

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0472440	(X3) Date Survey Completed 10/09/2025
Name of Provider or Supplier Elkview General Hospital	Street Address, City, State 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 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 493.1441; D6076: Laboratory Director, High 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 API (American Proficiency Institute) Performance Summaries and Comparative Evaluation records, the laboratory failed to successfully participate in a

	proficiency testing program for two consecutive testing events for Compatibility Testing, resulting in unsuccessful performance. Refer to D2181.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) (e) Failure to achieve an overall testing event score of satisfactory for 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 CASPER 0155D report and API (American Proficiency Institute) Performance Summaries and Comparative Evaluation records, the laboratory failed to achieve satisfactory performance for Compatibility Testing for two consecutive testing events in 2025. Findings include: (1) A review of the CASPER 0155D report identified the following unsatisfactory scores for Compatibility Testing: (a) First 2025 Event - 80% (b) Second 2025 Event - 80% (2) A review of the proficiency testing scores from API for 2025 confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 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 API (American Proficiency Institute) Performance Summaries and Comparative Evaluation records, the laboratory director failed to provide overall management and direction for two consecutive events in 2025, resulting in unsuccessful performance. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 CASPER 0155D report and API (American Proficiency Institute) Performance Summaries and Comparative Evaluation records, the laboratory director failed to ensure successful performance in an HHS approved proficiency testing program for Compatibility Testing in two consecutive testing events in 2025. Refer to D2181.