Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475431	01/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Coal County General Hospital Inc	6 N Covington, Coalgate, 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 recertification survey was performed on 01/07,08,09/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer, technical consultant #1, and the laboratory supervisor during an exit conference performed at the conclusion of the survey.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the

	laboratory failed to perform calibration verification procedures at least once every six months for the Triage Meter Pro test system during the review period of 04/14/2023 through the current date. Findings include: (1) On 01/08/2025 at 10:45 am, the technical consultant stated the laboratory performed D-Dimer testing using the D-Dimer cartridges and the Triage Meter Pro; (2) A review of records from 0414/2023 through the current date identified no evidence the calibration verification procedures had been performed for the Triage Meter Pro test system between 04/14/2023 and 04 /18/2024. (3) The findings were reviewed with the technical consultant, who stated on 01/08/2025 at 10:45 am, the calibration verification procedures had not been performed every six months as stated above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to perform QC (Quality Control) as stated in the IQCP (Individualized Quality Control Plan) for two of two test systems during the review period of January 2024 through the current date. Findings include: (1) On 01/09/2025 at 09:05 am, the technical consultant stated the following: (a) The Biomerieux Biofire analyzer was used to perform the Respiratory Panel and GI (Gastrointestinal) Panel testing; (b) An IQCP (Individualized Quality Control Plan) had been developed for each of the test systems. (2) A review of the QCP (Quality Control Plan) for each of the test systems identified positive and negative quality control materials were to be tested on a monthly basis; (3) A review of QC records from January 2024 through the current date identified QC testing had not been performed as stated in the QCP as follows: (a) Respiratory Panel - Not performed between 11/13/2024 and 01/02/2025 (b) GI Panel - Not performed between 11/14/2024 and 01/02/2025 (4) The records were reviewed with the technical consultant who stated on 01/09/2025at 09:35 am, QC had not been performed as stated above.