Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0476048	(X3) Date Survey Completed 07/10/2024
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 following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and from the proficiency testing provider. The laboratory was found out of compliance with the following CLIA Conditions: 493.803; D2016: Successful Participation 493.1407; D6000: Laboratory Director, Moderate Complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a desk review of proficiency testing scores obtained from the Casper 0155D report, and Performance Summary and Comparative Evaluations obtained from American Proficiency Institute, the laboratory failed to successfully participate in a

	proficiency testing program for the subspecialty of Routine Chemistry. Findings include: (1) The laboratory failed to achieve satisfactory performance in three of four consecutive testing events for HCG (Human Chorionic Gonadotropin). Refer to D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing scores obtained from the Casper 0155D report and the Performance Summary and Comparative Evaluations obtained from American Proficiency Institute, the the laboratory failed to achieve satisfactory performance for the analyte HCG (Human Chorionic Gonadotropin) in three of four consecutive testing events. Findings include: (1) The laboratory received the following scores: (a) 40% on the second 2023 event (b) 40% on the third 2023 event (c) 40% on the second 2024 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 desk review of proficiency testing scores obtained from the Casper 0155D report and the Performance Summary and Comparative Evaluations obtained from American Proficiency Institute, the laboratory demonstrated non-initial unsuccessful participation for the analyte HCG (Human Chorionic Gonadotropin) in three of four consecutive events. The laboratory director failed to provide overall management and direction of the laboratory services. 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 desk review of proficiency testing scores obtained from the Casper 0155D report and the Performance Summary and Comparative Evaluations obtained from American Proficiency Institute, the laboratory demonstrated non-initial unsuccessful

	participation for the analyte HCG (Human Chorionic Gonadotropin) in three of four consecutive testing events. The laboratory director failed to ensure successful participation in an HHS Approved proficiency testing program. Refer to D2096.