Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0476048	10/22/2021
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	A complaint survey was performed on 10/22/2021 (State Complaint OK00057845). The findings were reviewed with the director of operations, director of ancillary services, and the hospital administrator, available by phone, at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.801; D2000: Enrollment and Testing of Samples 493.1403; D6000: Laboratory Director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures, phone call and email received from laboratory director on 09/14/2021, and interview with the hospital administrative manager, director of operations, director of ancillary services, and interim laboratory manager, the laboratory failed to follow Subpart H for Lipase testing for one of three events in 2021. Findings include: (1) The laboratory referred Lipase proficiency testing samples to another laboratory for testing for one of three events in 2021. Refer to D2013.
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4)

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on a review of records, policies and procedures, phone call and email received from laboratory director on 09/14/2021, and interview with the hospital administrative manager, director of operations, director of ancillary services, and interim laboratory manager, the laboratory referred Lipase proficiency testing samples to another laboratory for testing for one of three events in 2021. Findings include: (1) On 09/14 /2021, the laboratory director contacted the Oklahoma State Agency to self-report proficiency testing referral for the analyte Lipase for the third 2021 event and provided the following information: (a) A testing person had referred Lipase proficiency testing samples to a sister facility - Eastern Oklahoma Medical Center in Poteau, OK (37D0476010) on 09/13/2021. The samples had been sent prior to the proficiency testing provider, API (American Proficiency Institute) submission cut-off date of 09/15/2021; (b) When the laboratory discovered the samples had been referred to the sister facility, the laboratory did not submit their results to API and reported the laboratory had a testing problem instead; (c) Corrective actions, to include but not limited to, education, training, and updating the proficiency testing policy began on 09 /14/2021. (2) On 10/22/2021 at 11:29 am, the hospital administrative manager and the interim laboratory manager explained the following to the surveyors during the onsite complaint survey: (a) Lipase testing was performed in the laboratory using the Ortho Vitros 5600 analyzer; (b) The laboratory had been having problems with Lipase testing and the testing person performing the third 2021 proficiency testing event was concerned about the accuracy of the results. The testing person poured off the specimens into plastic tubes, which were not identified as proficiency testing specimens, and sent them to the sister facility in Poteau, Oklahoma on 09/13/2021 to perform the testing. (3) The hospital administrative manager, director of ancillary services, and director of operations provided the following for the surveyors review: (a) Copies of Lipase proficiency testing records for 2021 (b) Proficiency Testing Policies (c) Incident report with signature dates of 09/22/2021 (4) The surveyors reviewed the documents with the following identified: (a) Lipase Proficiency Testing Records (i) First 2021 Event - The laboratory attained a score of 80% (ii) Second 2021 Event - The laboratory attained a score of 40% (iii) Third 2021 Event - The laboratory had tested the five samples (CH-11, CH-12, CH-13, CH-14, CH-15) on 09 /07/2021 (one of five specimens did not have a result and stated, "No Result") and the five specimens were repeated on 09/09/2021. (b) Proficiency Testing Policies (i) The laboratory had updated the policy titled, "Proficiency Testing Procedure" which had

	been signed and dated as approved by the laboratory director on 10/12/2021; (ii) The policy had been updated to state, "Proficiency samples or results will NOT be sent to other laboratories". (c) Incident Report (i) The laboratory completed an incident report, which included documentation of counseling and demotion of the testing person involved in the incident. The document had been signed by the testing person and the hospital administrative manager on 09/22/2021. (5) There was no documentation in the records to prove the laboratory had received the results for the proficiency testing samples that had been referred to and tested by the sister facility; (6) Based on the provided information and documentation, it was confirmed the laboratory engaged in proficiency testing referral for Lipase testing for the Third 2021 Proficiency Testing Event.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures, phone call and email received from laboratory director on 09/14/2021, and interview with the hospital administrative manager, director of operations, director of ancillary services, and interim laboratory manager, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H of this part for Lipase testing for the third 2021 event. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, phone call and email received from laboratory director on 09/14/2021, and interview with the hospital administrative manager, director of operations, director of ancillary services, and interim laboratory manager, the laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H of this part. Findings include: (1) The laboratory director failed to ensure Lipase proficiency testing samples had not been referred to another laboratory for testing for one of three events in 2021. Refer to D2013.