

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0476048	(X3) Date Survey Completed 10/19/2023
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 493.1403; 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 proficiency testing Comparative Evaluation obtained from American Proficiency Institute for the second and third 2023 events, 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 for two consecutive testing events for the analyte 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 proficiency testing graded evaluations obtained from American Proficiency Institute, the the laboratory failed to achieve satisfactory performance for the analyte HCG (Human Chorionic Gonadotropin) in two consecutive testing events. Findings include: (1) The laboratory received a score of 40% on the second 2023 event and a score of 40% on the third 2023 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 proficiency testing graded evaluations obtained from American Proficiency Institute, the laboratory failed to achieve satisfactory performance for the analyte HCG (Human Chorionic Gonadotropin) in two consecutive events. The laboratory failed to achieve a passing score of 80% for the second 2023 event and third 2023 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 desk review of proficiency testing scores obtained from the Casper 0155D report and the proficiency testing graded evaluations obtained from American Proficiency Institute, the laboratory failed to achieve satisfactory performance for the analyte HCG (Human Chorionic Gonadotropin) in two consecutive events. The

laboratory failed to achieve a passing score of 80% for the second 2023 event and third 2023 event. Refer to D2096.