Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472440	09/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Elkview General Hospital	429 West Elm, Hobart, 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 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 Certification and Survey Provider Enhanced Reporting (CASPER) 0155D report and American Proficiency Institute (API) Performance Summaries and Comparative Evaluation records, the laboratory failed to successfully participate in a proficiency testing program for two of three consecutive testing events in the subspecialty of Routine

	Chemistry for the analyte CK (Creatine Kinase) resulting in a non-initial unsuccessful performance. Refer to D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (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 review of proficiency testing scores obtained from the Certification and Survey Provider Enhance Reporting (CASPER) 0155D report and American Proficiency Institute (API) Performance Summaries and Comparative Evaluation records, the laboratory failed to achieve satisfactory performance for CK (Creatine Kinase) for two of three consecutive testing events in 2025 and 2026. Findings include: (1) A review of the CASPER 0155D report identified the following unsatisfactory scores for CK; (a) Third Event 2025 - 0% (b) Second Event 2026 - 60% (2) A review of the proficiency testing scores from API for 2025 and 2026 confirmed the above findings.
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 Certification and Survey Provider Enhanced Reporting (CASPER) 0155D report and American Proficiency Institute (API) Performance Summaries and Comparative Evaluation records, the laboratory director failed to provide overall management and direction for two of three consecutive events in 2025 and 2026, resulting in a non-initial unsuccessful performance. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) 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 Certification and Survey Provider Enhanced Reporting (CASPER) 0155D report and American Proficiency Institute (API) Performance Summaries and Comparative Evaluation records, the laboratory director failed to ensure successful performance in an HHS approved proficiency testing program for the analyte Creatine Kinase (CK) in two of three consecutive testing events in 2025 and 2026. Refer to D2096.