07/01/17 (j) Testing Person #10 - Performed on 06/02/17 and 06/16/18 (k) Testing Person #11- Performed on 07/23/17, 01/22/18 and 07/24/18 (3) There was no evidence the evaluations, performed for the above persons, included an assessment of Wet Prep and Post Vasectomy testing; (4) The surveyor reviewed the findings with the laboratory manager and technical consultant #1, who stated the above evaluations did not include Wet Prep and Post Vasectomy testing.