Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473327	01/11/2022
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 01/10,11/2022 The findings were reviewed with the laboratory manager, technical consultant, and the quality manager during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to review and evaluate proficiency testing results for one of 29 events. Findings include: (1) On 01/10/2022, the surveyor reviewed 2020 and 2021 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2021 Chemistry Core Event (i) Cholesterol HDL (High Density Lipoprotein) - 3 of 5 results exhibited a positive bias (aa) Sample CH-02 - SDI of 2.3 (bb) Sample CH-03 - SDI of 3.2 (cc) Sample CH-04 - SDI of 2.0 (dd) Sample CH-05 - SDI of 2.9 (b) First 2021 Chemistry Core Event (i) Albumin - 3 of 5 results exhibited a positive bias (aa) Sample CH-01 - SDI of 2.0 (bb) Sample CH-02 - SDI of 2.3 (cc) Sample CH-04 - SDI of 2.0 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory manager. The laboratory manager stated on 01/10 /2022 at 01:25 pm the biases had not been addressed.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

	The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant and laboratory manager, the laboratory failed to follow the manufacturer's instructions for test timing for Ammonia testing for three of three test reports. Findings include: (1) On 01/10/2022 at 10:10 am, the laboratory manager state to the surveyor: (a) The laboratory performed Ammonia testing using the Siemens Dimension EXL 200. (2) On 01/11/2022, the surveyor reviewed the manufacturer's instructions under the section titled, "Specimen Collection and Handling" the following was identified: (a) Ammonia - "The tube should be completely filled, stored tightly capped on ice, centrifuged immediately and analyzed within 20 minutes. Concentrations may more than double in plasma when stored at room temperature for 6 hours". (3) The surveyor then reviewed patient testing records on 12/06/2021 and 12/09/2021 and identified the following for three of three patient test reports: (a) Ammonia (i) Patient #14240 - The collection date and time was on 12 /06/2021 at 04:10 pm and the result date and time was on 12/06/2021 at 07:05 pm (two hours and 55 minutes later); (ii) Patient #25591 - The collection date and time was on 12/06/2021 at 06:45 pm and the result date and time was on 12/06/2021 at 07: 25 pm (40 minutes later); (iii) Patient #25591 - The collection date and time was on 12 /09/2021 at 05:10 am and the result date and time was on 12/09/2021 at 06:03 am (53 minutes later). (4) The surveyor reviewed the findings with the technical consultant and the laboratory manager. The laboratory manager stated on 01/11/2021 at 12:46 pm, the laboratory could not prove the specimen was collected, tested, and resulted as required by the manufacturer.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 the policy and procedure manual and interview with the laboratory manager, the laboratory failed to follow written procedures for establishing Quality Control ranges for four of four control lot numbers. Findings include: (1) On 0 /10/2022 at 10:10 am, the laboratory manager stated to the surveyor chemistry testing was performed on the Siemens Dimension EXL 200 analyzer; (2) On 05/11/2022, the surveyor reviewed written laboratory procedure titled, "PROCEDURE MANUAL" under the procedure titled, "ESTABLISHING QC RANGES" stated, (a) "1. Before the old lot expires, run each level of the new lot of QC material at least 10 times (over 10 days if possible) and determine the mean for the new lot.". (3) The surveyor reviewed six QC (quality control) lot numbers. For four of four lot numbers there was no indication the laboratory staff followed their written procedure as follows: (a) Bio-

	Rad Liquichek Ethanol/Ammonia Lot# 54361 ran 5 times before put into use; (b) Bio-Rad Liquichek Ethanol/Ammonia Lot# 54363 ran 5 times before put into use; (c) Bio-Rad Liquichek Immunology Control Lot# 68961 ran 5 time before put into use; (d) Bio-Rad Liquichek Immunology Control Lot# 68963 ran 5 time before put into use; (4) The surveyor reviewed the findings with the laboratory manager and technical consultant. The laboratory manager stated on 01/11/2020 at 01:20 pm that the procedure had not been followed as indicated above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the technical consultant and laboratory manager, the laboratory failed to follow the manufacturer's instructions for implementing one of one coagulation reagents. Findings include: (1) On 01/10/2022 at 10:20 am, the laboratory manager stated to the surveyor the ACL Elite analyzer was used to perform PT/INR (Prothrombin Time /International Normalized Ratio) testing (the INR was calculated using the PT reference interval mean); (2) On 01/10/2022 at 10:30 am, the surveyor observed the following: (a) Refrigerator where the testing reagents were maintained and identified the following reagent which appeared to be currently in use: (i) PT - HemosIL Recombiplastin2 reagent, lot #N0512868. (b) Geometric Mean - The analyzer stored a geometric mean of 11.8. (3) The laboratory manager stated to the surveyor on 01/10 /2022 at 10:40 am, the reagent lot number was currently in use, and had initially been put into use as follows: (a) HemosIL Recombiplastin2 reagent - 12/31/2021 (4) On 01 /11/2022, the surveyor reviewed the manufacturer's instructions contained in the "Hemostasis Performance Verification Manual" for implementing new reagents, which stated, "When changing to a new lot number of reagent or a new reagent, it is important to establish a new normal reference interval, establish new assay control ranges, and perform a comparison study for all tests". In addition, the manufacturer required the following: (a) Section titled "Establishing a Normal Reference Interval" (i) "Reference Interval should be established whenever there is a change in: * Instrumentation and/or methodology. * Lot number of reagent. * Sample collection procedures. * At least once a year." (ii) "Reference Intervals should be established for each assay the lab performs."; (iii) "Reference Intervals should be established over several days, at different times of the day, including such variables as age of reagent, different vials of reagent, different operators."; (iv) "Donors should be healthy and have no known pathological conditions. Don't use samples from in-patients (due to medical conditions and treatment regiments). Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high-does aspirin, etc."; (v) "Donors should span the adult age range. Pediatric ranges should be established separately."; (vi) "Donors should be equally divided between male/female."; (vii) "If the INR system is utilized to report PT's, note the geometric mean value of the PT normal reference interval in seconds and use along with the lot-specific ISI value in the INR setup calculation page". (b) Under the section, "Results" (i) Determine the mean, standard deviation (SD) and range once the data has been collected. The range is usually defined as the

