Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473327	01/30/2020
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 01/28/20 through 01/30/20. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager, technical consultant #2, hospital administrator, and chief clinical officer during an exit conference performed at the conclusion of the survey.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant #2, the laboratory failed to test proficiency testing samples the same number of times that patient samples were tested for 1 of 6 events. Findings include: (1) At the beginning of the survey, the laboratory manager and technical consultant #2 stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing using the Sysmex KX-21N analyzer; (2) The surveyor reviewed Hematology proficiency testing records for 6 events (First 2018, Second 2018, Third 2018, First 2019, Second 2019, and Third 2019 Events) and identified a specimen had been tested multiple times for 1 of 4 events as follows: (a) Third 2019 Event (i) Sample HSY-13 was tested two times (11/19/19 at 01:15 pm and 11/19/19 at 01:17 pm) with the results obtained from the first run reported to the proficiency testing program. (3) The surveyor reviewed the records with the laboratory manager and technical consultant #2 and asked if patient samples were tested in the same manner. The laboratory manager and technical consultant #2 stated patient specimens were routinely tested one time and not in duplicate as the proficiency testing specimens had been tested.
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES

	CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant #2, the laboratory failed to ensure blood products were stored under appropriate conditions in the blood bank refrigerator for 3 of 35 thermograph charts. Findings Include: (1) On the second day of the survey, the laboratory manager and technical consultant #2 stated to the surveyor the laboratory routinely maintained 2 units of O negative packed red blood cells in the Allegiance S/P Brand blood bank refrigerator. The units were available for emergency patient transfusions (packed red blood cells must be stored at 1-6 degrees Centigrade-C); (2) The surveyor observed the thermograph temperature recorder for the blood bank refrigerator. The refrigerator had a recorder connected to it for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees Centigrade). Each chart monitored the temperature for a 7 day period; (3) The surveyor reviewed 35 refrigerator charts dated from 04/24/19 through 12/27/19. The review indicated that 3 of 35 charts had not been changed by the 7th day of usage. The findings include: (a) Chart #6 - The chart was put into use on 05/29/19 and removed on 06/06/19 (8 days); (b) Chart #8 - The chart was put into use on 06/12/19 and removed 06/20/19 (8 days); (c) Chart #10 - The chart was put into use on 06/27/19 and removed 07/05/19 (8 days); (4) The surveyor reviewed the charts with the laboratory manager and technical consultant #2, who both stated the charts had not been changed by the 7th day of usage as indicated above. D3021 was cited on the recertification survey performed on 01/29,30,31/18.
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 and technical consultant #2, the laboratory failed to review and evaluate proficiency testing results for 1 of 27 events. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following failure: (a) First 2018 Chemistry Core Event (i) Alcohol (ALC-04) The laboratory received a score of 80% (failed 1 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure. (2) The surveyor further reviewed the records and could not locate documentation verifying the failure had been identified and addressed; (3) The surveyor then reviewed the records with the laboratory manager and technical consultant #2 and asked if the failures had been addressed. The laboratory manager and technical consultant #2 stated the failures had not been addressed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant #2, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results for 1 of 27 events. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology (i) 2019 First Event (aa) Blood Cell Identification ECI-07 (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) The surveyor asked the laboratory manager and technical consultant #2 if the results had been documented as evaluated. The laboratory manager and technical consultant #2 reviewed the records and stated the non-graded results had not been documented as reviewed.
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, and interview with the laboratory manager and technical consultant #2, the laboratory failed to follow the manufacturer's instructions for Coagulation for 1 of 1 reagent lot changes. Findings include: (1) On the second day of the survey, the laboratory manager and technical consultant #2 stated the following to the surveyor: (a) The IL ACL Elite analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) (b) Hemosil Recombiplastin 2 G PT Reagent Lot# N0696619 was put into use 11/27/19. (2) The surveyor reviewed the manufacturer's Hemostasis Performance Verification Manual instructions for "COMPARISON STUDY", which stated: (a) "4. At least 50% of the samples should be outside of the laboratory normal reference interval, if possible." (b) "5. At least 40 specimens should be analyzed. More samples will improve the confidence in the data." (3) The surveyor reviewed the comparison study records and identified that, although 60 specimens had been tested, there was no evidence that 50% of the specimens were outside the laboratory normal reference interval; (4) The surveyor review the manufacturer's instructions with the laboratory manager and technical consultant #2. Both stated the comparison study had not been performed according to manufacturer's instructions.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant #2, the laboratory failed to ensure corrective action was taken when quality control was not performed for 1 of 12 months. Findings include: (1) At the beginning of the survey, the laboratory manager and technical consultant #2 stated the following to the surveyor: (a) The laboratory performed the D-Dimer test using the Alere Triage Meter Pro; (b) Two levels of quality control materials were tested monthly, according to the laboratory IQCP (Individualized Quality Control Plan); (c) The results for two levels of control materials must be acceptable in order to report patient results. (2) On the third day of the survey, the surveyor reviewed quality control records for testing performed from January 2019 through December 2019. For the review period, the following was identified for 1 of 12 months: (a) Quality control results could not be located for April 2019. (3) The surveyor asked the laboratory manager and technical consultant #2 if two levels of quality control had been performed and if corrective action had been taken to determine if results had been adversely affected. The laboratory manager and technical consultant #2 stated monthly quality controls were not performed in April 2019 and corrective action had not been performed.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that 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 review of records and interview with the laboratory manager and technical consultant #2, the laboratory director or designee failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 3 of 27 events. Findings include: (1) On the first day of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records. It was identified for 3 of 27 events, the attestation statements had been signed approximately 2-3 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Immunology Second event of 2018 - The samples had been tested on 08/08/18 and the attestation statement had not been signed by the laboratory director until 10/16/18; (b) Chemistry Core First event of 2019 - The samples had been tested on 01/24/19 and the attestation statement had not been signed by the laboratory director until 04/25/19; (c) Microbiology First event of 2019 - The

	samples had been tested on 02/21/19 and the attestation statement had not been signed by the laboratory director until 04/25/19. (2) The surveyor reviewed the findings with the laboratory manager and technical consultant #2 and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.
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 laboratory manager and technical consultant #2, the technical consultant failed to ensure that a person performing moderate complexity testing had been evaluated semiannually during the first year of testing for 2 of 4 testing persons. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records. The following was identified: (a) Testing Person #1 - The initial training for this person was completed on 06/06/18. There was no evidence that a semiannual evaluation had been performed (due 12/18); (b) Testing Person #8 - The initial training for this person was completed on 10/26/18. There was no evidence that a semiannual evaluation had been performed (due 04/19). (2) The surveyor reviewed the records with the laboratory manager and technical consultant #2 who stated there were no records to prove the above person had been evaluated semiannually.