Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475908	02/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Creek Nation Community Hospital	1800 E Coplin Rd, Okemah, 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 02/03,04,05/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory quality assurance specialist, quality improvement specialist, laboratory supervisor, hospital administrator, director of laboratory services, assistant director of laboratory services, and laboratory director during an exit conference performed at the conclusion of the survey.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's operator manual, and interview with the laboratory supervisor, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Abbott Cell-Dyn Emerald 22 analyzer during the review period of January 2024 through January 2025. Findings include: (1) On 02/03/2025 at 10:00 am, the laboratory supervisor stated the laboratory began using the Abbott Cell Dyn Emerald 22 as a backup method for performing CBC (Complete Blood Count) testing on 04/21/2023; (2) A review of the Abbott Cell-Dyn Emerald 22 Operator's Manual, section 9-12 titled "Preventive Maintenance Schedule" stated the syringe piston should be lubricated quarterly; (3) A review of maintenance logs from January 2024 through January 2025 identified required quarterly maintenance had not been documented as performed for the following periods: (a) Between 01/01/2024 and 06/21/2024 (b) Between 06/21/2024 and 12/25/2024 (4) The records were reviewed with laboratory supervisor who stated on 02/05/2025 at 03:15 pm, maintenance procedures had not been documented as performed as stated above.

D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for performing calibrations for one of two analyzers. Findings include: (1) On 02/03/2025 at 10:00 am, the laboratory supervisor stated the laboratory began using the Abbott Cell Dyn Emerald 22 as a backup method for performing CBC (Complete Blood Count) testing on 04/21/2023; (2) A review of the Cell Dyn Emerald 22 operator's manual, section 6-3 titled, "When to Calibrate" stated calibration should occur at least once every six months; (3) A review of records from November 2022 through July 2023 identified no documentation to prove the analyzer had been calibrated between installation on 11/02/2022 and 07/06/2023 (due May 2023); (4) Interview with the technical consultant on 02/05/2025 at 12:00 pm confirmed there were no records to prove the analyzer had been calibrated as required by the manufacturer.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 laboratory quality assurance specialist, the laboratory failed to perform calibration verification procedures at least once every six months for the Abbott Architect test system during the review period of 02/01/2023 through the current date. Findings include: (1) On 02/04/2025 at 10:45 am, the laboratory quality assurance specialist stated the laboratory performed Acetaminophen, Albumin, Alkaline Phosphatase, Ammonia, Amylase, Aspartate Transferase, Direct Bilirubin, Total Bilirubin, Blood Urea Nitrogen, Calcium, Chloride, Cholesterol, Creatinine Kinase, Carbon Dioxide, Creatinine, Ethanol, Glucose, High-Density Lipoprotein, Hemoglobin A1C, Lactate, Lipase, Magnesium, Phosphorus, Potassium, Salicylate, Sodium, Total Protein, Triglyceride, and Thyroid Stimulating Hormone testing using the Abbott Architect ci4100 chemistry and immunoassay analyzer; (2) A review of records from 02/01/2023 through the current date identified no evidence the calibration verification procedures had been performed for each analyte listed above between 12/28/2023 and 11/25/2024. (3) The findings were reviewed with the laboratory quality assurance specialist, who stated on 02/04 /2025 at 10:45 am, the calibration verification procedures had not been performed every six months as stated above.