	mean +/- 2 SD. (5) The surveyor reviewed the implementation records for Recombiplastin2 reagent lot #N0512868 with the following identified: (a) Recombiplastin2 lot #N0512868 (i) Although the laboratory had established a geometric range of 12.1 seconds, there was no evidence the laboratory had entered the value into the analyzer; (ii) There was no evidence the laboratory has defined a range of +/- 2SD. (6) The surveyor reviewed the findings with the technical consultant and laboratory manager. The laboratory manager stated on 01/11/2022 at 01:25 pm, the manufacturer's instructions had not been followed for the reagent lot change as specified above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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, manufacturer's reportable ranges, and interview with the technical consultant, the laboratory failed to ensure the reportable ranges were utilized for one of one new test methods. Findings include: (1) On 01/10/2022 at 10:15 am, the laboratory manager stated the following to the surveyor: (a) The iSTAT 1 analyzer and the EG8+ cartridge were used to perform Blood Gas (pH, pO2, and pCO2) testing. (2) The surveyor reviewed the performance specification records for the two new test systems and identified the laboratory had demonstrated the following reportable ranges for the following: (a) EG8+ (i) pH - 6.5 - 7.877 (ii) pCO2 - 17.80 - 92.30 mmHg (iii) pO2 - 57 - 414 mmHg (3) The surveyor then reviewed the manufacturer's reportable ranges, which were being used by the laboratory. The manufacturer's reportable ranges were as follows: (a) EG8+ (i) pH - 6.50 - 8.20 (ii) pCO2 - 5.0 - 130.0 mmHg (iii) pO2 - 5 - 800 mmHg (4) The surveyor reviewed the findings with the technical consultant, who stated on 01/10/2022 at 03:37 pm, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory as shown above.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with laboratory manager and technical consultant, the laboratory failed to make appropriate reference ranges available for two of two patient Hematology reports; and failed to make appropriate therapeutic reference intervals available for one of one patient coagulation report. Findings include: SYSMEX KX-21N (1) On 01/10/2022 at 10:25 am, the laboratory manager

	stated the laboratory performed CBC (Complete Blood Count) testing using the Sysmex KX-21N analyzer; (2) On 01/11/2022, the surveyor reviewed two patient CBC reports - the first report was for an adult female patient with the testing performed on 02/05/2021 at 04:03 pm; the second report was for an adult male patient with the testing performed on 02/05/2021 at 11:25 am. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit which were: (a) RBC - 3.6 - 6.00 M/l (b) Hemoglobin - 12.0 - 18.0 g /dL (c) Hematocrit - 36.0 - 55.0 % (3) The surveyor reviewed the findings with the technical consultant. The technical consultant stated on 01/11/2022 at 12:54 pm the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals. ACL ELITE (1) On 01/11/2022, the surveyor reviewed a patient INR (International Normalized Ratio) report for a patient who had testing performed on 01/10/2022 at 11:58. It did not include a therapeutic range (range for treatment of venous thrombosis, treatment of pulmonary embolism, prevention of systemic embolism, etc); (2) The report was reviewed with the technical consultant and laboratory manager. The laboratory manager and technical consultant stated on 01 /11/2022 at 01:20 pm that INR report did not include a therapeutic range.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. 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 that persons performing moderate complexity testing had been evaluated semiannually during the first year of testing for one of two persons hired after the previous recertification survey. Findings include: (1) On 01/10/2022, the surveyor reviewed personnel records. The following was identified: (a) Testing Person #5 - The initial training for this person was completed on 10/19/2019. There was no evidence that a semiannual evaluation had been performed (the next competency evaluation had been performed on 10/13/2020). (2) The surveyor reviewed the records with the technical consultant, who stated on 01/10/2022 at 02:15 pm, there were no records to prove the above persons had been evaluated semiannually.