Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473327	03/26/2026
Name of Provider or Supplier	**Street Address, City, State**	
Pawhuska Hospital Inc	1101 East 15th Street, Pawhuska, 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 03/24, 25, 26/2026. Standard-level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of policies and procedures and interview with the technical consultant and testing person #1, laboratory failed to have a written procedure that reflected the current practices and procedures for one of five test methods reviewed. Findings include: (1) On 03/24/2026 at 01:40 pm, the technical consultant and testing person #1 stated the laboratory performed Blood Gas (pH, pO2, and pCO2) testing using the iSTAT 1 analyzer (Serial Numbers 339476) and the EG6+ cartridge; (2) A review of the procedure titled "Policy & Procedure - iSTAT Procedure" under the heading "3. Cartridges" included reference to the G3+ cartridge instead of the EG6+ cartridge; (3) The findings were reviewed with the technical consultant and testing person #1, who stated on 03/25/2026 at 11:09 am, the procedure for the Blood Gas testing had not been written to reflect current practices and procedures.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage

	requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with testing person #1, the laboratory failed to label one of three containers containing staining material with the name of the content. Findings include: (1) On 03/24/2026 at 01:56 pm, testing person #1 stated the laboratory stained peripheral blood smears to perform manual differential testing; (2) Observation on 03/24/2026 at 01:56 pm identified one of three Coplin jars, appearing to contain material used to stain peripheral blood smears had not been labeled with the identity of the reagent; (3) The findings were reviewed with testing person #1 who stated on 03/24/2026 at 01:58 pm, the Coplin jar contained staining material had not been labeled with the identity.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and testing person #1, the laboratory failed to utilize the demonstrated reportable ranges for one of two new test systems introduced in the laboratory in March 2025. Findings include: (1) On 03/24/2026 at 01:50 pm, testing person #1 stated the laboratory began performing PT/INR (Prothrombin Time/International Normalized Ratio) using Hemochron Signature Elite analyzer in March 2025; (2) A review of the performance specification records identified the laboratory had demonstrated a reportable range of 1.0 -5.0 seconds for the INR; (3) Interview with the technical consultant and testing person #1 on 03/26/2026 at 11:00 am confirmed the laboratory was using a reportable range of 0.5-12.0 seconds instead of the reportable range that had been demonstrated by the laboratory.
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 technical consultant and testing person #1, the laboratory failed to perform calibration verification procedures at least once every six months for the Triage Meter Pro test systems during the review period of July 2024 through the current date. Findings include: (1) On 03/24/2026 at 01:45 pm, the technical consultant and testing person #1 stated the following: (a) The laboratory performed CKMB (Creatine Kinase) and Troponin I testing using the Triage Meter Pro analyzer and Cardiac cartridge; (b) The laboratory performed D-Dimer testing using Triage Meter Pro analyzer and D-Dimer cartridge. (2) A review of records from July 2024 through the current date identified no evidence calibration verification had been performed at least once every six months between 02/10/2025 and 01/27/2026; (3) The records were reviewed with the technical consultant and testing person #1 who stated on 03/25/2026 at 12:04 pm, calibration verification procedures had not been performed every six months as stated above.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on a review of policies and procedures and interview with the technical consultant and testing person #1, the laboratory failed to have a system in place that twice a year evaluated and defined the relationship between the test results for seven of seven analytes using two different test methods. Findings include: (1) On 03/24 /2026 at 02:00 pm, the technical consultant and testing person #1 stated the following: (a) The laboratory performed Chemistry testing which included the analytes BUN, Chloride, CO2, Creatinine, Glucose, Potassium, and Sodium using the Siemens Dimension EXL 200 analyzer; (b) The laboratory performed Chemistry testing which included the analytes BUN, Chloride, CO2, Creatinine, Glucose, Potassium, and Sodium using iSTAT analyzer (Serial Number 339476) and the CG8+ cartridge. (2) On 03/25/2026, a review of the laboratory policy and procedure manual identified no evidence of a procedure describing the laboratory's method to compare BUN, Chloride, CO2, Creatinine, Glucose, Potassium, and Sodium testing performed on the Siemens Dimension EXL 200 analyzer and the iSTAT analyzer and the CG8+ cartridge at least twice annually; (3) Interview with the technical consultant and testing person #1 on 03/25/2026 at 10:45 am, confirmed the laboratory did not have a system in place to evaluate the testing performed using the different methods.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	(b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for one of eight testing persons during the review period of January 2024 through the current date. Findings include: (1) On 03/24/2026, a review of personnel records for eight persons performing moderate complexity testing from January 2024 through the current date identified no evidence an annual competency evaluation had been performed for one of eight testing persons as follows: (a) Testing Person #6 - not performed prior to 09/13/2025. (2) The records were reviewed with the technical consultant who stated on 03/24/2026 at 10:28 am, the annual evaluations had not been documented as performed as stated above.